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Self-Efficacy And Sexual And Reproductive Health In Women With Cystic Fibrosis: A Mixed Methods Study

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SELF-EFFICACY AND SEXUAL AND REPRODUCTIVE HEALTH IN WOMEN WITH CYSTIC FIBROSIS: A MIXED METHODS STUDY

by

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A DISSERTATION

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JANET BROWN

DOCTOR OF PHILOSOPHY IN NURSING

ABSTRACT

BACKGROUND: Cystic fibrosis (CF) is the most common life-limiting genetic disorder among Caucasians. There are approximately 30,000 individuals with CF in the United States and over 70,000 worldwide, with approximately 1,000 new cases diagnosed globally each year. In other chronic diseases, a positive relationship between self-efficacy and behavior has been identified. Self-efficacy may be a factor related to behaviors, including underutilization of sexual and reproductive health (SRH) care services for women with CF.

METHODS: Self-efficacy and utilization of SRH care services by women were explored using a concurrent mixed methods study design. The sample included 59 women ages 25 years or older with CF recruited from an accredited CF center located at a university setting in the southeastern United States. Participants completed the Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6) in addition to questions regarding age, marital status, and lung function. The SEMCD6 scores and utilization of SRH care scores were analyzed using R version 3.4.1 software. A subsample of 10 women completed a semi-structured interview to explore self-efficacy and utilization of SRH care services further. The interviews were transcribed verbatim and analyzed using Braun and Clark's method of thematic analysis and NVivo 12 software.

RESULTS: Participants had an age range of 25 to 68 with a median age of 34 years, were Caucasian (95%), had lung function greater than 70% predicted (47%), and mostly married (57%). Quantitative analysis revealed a positive correlation between self-efficacy and utilization of SRH care services (Spearman’s rho = .28, *p* = .04). Qualitative analysis revealed four overarching themes: (a) women (8/10) felt confident utilizing SRH care services and reported receiving SRH care in the past 12 months; (b) the women’s confidence toward SRH care utilization was attributed to communicating with other women with CF, verbal encouragement from a trusted CF healthcare team member or from a trusted family member or close friend, or from the stories of women with CF related to utilizing SRH care services; (c) information provided by CF care team members about SRH was lacking due to a lack of current research (8/10); and (d) the women’s CF care team did not initiate SRH conversations (9/10). Integration of the findings revealed: (a) women with CF are confident; (b) women with CF utilize SRH care services; (c) there is a positive relationship between self-efficacy and utilization of SRH care services; and (d) better lung function does not relate to higher self-efficacy.

CONCLUSIONS: This is the first study to explore self-efficacy in relation to the utilization of SRH services among women with CF. The results of this study may guide future development of care protocols designed to increase the self-efficacy of women with CF toward the utilization of SRH care and assist providers with carrying out these discussions with patients in the future.

Keywords: cystic fibrosis, sexual and reproductive health, self-efficacy

DEDICATION

I would like to dedicate this dissertation to my husband, Byron Brown, and my children, Jill, Andy, and Emily. This journey would not have been possible without their support and encouragement. Thank you all for believing in my dream and helping me achieve it. This work is dedicated to the women with cystic fibrosis who took time to share their stories with me and who gave me overwhelming support and encouragement. My hope is that this dissertation is the beginning of research that will improve the lives of all women with cystic fibrosis.

ACKNOWLEDGMENTS

This work would not have been possible without the guidance of my mentor and dissertation chair, Dr. Sigrid Ladores. I appreciate the hours she invested in guiding, encouraging, and supporting my PhD journey. I would like to sincerely thank the members of the dissertation committee, Dr. Sylvie Mrug, Dr. Traci Kazmerski, Dr. Peng Li, and Dr. Leigh Ann Bray. Thank you all for serving as content experts and supporting and encouraging this work. I am grateful for everything you taught me and the hours you invested in teaching me.

I would like to thank the Jonas Foundation, the family of Jarman Lowder, and the University of Alabama at Birmingham School of Nursing for financial support that made this work possible.

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CHAPTER 1

INTRODUCTION

Cystic fibrosis (CF) is the most common genetic condition worldwide and affects over 30,000 individuals in the United States alone (Cystic Fibrosis Foundation [CFF], 2019a). Cystic fibrosis is an autosomal recessive disease characterized by an interruption in the sodium chloride transportation mechanism at the cellular level, caused by a mutation of the gene that produces cystic fibrosis transmembrane conductance regulator (CFF, 2019a). This results in copious amounts of tenacious secretions which impact primarily the pulmonary but also the gastrointestinal, endocrine, and in women, reproductive systems (CFF, 2019a).

There is no cure for CF; however, the predicted survival age has reached 47.7 years due to advances in medical care and the advent of new therapies (CFF, 2019a). Greater than half of the CF population is over the age of 18 years (CFF, 2019a), presenting adult health care challenges not previously encountered, including sexual and reproductive health (SRH) care. Women with CF are becoming mothers, making decisions about SRH, achieving career or college goals (CFF, 2019a), and meeting developmental milestones on a timeline close to that of their unaffected peers (Frayman & Sawyer, 2015; Tonelli & Aiken, 2007). For those choosing pregnancy, it is encouraging that research has shown that pregnancy does not shorten life expectancy for women with CF (Goss et al., 2003). In fact, there is evidence of pregnancies carried to term with healthy babies born to women with CF (Kaminski & Nazareth, 2016; Ladores et al., 2017) and the number of pregnancies among women with CF has steadily increased throughout the past two decades (CFF, 2019b). Despite this, SRH care utilization is lower in women with CF (Kazmerski et al., 2018a), and gaps in the provision of SRH care have been noted (Kazmerski et al., 2018b). Therefore, it is important to explore factors related to utilization of SRH care. Self-efficacy, or an individual's confidence they can complete a specific task (Bandura, 1977), may be a factor associated with SRH care utilization in women with CF. The purpose of Chapter 1 is to: (a) introduce the problem of underutilization of SRH care by women with CF, (b) provide the background and significance of this problem, (c) state the purpose of this dissertation study, (d) list the research questions, (e) introduce the conceptual framework upon which this study is based, and (f) define key terms conceptually and operationally.

Problem Statement

Despite evidence that women with CF have similar SRH behavior to that of their healthy peers (Simcox et al., 2009), provision of comprehensive CF care may not routinely and adequately address SRH (Withers, 2012). Specifically, 55% of women with CF used contraception, compared to 74% of healthy controls who participated in a recent National Survey of Family Growth (NSFG) (Kazmerski, Gmelin, & Slocum et al., 2017). Additionally, of the women with CF who reported having had sex in the past three months, 35% did not use contraception, compared to 26% in the NSFG healthy control group (Kazmerski, Gmelin, & Slocum et al., 2017). Self-efficacy is a factor that may be related to utilization of SRH care services by women with CF.

Research in other chronic illnesses such as asthma, Parkinson's disease, congestive heart failure, and arthritis has revealed a positive correlation between self-efficacy and adherence to therapies with resultant improvements in outcomes (Marks et al., 2005). Self-efficacy is required to establish and maintain CF care (Bandura, 1977; Bartholomew et al., 1993). This topic has not, however, been well established in CF research, revealing a gap in the current literature, and presents the overarching research question: *What is known about self-efficacy, and what is the relationship between self-efficacy and SRH care utilization among women with CF?*

Background and Significance of the Problem

This underutilization of SRH care services has potential to adversely affect the health outcomes of women with CF. Rousset-Jablonski et al. (2018) revealed that 42.5% of women with CF had an SRH-related abnormality such as cervical inflammation, or cervical or vulvovaginal condyloma. This high proportion of women with CF with abnormal Pap smear tests and cervical dysplasia places them at a greater risk for cervical cancer, the ninth leading cause of cancer deaths worldwide in 2013 (Fitzmaurice et al., 2015). Additionally, the underutilization of SRH care services related to pregnancy, expected or unexpected, has potential to impact health outcomes for women with CF and their infants. For these reasons, it is important to explore factors that may be related to this underutilization of SRH care services.

Self-efficacy has been shown to be modifiable and sustainable with a task-specific behavioral intervention program (Cummings et al., 2011). Because SRH care utilization for women with CF is less than for women without CF, a better understanding of the influence of self-efficacy on SRH care utilization could lead to intervention development to increase self-efficacy and potentially increase SRH care utilization in women with CF. To date, evidence on the influence of self-efficacy on CF-specific SRH concerns, care utilization, and preferences in women with CF is lacking. This mixed methods study examined the self-efficacy of women with CF related to SRH concerns, care utilization, and preferences using the Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6) (Gruber-Baldini et al., 2017), followed by semi-structured interviews to better explain preferences and experiences of women with CF related to utilization of SRH care.

Study Purpose and Research Questions

The purpose of this study was to explore self-efficacy in relation to CF-specific SRH concerns, care utilization, and preferences of women with CF. The following study aims and research questions were designed to specifically guide this exploration.

Quantitative Research Question

Is there an association between self-efficacy as measured by a cross-sectional survey using the Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6) and utilization of SRH care services among women with CF?

Qualitative Research Question

What are the perceptions and experiences of women with CF related to self-efficacy and utilization of SRH care services?

Overall Mixed Methods Question

How do quantitative questionnaire results and qualitative semi-structured interview results jointly explain the relationship of self-efficacy to utilization of SRH care services in women with CF?

Study Aims

Aim 1: Assess the relationship between self-efficacy and utilization of SRH care services of women with CF.

Approach: In addition to the Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6), questions regarding utilization of SRH care services were used to examine a rating of the utilization of SRH care services in the past year, specifically a routine gynecological office visit, use of contraceptives, or receipt of a Pap smear.

RQ 1: What is the relationship between self-efficacy scores and utilization of SRH care services (i.e., routine gynecological office visit, use of contraceptives, or receipt of a Pap smear)?

Aim 2: Describe the preferences and experiences surrounding both self-efficacy and utilization of SRH care services in women with CF.

Approach: Individual, semi-structured, qualitative interviews were conducted in person or by telephone with a subset of 10 women with CF who completed the survey.

RQ 2.1: How do women with CF describe their confidence with expressing concerns regarding SRH care to the CF health care team?

RQ 2.2: How do women with CF describe their SRH care utilization?

RQ 2.3: What factors do women with CF feel most influence their level of confidence when communicating SRH preferences to the CF health care team?

Aim 3: Describe the integrated quantitative and qualitative findings to provide a better understanding of the relationship of self-efficacy to SRH care utilization of services, preferences, and concerns of women with CF.

Approach: Findings from the quantitative arm of the study (surveys and demographic data) were integrated with findings of the qualitative arm (semi-structured interviews) to gain a fuller understanding.

RQ3: How do quantitative and qualitative findings intertwine to overall describe and better explain the relationship of self-efficacy and SRH care utilization, concerns, and preferences of women with CF?

Introduction of the Theoretical/Conceptual Framework

The theoretical framework for this study was based on the self-efficacy construct of Bandura's Social Cognitive Theory (Bandura, 1977). Bandura's 1977 theory states that an individual's personal (self) efficacy is the factor that determines whether an individual can manage a situation. This theory posits that mastery of tasks can improve self-efficacy (Bandura, 1977). In this model, self-efficacy develops from four main areas: mastery experiences, vicarious experiences, verbal persuasion, and physiological states (Bandura, 1977). Self-efficacy has a key role in personal change in this model (Bandura, 2004), making this model a good fit for the study. Self-efficacy has been shown to be associated with improved outcomes in chronic disease (Faint et al.,2017), making this framework appropriate for the proposed study.

Introduction of the Design and Methods

This concurrent mixed methods study examined the self-efficacy of women with CF related to SRH concerns, care utilization, and preferences. A cross-sectional survey was administered to examine self-efficacy in relation to SRH care utilization to women with CF (*n* = 59). Interviews were conducted with a subset of women (*n* = 10) to supplement the survey results and more fully explore the current state of self-efficacy in relation to SRH for women with CF.

Study Design

The design of this study was a concurrent mixed methods design, which is appropriate for use in an area where little is known and when the purpose is to describe (Polit & Beck, 2017). The review of literature established that little is known about this topic, and that gaps in care exist, making this approach appropriate for this dissertation study.

The approach was a cross-sectional survey using the Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6) to examine the self-efficacy of women with CF aged 25 years and older (*n* = 59) recruited from an accredited CF center in a university setting in the southeastern United States. The 59 participants were part of a larger, 10-site, parent study. The sample size was determined by the parent study, and the SEMCD6 was added to the survey of the parent study. A previous study by the principal investigator of the parent study, Kazmerski et al. (2017) included younger girls, thus the inclusion criterion of age 25 years and older was selected for this study to continue the examination of experiences by older women. The subset of data comprising the qualitative arm (*n* = 10) was guided by the literature (Creswell & Poth, 2016) and continued until reaching data saturation.

Definition of Study Terms

For the purposes of this study, the following terms are defined.

1. *Age:* age of the participant in years
2. *Control variables:* variables that will be included in the statistical analysis, including the participant's age in years and their health as measured by their FEV1 (forced expiratory volume in one second, a measure of lung function)
3. *Cystic fibrosis:* chronic, autosomal recessive, multisystem disease affecting primarily the pulmonary, gastrointestinal, endocrine, and reproductive systems
4. *Dependent variable:* utilization of sexual and reproductive health (SRH) care services
5. *Dimensions of SRH:* four dimensions of SRH, identified as comfort with topic of SRH, knowledge of topic of SRH, previous experiences with SRH, and prioritization of care
6. *Education:* educational level achieved by the participant, measured in years
7. *Health:* health of the participant, defined as their lung function measured by the forced expiratory volume in one second (FEV1), a measure of lung function
8. *Independent variable:* self-efficacy, as measured by participant scores on the Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6)
9. *Self-efficacy:* Bandura's (1977) definition of one's belief in their ability to complete a task

10. *Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6):* reliable and valid instrument used for measuring self-efficacy in people with chronic disease
11. *Sexual and reproductive health care services:* routine SRH care, as measured by routine obstetrician/gynecologist (OB/GYN) office visit, contraceptive use, or receipt of a Pap smear
12. *Sexual and reproductive health:* SRH is defined as aspects of individual health specifically related to sexual health, including but not limited to, routine sexual health maintenance care, reproductive concerns, or cancer prevention such as a Pap smear
13. *Sources of self-efficacy:* Bandura's 2004 definition comprised of mastery experiences, vicarious experiences, verbal persuasion, and physiological state
14. *Utilization of SRH services:* SRH care services utilized by participants, specifically a routine visit to the obstetrician/gynecologist, a Pap smear, or use of contraceptives

Chapter Summary

This dissertation study provides new information on the perspectives of women with CF regarding self-efficacy and utilization of SRH care services. Using a concurrent mixed methods approach, this study examined self-efficacy in women with CF and the association of self-efficacy to utilization of SRH care services, establishing the basis for future studies designed to improve outcomes for this population regarding SRH care utilization. Chapter 2 presents two integrated reviews of the literature: 1) a review of SRH and CF, which establishes what is known about SRH in CF; and 2) a review of self-efficacy and CF, which establishes what is not known about this topic. Chapter 2 also describes the conceptual framework guiding this study and explains the need for the study.

CHAPTER 2

LITERATURE REVIEW

The purpose of Chapter 2 is to present the state of the science of SRH and self-efficacy in women with CF and to review the literature of SRH and self-efficacy in women with CF. This chapter discusses the theoretical framework and identifies the study design and methods. Presentation of the conceptual framework, epidemiology, review of the literature, and design and methods provides rationale for the study. Because little is known about self-efficacy and SRH among women with CF, this study makes a valuable contribution to the research in this field.

Conceptual Framework

The theoretical framework for this study was the self-efficacy construct of Bandura's Social Cognitive Theory (Bandura, 1977). The model evolved from Bandura's (1977) original construct to include dimensions of SRH (comfort with topic, knowledge of topic, previous experiences, and prioritization of care) identified from a concept analysis of SRH in CF (Brown et al., 2018) and Bandura's (2004) sources of self-efficacy (mastery experiences, vicarious experiences, verbal persuasion, and physiological status) as influencers of self-efficacy. Self-efficacy has a key role in personal change in this model (Bandura, 2004). Notably, self-efficacy has been shown to be associated with improved outcomes in chronic disease (Faint et al., 2017), making this framework appropriate for this study. Dr. Bandura was contacted via email to request permission to adapt the model for this study. Email consent was obtained. Please see Appendix A.

Conceptual Model

Figure 1 represents Bandura’s (2004) model of self-efficacy affecting personal change. In this model, self-efficacy affects goals, which subsequently affects behavior. Self-efficacy impacts outcome expectations, and these outcome expectations affect both goals and behavior. Self-efficacy affects sociocultural factors, which in turn affect goals. The core of the model is self-efficacy, which directly impacts behavior. Figure 2 is a representation of the core of the model, specifically the tenet that self-efficacy affects behavior. For this study, the core model depicted in Figure 2 was expanded to include Bandura’s (1977) sources of self-efficacy (mastery experiences, vicarious experiences, verbal persuasion, and physiological state) as potential influences on the development of self-efficacy. The model was further expanded to include dimensions of SRH (comfort with topic, knowledge of topic, previous experiences, and prioritization of care) noted in literature (Brown et al., 2018) as additional potential influencers of self-efficacy. This adapted model is depicted in Figure 3.

Figure 1

Bandura's (2004) Model of the Self-Efficacy Construct of the Social Cognitive Theory

Figure 1. Structural paths of influence wherein perceived self-efficacy affects health habits both directly and through its impact on goals, outcome expectations, and perception of sociostructural facilitators and impediments to health-promoting behavior.

Figure 2

Self-Efficacy Construct of Bandura's Social Cognitive Theory as Framework

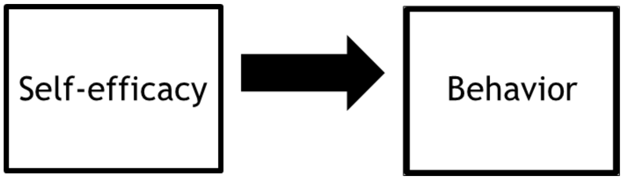
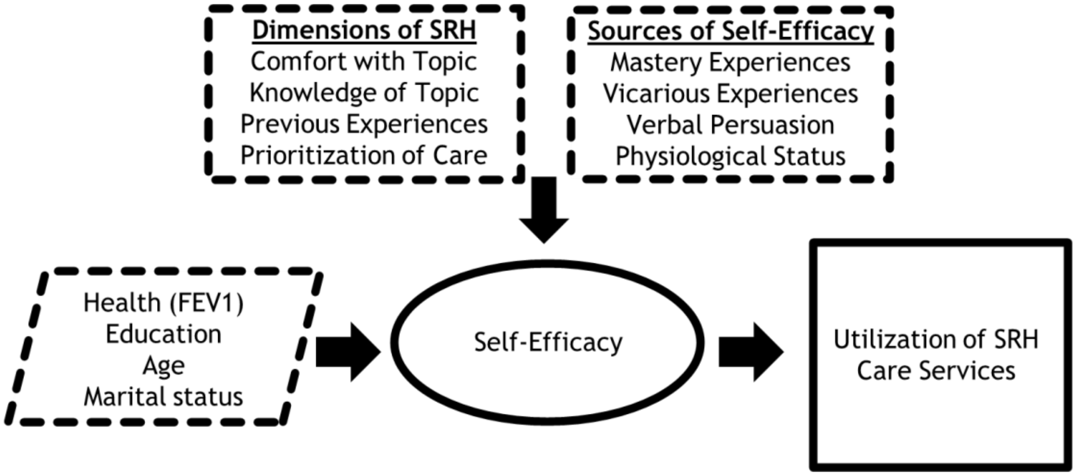


Figure 3

Expansion of Bandura's Model



Note. Bandura's model is expanded to represent the impact of health, education, age, and marital status on self-efficacy and the influences of dimensions of SRH (Brown et al., 2018) and sources of self-efficacy (Bandura, 2004) on utilization of SRH care services.

Variables and Measurement

Variables for this study included self-efficacy, utilization of SRH care services, age, marital status, and health as measured by the forced expiratory volume in one second (FEV1), or the amount of air an individual can force from their lungs (exhale) in one second. Self-efficacy was conceptually defined using Bandura's (1977) definition of *confidence in one's ability to complete a task.* Self-efficacy was operationally defined as the comprehensive score of each completed Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6) instrument included in the survey. The empirical indicator was that higher SEMCD6 scores were indicative of higher self-efficacy. Utilization of SRH care services was conceptually defined as self-report on the survey of having received at least one SRH care service in the past year (use of contraception, Pap smear, or gynecological office visit). Utilization of SRH care services was operationally defined as the number of SRH care services participants received in the past year.

The variables of age, health, and marital status may influence self-efficacy. Age was defined as the participant’s age in years and measured by self-report on the survey. Education was defined as level of education obtained by the participant and was measured by self-report on the survey. Lung health was defined as the disease severity of the participant and was measured by the participant’s self-reported FEV1, with higher scores indicative of better lung health.

Four dimensions of SRH identified in literature were included in the model as potential influencers of self-efficacy: comfort with topic of SRH, knowledge of topic of SRH, previous experiences with SRH, and prioritization of care (Brown et al., 2018). Participants’ dimensions of comfort with topic, knowledge of topic, previous experiences, and prioritization of care were conceptually defined as self-disclosure and discussion during the individual interview and operationally defined as self-report of experiences and measured by qualitative analysis using thematic analysis (empirical indicator).

Bandura’s (2004) sources of self-efficacy, mastery experiences, vicarious experiences, verbal persuasion, and physiological state, were included in the model as potential influencers of self-efficacy. These four concepts were conceptually defined as discussion of the topic during the individual interview and operationally defined as self-disclosure or discussion and measured by qualitative analysis using thematic analysis (empirical indicator). Table 1 presents the definitions and empirical indicators of the variables.

Table 1

Conceptual and Operational Definitions of Variables and Their Indicators

Variable	Conceptual Definition	Operational Definition	Empirical Indicators
Self-efficacy	Confidence in one's ability to complete a task	Comprehensive score of each completed Self-efficacy for Managing Chronic Disease 6-item scale (SEMCD6)	Higher SEMCD6 global scores indicative of higher self-efficacy
Utilization of SRH care services	At least one SRH care service in the past	Receipt of at least one SRH service in the past year	Score of 0-3 of number of SRH services utilized in the past year
Comfort with topic	Self-report of their experiences	Discussion of this topic during an individual interview	Qualitative analysis using thematic analysis
Knowledge of topic	Self-report of their experiences	Discussion of this topic during an individual interview	Qualitative analysis using thematic analysis
Previous experiences	Self-report of their experiences	Discussion of this topic during an individual interview	Qualitative analysis using thematic analysis
Prioritization of care	Self-report of their experiences	Discussion of this topic during an individual interview	Qualitative analysis using thematic analysis
Age	Participant age in years	Self-reported age in years on survey	Age measured in years
Education	Highest level of education obtained	Self-reported level of education on survey	Education measured in years

Health (disease severity)	Lung function, indicative of overall health	Self-report of lung function on survey reported as FEV1	Numerical value of FEV1, with higher values indicative of better lung health
Marital status	Married or not married	Self-report of marital status on survey	Marital status dichotomized to “yes” married, or “no” not married

Epidemiologic Basis and Concepts of Interest

Cystic fibrosis is the most common life-limiting genetic disorder among Caucasians. There are approximately 70,000 individuals living with CF worldwide, with approximately 1,000 new cases diagnosed globally each year (CFF, 2019a). This autosomal recessive genetic mutation alters the cystic fibrosis transmembrane conductance regulator, thereby affecting sodium chloride transport channels at the cellular level, with resultant thick mucus that affects many body systems (CFF, 2019a).

Improved therapies have altered the trajectory of CF from that of a childhood terminal illness to a chronic disease that extends into adulthood. Advances in medical care, including new medications that correct the sodium chloride channel defect or facilitate the protein transport (modulators and correctors), have yielded prolonged life expectancies and improvements in quality of life for people with CF. Individuals with CF now have a median life expectancy of 47.4 years (CFF, 2019a) and achieve both childhood and adult developmental milestones at the same time as their peers without CF (Frayman & Sawyer, 2015). In fact, greater than half of the CF population are now adults (CFF, 2019a). With a longer predicted life expectancy, adherence to therapies, self-management behaviors, and active participation in care have become increasingly important (Bartholomew et al., 1997). With a daily care regimen that requires an investment of up to two or more hours daily, adherence can be daunting (CFF, 2019a). Research has shown that adherence to the prescribed daily care regimen is essential for optimizing health and results in better lung function, fewer exacerbations, and fewer hospitalizations (CFF, 2019a). However, poor adherence has been reported even in the era of modulator and corrector medications (Grossoehme et al., 2015).

Sexual and Reproductive Health Care

Routine health care, such as SRH care, is underutilized by women with CF. Despite evidence that women with CF have similar SRH behaviors as their healthy peers (Simcox et al., 2009), provision of comprehensive CF care may not routinely and adequately address SRH (Withers, 2012).

Utilization of SRH Care Services

Underutilization of SRH care services may put women with CF at risk for undetected cervical cancer; or the risk of an unplanned pregnancy when health is not optimized, or pregnancy is not desired. For these reasons, it is important to explore factors that may be related to adherence or utilization of SRH care services. Self-efficacy may be a factor related to adherence or utilization of services.

Self-Efficacy

Bandura's (1977) self-efficacy construct of the Social Cognitive Theory states that an individual's personal self-efficacy level dictates whether there will be a resultant behavioral change. Self-efficacy is determined by mastery experiences, vicarious experiences, verbal persuasion, or the physiological status of the individual. The construct posits that a relationship exists between self-efficacy and behavioral change.

Self-Efficacy in Healthy Individuals

Self-efficacy beliefs are often related to an individual's performance (Creer & Wigal, 1993). Those with a higher perceived self-efficacy are more likely to engage more fully and exert effort to achieve superior performance (Artistico et al., 2003). Individual beliefs about self can cultivate high and low self-efficacy across diverse situations (Artistico et al., 2003). An individual's perceived self-efficacy, and their confidence that they will be successful in their endeavor, impact an individual's behavior (Creer & Wigal, 1993). Self-efficacy influences lives in three major arenas. First, perceived self-efficacy influences the choices individuals make (Creer & Wigal, 1993). Individuals make decisions based on things they feel can be mastered and tend to avoid those they do not feel can be mastered. Secondly, motivation to initiate a behavior or attempt a skill or task is influenced by self-efficacy (Creer & Wigal, 1993). Perceived high self-efficacy motivates an individual to attempt mastery of learning, including mastery of skills or willingness to attempt new experiences, and is related to perseverance in the presence of obstacles. Thirdly, perceived self-efficacy impacts cognitive processes, including thinking (Creer & Wigal, 1993). Individuals with low perceived self-efficacy experience self-doubt and lack the confidence in their ability to complete a task or develop a skill. Those with high perceived self-efficacy persevere despite roadblocks (Creer & Wigal, 1993).

In its simplest expression, the model for self-efficacy posits that an individual's level of perceived self-efficacy (efficiency expectations) affects their behavior and the resultant outcome (outcome expectations). Psychological events, in whatever form they occur, either strengthen or weaken perceived self-efficacy, therefore impacting behavior outcomes (Bandura, 1977). This is not the same as simply a prediction of behavior (outcome) but is defined as an individual's confidence in their ability to complete a behavior or task to achieve the desired result (Bandura, 1977). This confidence alone does not determine whether they will be successful, as they must possess the necessary skill, but it is related to whether they will attempt the activity, regardless of their actual skill level. Conversely, an individual with adequate skill and low perceived self-efficacy would not be likely to undertake the activity. However, if skill is adequate and motivation exists, perceived self-efficacy is a major determinant in an individual's choice to attempt (or not attempt) any given task or activity.

Studies have shown self-efficacy to be a key predictor of performance (Feltz & Magyar, 2006). In his 2019 study, Shipherd demonstrated self-efficacy predictors changed over four trials with college students completing a wooden skill puzzle. On trial one, verbal and imagined experiences were the two most important self-efficacy sources, but by the fourth trial with the puzzle, mastery experiences and verbal information (persuasion) were the most important. These studies highlight that self-efficacy can be improved and specific cognitive behavioral therapy interventions may affect an individual's perceived self-efficacy.

Mastery Experiences

An individual's previous successful experiences are valuable sources of self-efficacy because they give an individual evidence of their ability to succeed. Performance outcomes have a cumulative effect and result in increased self-efficacy if the task is mastered or the experience is positive. This is particularly noted when an unsuccessful experience occurs prior to developing self-efficacy, particularly during childhood or adolescence (Shipherd, 2019).

Vicarious Experiences

Vicarious experiences are also identified as modeling or observational learning and can impact development (or lack of development) of self-efficacy. Observing another's success or failure can reinforce an individual's confidence in their own ability to perform the same task. The vicarious experience can serve as a motivator to attempt a new task when success is modeled (Shipherd, 2019).

Verbal Persuasion

Verbal persuasion occurs when a person of influence explains, encourages, or verbally supports the efforts of an individual contemplating attempting a new skill or task. Verbal discouragement can contribute to failure to develop self-efficacy toward the task or skill (Shipherd, 2019).

Physiological State

Factors influencing the physiological state include pain, fatigue, physical limitations, physical strength, or an individual’s perception of physical fitness. Negative physiological factors have been correlated with lower self-efficacy, particularly when related to physical factors of wellness such as exercise (Shipherd, 2019).

Self-Efficacy in Chronic Illness

Higher self-efficacy has been shown to be associated with improved outcomes in chronic disease (Faint et al., 2017). In a 2019 study conducted among rural patients, results indicated that health self-efficacy predicts engagement in both treatment adherence and health-promoting behaviors (Roncoroni et al., 2019). A review and synthesis of research evidence for self-efficacy enhancing interventions highlighted an arthritis program based on Bandura’s (1977) self-efficacy construct and linked sustained clinical improvements to improved arthritis self-efficacy (Marks et al., 2005). Another study reviewed by Marks et al. (2005) discussed self-efficacy as a significant outcome predictor for women with heart disease. In a 2011 study, Mishali et al. demonstrated that self-efficacy impacts adherence to treatments in patients with diabetes, therefore impacting clinical outcomes. A study of children with asthma showed that self-efficacy increased after education, indicating self-efficacy can be a modifiable factor (Kocaaslan & Kostak, 2019). A study of self-efficacy as a relevant construct in understanding sexual response and dysfunction found self-efficacy a predictor for cognitive, affective, motivational, and behavioral responses (Rowland et al., 2015). Additionally, an intervention study among adolescents with thalassemia major indicated self-efficacy scores were improved following an educational intervention (Borimnejad et al., 2018). The cited studies highlight the diversity of chronic diseases in which self-efficacy has been studied and demonstrate the relationship between self-efficacy and behavior in chronic illness. Bandura’s (1977) self-efficacy construct of the Social Cognitive Theory, the basis of the theoretical framework for this study, posits that self-efficacy shapes the outcomes individuals expect from their efforts. Bandura’s (1977) theory states that an individual’s personal (self) efficacy is the factor that determines whether an individual can manage a situation; furthermore, mastery of tasks can improve self-efficacy. In this model, self-efficacy develops from four main areas: performance accomplishments (mastery experiences), vicarious experiences, verbal persuasion, and physiological states (Bandura, 1977; Shipherd, 2019).

Self-Efficacy in Cystic Fibrosis

While there are many examples of studies evaluating self-efficacy in other chronic illnesses, an exhaustive review of literature with expanded MeSH search terms and multiple databases produced a total of 11 full-text articles related to CF and self-efficacy. The 11 full-text articles related to self-efficacy and CF were evaluated. Findings include: (a) self-efficacy is related to CF outcomes (Cramm et al., 2013; Grossoehme et al., 2015; Parcel et al., 1994; Wahl et al., 2005), and (b) interventions have been shown to improve self-efficacy (Bartholomew et al., 1997; Cummings et al., 2011; McDonald et al., 2013). Conversely, one study found that self-efficacy is not associated with adherence to therapies in adolescents with CF (Faint et al., 2017).

In a recent study of adults with CF, self-confidence predicted persistence with therapies, demonstrating opportunity for intervention development to improve self-efficacy and CF outcomes (Sherman et al., 2019). Self-efficacy in those with CF has been shown to be modifiable with a behavioral intervention program (Cummings et al., 2011), and higher self-efficacy is associated with improvements in CF symptoms, physical and emotional well-being, and in social activity (Wahl et al., 2005).

Evaluation of the 11 full-text articles revealed that the construct of self-efficacy in CF is similar to self-efficacy in other chronic illnesses in that: (a) interventions have increased self-efficacy, (b) higher self-efficacy correlates with improved outcomes, and (c) self-efficacy has been shown to be a predictor for adherence to therapies except in one study conducted with adolescents in which self-efficacy was not related to improvement in adherence to therapy (Faint et al., 2017).

Self-Efficacy Across the Lifespan

Self-efficacy in healthy individuals is determined by four developmental influences: biological, psychological, sociocultural, and life cycle (Cavanaugh & Blanchard-Fields, 2002). These forces impact an individual throughout the lifespan to promote or prevent development of self-efficacy. In early infancy, the infant begins to learn cause-and-effect relationships, including the reciprocal effects of self in the world (Cervone et al., 2006). Experiences early in life shape and influence development (or lack of development) of the child’s sense of personal agency, which leads to their self-perception of self-efficacy (or lack thereof). As the child moves toward adolescence and subsequently adulthood, perceived self-efficacy continues to be impacted by biological influences (health status, diagnosis of disease, genetics), psychological influences (experiences, vicarious experiences, mastery experiences), sociocultural influences (socioeconomic status, education, familial influences), and life cycle (development of adult cognition, slowing of cognition related to aging or disease). Life experiences may increase or decrease development of perceived self-efficacy with impact from mastery experiences, vicarious experiences, verbal persuasion, and physiological state throughout the lifespan (Cavanaugh & Blanchard-Fields, 2002). Normal cognitive development paired with impact from the influencers produces varied levels of self-efficacy across the lifespan.

Analysis of the Literature Relative to Concepts

Two literature reviews were conducted to fully understand the concepts of self-efficacy, SRH, and CF. An initial search using terms related to self-efficacy, SRH, and CF did not yield any articles. Therefore, the search terms were expanded, and two reviews were conducted. The first review of literature was related to the concepts of self-efficacy and CF, and the second review of literature was related to SRH and CF.

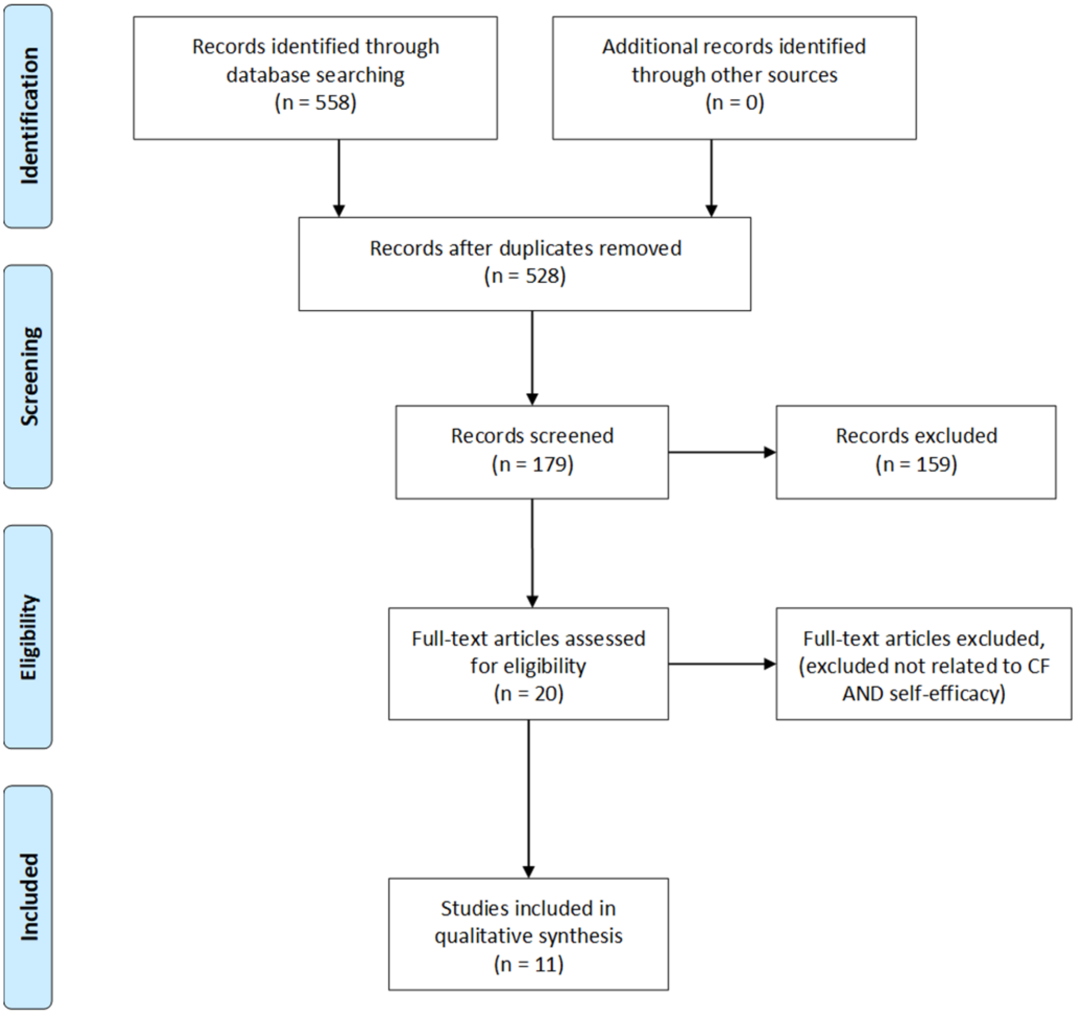
Review of Literature on Self-Efficacy and Cystic Fibrosis

An extensive review of the literature did not yield any studies related to SRH and self-efficacy in women with CF. The literature on self-efficacy and CF is sparse, and includes qualitative and quantitative studies of children, adolescents, and adults with CF as well as parents of children with CF. For these reasons, search terms were expanded to include self-efficacy AND CF. A review of the literature was initiated following the

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) methodology (Figure 4). A database search was conducted using CINAHL, PubMed, Scopus, and PsycINFO. Truncated key terms used in various combinations included: cystic fibrosis AND self-efficacy, sexual and reproductive health, sexual health, reproductive health, and women OR female. Table 2 summarizes the search terms used for each database. The expanded CINAHL search with medical subject headings (MeSH) for CF and self-efficacy (see Table 2) resulted in 394 articles with six related to CF AND self-efficacy. The PubMed search yielded 87 articles with six duplicates, and one related to CF AND self-efficacy. The PsycINFO search yielded 30 articles with four duplicates and two related articles. The Scopus search yielded 47 results with eight duplicates and one related to the topic.

Figure 4

Steps in the Self-Efficacy and CF Review of Literature



Note. Adapted from "*P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement" by D. Moher, A. Liberati, J. Tetzlaff, D. G. Altman, The PRISMA Group, 2009, *Public Library of Science Medicine, 6*(7): e1000097 (https://doi.org/10.1371/journal. pmed1000).

Table 2

Search Terms for CF and Self-Efficacy Review of Literature

Database Searched	**Terms Searched**
PubMed	cystic fibrosis AND self-efficacy Cystic Fibrosis AND (Sexual Health OR Reproductive Health OR Reproductive Techniques OR Reproductive Health Services OR Reproductive Health Medicine OR Family Planning OR Family Planning Services OR Maternal Health Services) AND (Sick Role OR Self-Efficacy OR Self-Concept OR Self-Perception OR Self-Esteem OR Self-Confidence OR Personal-Autonomy OR Self-Disclosure OR Self-Assessment OR Egocentrism OR Belief OR Motivation OR Emotional Intelligence) AND (women OR female)
CINAHL	cystic fibrosis AND self-efficacy Cystic Fibrosis AND (Sexual Health OR Reproductive Health) AND (Self-Efficacy OR Self-Concept OR Confidence OR Self-Actualization OR Self-Awareness OR Self Disclosure OR Self Transcendence) AND (Women OR Female) (MH "Cystic Fibrosis") OR TI cystic-fibrosis OR AB cystic-fibrosis OR TI mucoviscidosis OR AB mucoviscidosisAND(MH "Self-Efficacy") OR TI self-efficacy OR AB self-efficacy OR TI self-management OR AB self-management OR TI self-advocacy OR AB self-advocacy OR TI motivation OR AB motivation OR TI belief OR AB belief OR TI believe OR AB believe OR TI self-concept OR AB self-concept OR TI self-ownership OR AB self-ownership OR Perception* OR AB perception* OR TI perceived OR AB perceived OR TI execute-behavior* OR AB execute-behavior* OR TI behavior-management OR AB behavior-management OR TI mastering-problem* OR AB mastering-problem* OR TI undertake OR AB undertake OR TI persevere OR AB persevere OR TI competencies OR AB competencies OR TI self-confidence OR AB self-confidence OR TI self-awareness OR AB self-awareness OR TI self-actualization OR AB self-actualization OR TI self-disclosure OR AB self-disclosure OR TI self-transcendence OR AB self-transcendence OR TI self-esteem OR AB self-esteem OR TI self-assessment OR AB self-assessment OR TI egocentrism OR AB

	egocentrism OR TI emotional-intelligence OR AB emotional-intelligence OR TI personal-autonomy OR AB personal-autonomy OR TI helplessness OR AB helplessness OR TI self-evaluation OR AB self-evaluation
PsycINFO	cystic fibrosis AND self-efficacyMAINSUBJECT.EXACT. EXPLODE ("Cystic Fibrosis") OR AB, TI ("cystic fibrosis" OR CF) AND (MAINSUBJECT.EXACT. EXPLODE ("Self-Efficacy") OR AB, TI (self-efficacy OR self-concept OR expectations OR helplessness OR instrumentality OR self-confidence OR self-evaluation OR self-fulfilling prophecies OR self-perception OR efficacy-expectations)
Scopus	cystic fibrosis AND self-efficacy (cystic AND fibrosis)) AND ((reproductive AND health) OR (sexual AND Health)) AND (self-efficacy)

Study Selection

The search yielded a total of 558 articles that were screened by title, yielding 179 articles that were then screened for relevance by abstract. Thirty duplicates were removed. Screening of the 179 articles resulted in 20 full-text articles related to topic that were evaluated. Articles were excluded that did not include both self-efficacy AND CF, yielding 11 full-text articles written in English that were included in this review. Table 3 includes these 11 articles.

Table 3

Self-Efficacy and CF Articles

Study	**Design**	**Sample**	**Major Variables & Definitions**	**Measurement**	**Data Analysis**	**Intervention**	**Findings**
Bartholomew 1993 Development and evaluation psychometrics of an instrument to measure self-efficacy in CF	Instrument Development Piloted with 96 parents of children with CF from the CF Center at Baylor College of Medicine & Texas Children's Hospital	N=199		Caretaker and adolescent self-efficacy instrument	Factor Analysis	none	Caretaker and adolescent self-efficacy instruments are internally consistent measures of self-efficacy in CF Strengths: high α-coefficients (Cronbach's α-coefficients .73-.85) demonstrate internal consistency of instrument Limitation: findings may not be replicable
Bartholomew, et al., 1997 Study tested the efficacy of the CF Family Education	Quantitative Quasi-experimental pre/post test Non-equivalent	N=104 N=95 Non-Equi-valent Control group	Dependent variable=self-efficacy Independent variable = education intervention	Self-efficacy Scale developed by the author	ANCOVA	CF Self-Management Program	Significant differences between intervention and control group for caregiver and child self-efficacy

Program	comparison group						
Cheng, 2015 Chaplain intervention designed to promote adherence to therapy for adolescents with CF	Qualitative Semi-structured Interviews Pilot study	N=24		Not reported	Not reported	Chaplain Intervention (not described or named)	Intervention was acceptable to 11-19-year-old adolescents with CF Strengths: Based on Theory of Reasoned Action Limitations: intervention is not described, convenience sample was used, sample included mostly adolescents with mild disease and *mild* disease was not defined
Cramm, 2013 Evaluated the effect of general self-efficacy perceived by adolescents with chronic	Quantitative Cross-sectional Study Surveys	N=24	Dependent variable = quality of life Independent variable=self-efficacy	10-item General Self-Efficacy Scale DISABKIDS Instrument	Multiple Regression	none	General self-efficacy of adolescents may affect quality of life Strengths: used validated scale Limitations: cross-sectional, causal relationships cannot be inferred, one

illness on quality of life							measurement point, did not look at whether interventions improved quality of life
Faint, 2017 Disease knowledge & self-efficacy was assessed	Quantitative Survey	N=39		10-item General Self-Efficacy Scale Knowledge of Disease Management-CF	t-test	none	Self-efficacy is not associated with adherence to therapies in adolescents with CF Strengths: used a validated scale, treatments for CF are widely used worldwide, used objective measure for adherence (pharmacy refill records) Limitations: small sample size; underpowered. Knowledge of Disease Management-CF did not include questions about study medications
Grissoehme, 2015 Adherence and self-efficacy	Quantitative multi-site, prospective, observational study	N=160 Site 1 N= 175 Site 2		Self-efficacy Scale designed from Bandura's guidelines		none	Self-efficacy was the only theoretical adherence determinant that was significant among the

was evaluated in parents of children younger than 13 years of age							groups Future study and interventions related to self-efficacy are needed Strengths: Based on the theory of reasoned action Limitations: Cross-sectional design does not allow causality, adherence measures may not be accurate
McDonald, 2013	Qualitative & Qualitative QI project using a convenience sample	N=30				CF parent website Email newsletters Facebook page	Parents reported increased confidence in self-management skills Strengths: Limitations: QI project, used a convenience Sample, small sample size
Cummings et al., 2011 Evaluated two	Quantitative Randomized single control trial	N=20	Dependent variable= Intervention	Self-efficacy measures chronic disease 6 (SEMCD6)		Intervention 1= self-efficacy program with mentor	Self-efficacy increased in both intervention groups as compared to control

Strategies designed to improve self-efficacy using mentoring and Self-monitoring using a mobile phone application			Independent variable= Self-efficacy			Intervention 2= same self-efficacy program + mobile phone control=normal CF care	Strengths: RCT, included a control group Limitations: small sample size
Parcel, 1994 Study to evaluate the efficacy of an education program to improve self-management of CF	Quantitative Knowledge surveys Cross-sectional	N=199	Dependent variable= education Program Independent variable=self-efficacy	Self-efficacy measure for caretakers	Factor analysis	Health education program	Self-efficacy was best predictor of self-management
Sherman et al., 2019	Quantitative Surveys	N=66	Dependent variable = persistence Independent variable =self-efficacy	Cystic Fibrosis Treatment Questionnaire (CFTQ) Medication Adherence Report Scale (MARS)	Bivariate analyses	none	Self-efficacy predicted persistence in adhering to airway clearance therapy (ACT)

				Self-Efficacy for Airway Clearance Beliefs about Medications Questionnaire-Specific (BMQ-Specific) Marlowe-Crowne Social Desirability Scale Hospital Anxiety and Depression Scale (HADS)			
Wahl, 2005 Study examined self-efficacy as a modifier of the relationship of perceived health status and global quality of life	Quantitative surveys	N=86	Dependent variable = pulmonary function, health status & global quality of life Independent variable = age, gender,	General self - efficacy measure (GSS) Quality of Life Scale (QOLS)	Pearson's correlations Multiple Linear regressions	none	Self-efficacy is a factor in explaining health status and global quality of life Strengths: Limitations: cross-sectional, no control group

in adults with CF			marital status, self-efficacy				

Results

The studies included in this review (*n* = 11) were quantitative (*n* = 9) and qualitative (*n* = 1), and one study used both quantitative and qualitative methods (*n* = 1). Publication dates ranged from 1993 to 2017. The oldest study (1993) described the development of a scale to measure self-efficacy. The studies were conducted in Australia, the Netherlands, Norway, and the United States. Two studies recruited only adults, two studies recruited children with CF and their parents, two studies recruited adolescents with CF and their parents, one study recruited adults and adolescents with CF, two recruited parents of children with CF, and two recruited only adolescents. Six of the studies were small, with sample sizes ranging from 20 to 39; the other five studies had sample sizes ranging from 86-199. Measures utilized in the studies to assess self-efficacy included: (a) Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6), (b) the General Self-Efficacy Scale (GSE), (c) Cystic Fibrosis Self-Efficacy Instrument for Caretakers, and (d) Self-Efficacy Instrument for Caretakers. One study was a randomized single control trial, one used a quasi-experimental pretest-posttest design, one was qualitative utilizing semi-structured interviews, one utilized both quantitative and qualitative measures, and the rest were comparison, correlation, or observational studies.

Intervention Studies on Self-Efficacy.

Interventions were incorporated into five of the studies and included a mobile phone self-monitoring application (Cummings et al., 2011); parent website and Facebook page (McDonald et al., 2013); a self-paced print curriculum focused on social cognitive theory, behavioral ability, and self-efficacy (Bartholomew et al., 1997); a chaplain intervention that was not described (Cheng et al., 2015); and an educational intervention (Parcel et al., 1994). Table 3 displays the studies by design, independent and dependent variables, type of measure used, data analysis, intervention, and findings.

Bartholomew et al. (1993) developed and validated a survey to measure self-efficacy in children with CF and their primary caregivers. Bartholomew et al. (1997) later used the survey to evaluate the effectiveness of a self-management program to improve self-efficacy in children and adolescents with CF and their parents. The intervention resulted in improved self-efficacy as compared to the dyads in the non-intervention group.

Nonintervention Studies on Self-Efficacy.

Five of the studies did not include an intervention. These studies assessed correlations between general self-efficacy and quality of life and evaluated quality of life predictors (Cramm et al., 2013), evaluated disease knowledge and self-efficacy related to adherence measured by pharmacy refill records (Faint et al., 2017), reported psychometrics related to development of the self-efficacy for parents or caretakers measure (Bartholomew et al., 1993), evaluated self-efficacy via a survey in an observational study (Grossoehme et al., 2015), and assessed perceived self-efficacy via a survey using the General Self-Efficacy Scale (Wahl et al., 2005).

Qualitative Studies on Self-Efficacy.

One of the studies was qualitative, and one study included both a qualitative and quantitative component. Semi-structured interviews were utilized to evaluate a chaplain intervention program (Cheng et al., 2015), and informal interviews were used to evaluate parent-driven educational strategies (McDonald et al., 2013). Responses of parents of children in the

McDonald et al. (2013) study indicated that parents felt more confident in their capability to manage CF care for their child after the educational intervention.

Comparison of Measures.

Self-efficacy was measured with the Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6) in one study (Cummings et al., 2011), with the General Self-Efficacy Scale in three studies, (Cramm et al., 2013; Faint et al., 2017; Wahl et al., 2005), with a Self-Efficacy Scale developed by the author in one study (Bartholomew et al., 1997), with a Self-Efficacy Scale designed from Bandura's guidelines (Grossoehme et al., 2015), and with the Self-Efficacy Instrument for Caretakers (Parcel et al., 1994). Studies reporting psychometrics for the measure include the Caretaker and Adolescent Self-Efficacy Instrument developed by the study author (Bartholomew et al., 1993) and the General Self-Efficacy Scale (Cramm et al., 2013; Wahl et al., 2005).

Strengths

Strengths of the studies include use of a validated instrument (Bartholomew et al., 1993; Cramm et al., 2013; Wahl et al., 2005), inclusion of a control group (Bartholomew et al., 1997; Cummings et al., 2011), having a theoretical basis (Bartholomew et al., 1997; Cheng et al., 2015; Grossoehme et al., 2015; Parcel et al., 1994), use of objective measure for variable (Faint et al., 2017), and use of randomized control study (Cummings et al., 2011).

Limitations

Limitations noted include use of a convenience sample (Cheng et al., 2015; McDonald et al., 2013), which limits generalizability; cross-sectional design (Cramm et al., 2013; Grossoehme et al., 2015; Parcel et al., 1994; Wahl et al., 2005), which impacts causality; and small sample size (Cheng et al., 2015; Cramm et al., 2013; Cummings et al., 2011; Faint et al., 2017; McDonald et al., 2013).

Findings

Findings include: (a) self-efficacy is a factor associated with health status, quality of life (Cramm et al., 2013; Wahl et al., 2005), and self-management (Parcel et al., 1994); (b) interventions have been shown to improve self-efficacy (Bartholomew et al., 1997; McDonald et al., 2013); (c) it is reasonable to incorporate interventions to improve self-efficacy (Cummings et al., 2011); and (d) more research is needed in this area. Conversely, one study found that self-efficacy is not associated with adherence to therapies in adolescents with CF (Faint et al., 2017).

Relevance to Clinical Practice

Studies included in this review revealed that a relationship exists between quality of life, health status, and self-efficacy, with higher self-efficacy indicative of better quality of life and health status (Wahl et al., 2005). Thus, with evidence of interventions that improved self-efficacy, these findings may be used to develop care protocols designed to increase self-efficacy with the expected goal of improved health status and quality of life.

Conclusion

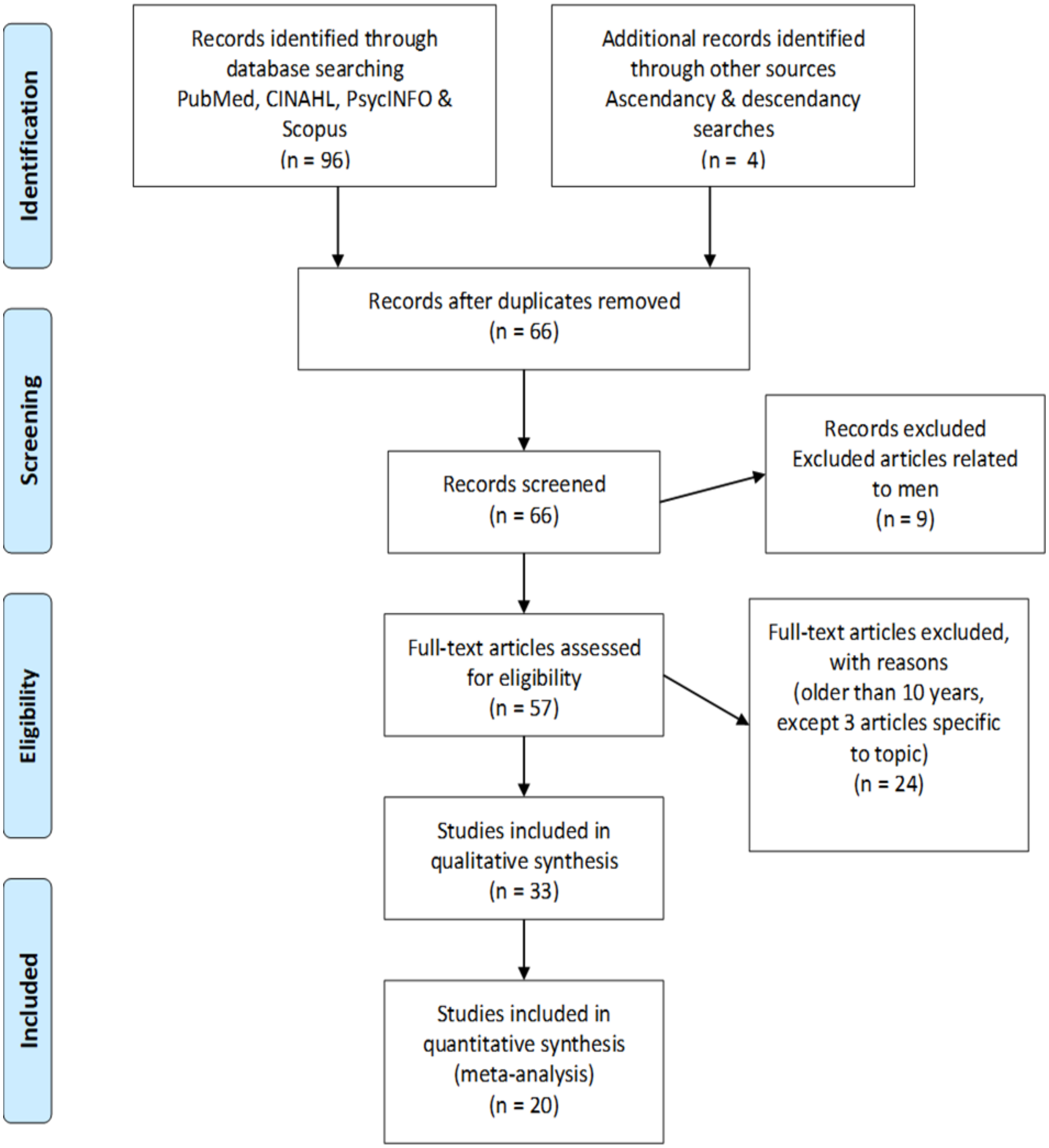
This review revealed that more research is needed in self-efficacy as it relates to CF. It has been demonstrated that self-efficacy, which is a vital component required for effective self-management of a chronic disease, can be improved with behavioral interventions that increase the individual's confidence with completing a self-management task. With the scarcity of research available related to CF and self-efficacy, it may be helpful to explore self-efficacy in other chronic diseases.

Review of Literature on Sexual and Reproductive Health and Cystic Fibrosis

A database search was conducted using CINAHL, PubMed, Scopus, and PsycINFO. Truncated key terms used in various combinations included: sexual, reproductive, cystic fibrosis, fertility, education, and women. Figure 5 depicts the steps in the literature search, and Table 4 summarizes the search terms used for each database. English articles published in the last 10 years were included for preliminary review, and articles focusing on men with CF were excluded. Initially, a filter was utilized to limit articles to those published within the past 10 years (2008-2018); however, this filter was subsequently removed due to the limited number of articles that emerged from the initial search. After removal of duplicates and nonrelevance, the initial yield of 96 articles was narrowed down to 20 that were included in the final analysis. Table 5 presents a synthesis of the review of this literature.

Figure 5

Steps in the SRH and CF Review of Literature



Note. Adapted from "*P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement" by D. Moher, A. Liberati, J. Tetzlaff, D. G. Altman, The PRISMA Group, 2009, *Public Library of Science Medicine*, *6*(7): e1000097 (https://doi.org/10.1371/journal.pmed1000097).

Table 4

Databases Searched in the SRH AND CF Review of Literature

Database Search	Terms Searched
PubMed	▪ Sexual AND women AND reproductive AND cystic fibrosis ▪ Fertility AND cystic fibrosis ▪ Sexuality AND reproductive AND education AND cystic fibrosis
CINAHL	▪ Sexual AND women AND reproductive AND cystic fibrosis ▪ Fertility AND cystic fibrosis ▪ Sexuality AND reproductive AND education AND cystic fibrosis
PsycINFO	▪ Sexual AND women AND reproductive AND cystic fibrosis
Scopus	▪ Sexual AND women AND reproductive AND cystic fibrosis

Table 5

Synthesis of Review of Literature

Author (Date)	Major Finding	Dimension	Perspective
Askew (2017)	More information regarding SRH is wanted.	▪ Knowledge of topic	Patient Parent
Frayman (2015)	Gaps exist in SRH education for adult women with CF.	▪ Knowledge of topic	Patient Parent
Gage (2012)	Women with CF want SRH information.	▪ Knowledge of topic ▪ Comfort with topic	Patient Provider
Gatiss (2018)	Women with CF have high rates of unplanned pregnancy and do not receive optimal SRH care. CF teams lack training in SRH care.	▪ Knowledge of topic ▪ Prioritization of care	Patient Provider
Goss (2003)	Women with CF who become pregnant do not have shortened lifespans. Healthcare providers should not impose their view onto patients.	▪ Prioritization of care	Patient Provider
Havermans (2011)	Mothers of children with CF want more SRH	▪ Comfort with topic	Patient Parent

	information. CF healthcare team should initiate SRH care.	▪ Knowledge of topic	
Hull (2000)	Unplanned pregnancies among women with CF may be related to lack of knowledge regarding fertility.	▪ Knowledge of topic ▪ Prioritization of care	Patient Provider
Jacobs (2015)	Adolescents with CF want SRH information.	▪ Knowledge of topic	Patient Provider
Kazmerski et al. (2018)	80% of women in study desire to have children. SRH care is unaddressed during routine CF care.	▪ Knowledge of topic ▪ Comfort with topic ▪ Previous experiences	Patient Provider Parent
Kazmerski et al. (2017)	Barriers exist in the provision of SRH care.	▪ Comfort with topic	Patient Provider
Kazmerski et al. (2016)	CF providers face barriers to provision of SRH care (embarrassment [comfort] with topic], lack of knowledge.	▪ Comfort with topic ▪ Prioritization of care ▪ Knowledge of topic	Patient Provider Partner
Kazmerski, Miller,Abebe, Matisko, Schachner,& Spahr (2015)	Association exists between knowledge of condition and adherence to therapy.	▪ Knowledge of topic	Patient Provider

Ladores (2017)	Women have carried pregnancies to term and delivered healthy babies while taking ivacaftor.	▪ Knowledge of topic	Patient
Sawyer (2001)	Training is needed for providers regarding SRH.	▪ Knowledge of topic	Provider
Sawyer,Phelan, & Bowes (1995)	Lack of knowledge about SRH has a major impact on lives of women with CF.	▪ Knowledge of topic	Patient
Tsang (2010)	CF healthcare providers lack SRH expertise. Adolescent girls with CF and their mothers want SRH information.	▪ Knowledge of topic ▪ Comfort with topic	Patient Provider Partner
Simcox (2009)	Those with CF are as likely as healthy peers to consider starting a family.	▪ Knowledge of topic ▪ Prioritization of care	Patient Partner
Withers (2012)	Adolescents with CF have unmet SRH care needs.	▪ Knowledge of topic ▪ Comfort with topic	Patient Provider Parent

Results

This analysis revealed four dimensions related to the topic of SRH in women with CF: comfort with topic, knowledge of topic, previous experiences, and prioritization of care. Comfort with topic concerns the discomfort or embarrassment that may be experienced by the patient, partner/parent, or provider in discussing the topic of SRH (Gage, 2012). Knowledge of topic refers to knowledge that is or is not possessed by the patient or provider and impacts the decision-making of the woman with CF (Tsang et al., 2010). Previous experiences of the patient or provider relates to the importance women with CF place on the experiences of others, as well as their previous experiences related to SRH care (Simcox et al., 2009), and previous experiences of the provider in the provision of SRH which may impact their decision to initiate or fail to initiate conversations about SRH (Kazmerski et al., 2018a). Prioritization of care relates to the provider who feels SRH care is important but is not a priority of care for the patient (Kazmerski, Borrero, Tuchman et al., 2016). A review of the 20 articles suggests that there is a significant gap in the provision of SRH care to women with CF.

Comfort with Topic.

The dimension of comfort with topic is noted in the literature for both the patient (Havermans, 2012) and the provider (Kazmerski, Borrero, Tuchman et al., 2017) and is represented as a potential barrier to the provision of SRH care for women with CF. CF program directors reported “embarrassment” or “discomfort” with the topic of SRH as a reason that they do not introduce the topic (Kazmerski, Borrero, Tuchman et al., 2016). Other providers linked discomfort with the topic to concerns about communicating a sensitive topic (Tsang et al., 2010).

Knowledge of Topic.

The dimension of knowledge of topic is described in the literature as the patient's deficit of knowledge (Gage, 2012) and educational deficits on the part of the provider (Kazmerski, Borrero, Tuchman et al., 2017). Women with CF often feel that they do not have enough information to make informed choices about sexual and reproductive aspects of their lives (Sawyer et al., 1995). Providers indicated that they need additional training regarding CF-specific SRH topics (Kazmerski, Borrero, Tuchman et al., 2016). Despite limited research in SRH for women with CF, it is apparent that deficits exist in the knowledge of SRH topics.

Previous Experiences.

Previous experiences of the patient and provider are noted in the literature (Kazmerski, Borrero, Tuchman et al., 2017). Whether the experience was positive, or negative may impact how the patient or provider addresses the topic of SRH. A patient's previous negative experience may make her reluctant to ask questions or introduce the topic of SRH, although this may be necessary to begin the conversation (Tsang et al., 2010).

Prioritization of Care.

The dimension of prioritization of care is evident in the literature in studies that have shown that women with CF desire SRH care to be provided by their CF health care team (Gage, 2012). CF providers value SRH care education for their patients and identify it as a critical element of CF care (Kazmerski, Borrero, Tuchman et al., 2016). Parents described that they feel SRH education should be provided to patients at about age 13-14, demonstrating parents' prioritization of SRH. Mothers of girls with CF have indicated that they would like more information regarding SRH, showing that they value SRH education for their daughters with CF (Nixon et al., 2003). The dimension of prioritization of care is well documented in the literature, and SRH care for women with CF is prioritized by the patient, partner/parent, and the provider.

Related to the dimension of prioritization of care, the patient may place a high value on SRH, while the provider may prioritize lung health above SRH. That is, providers may place a "low priority" (Kazmerski, Borrero, Tuchman et al., 2016) on SRH and instead focus on current pulmonary symptoms or other physical issues. Sensitivity from the CF provider, while meeting the needs of each patient, is needed to provide patient-centered, comprehensive CF care (Simcox, 2009). In fact, if the provider does not initiate conversations about SRH, patients may feel that their provider does not support their decisions related to SRH (Simcox, 2009).

Relevant Perspectives.

The dimensions of prioritization of care, knowledge of topic, comfort with topic, and previous experiences may vary, depending on whether they are viewed from the perspective of the patient, parent/partner, or the provider. Less research is available on the perspective of the partner/parent of the woman with CF. Importantly, these differing perspectives may impact the delivery of comprehensive care to women with CF.

The perspective of the patient regarding the dimension of knowledge of topic is well established in literature as a priority. Women with CF report that they want more knowledge about CF-specific SRH (Kazmerski et al., 2018a). It is also well documented that providers indicate knowledge of this topic is important, yet the very omission of SRH education may convey the opposite message to the patient. This perceived contradiction is evident in the literature, in which the provider's perspective of knowledge of SRH topics is purportedly the same as the patient's perspective (Gage, 2012).

The patient perspective related to the dimension of comfort with topic may vary from patient to patient and may also vary from provider to provider, resulting in a complicated combination of perspectives. If a provider feels the patient is uncomfortable with the topic, they may defer initiating a conversation about SRH with the patient herself, leaving it instead to the parent or primary health care provider, even if they are comfortable with the topic. Conversely, the provider who is uncomfortable may defer a needed conversation with their patient to their primary health care provider or parent.

The perspectives of the patient, partner/parent, and provider related to the dimension of previous experiences of SRH may impact the delivery of care by the health care provider, affect the reception of SRH care by the patient, or influence whether the significant other is included in the conversation or education regarding SRH. Previous experiences with providers may be a factor in the reluctance of the patient to introduce the topic of SRH (Kazmerski et al., 2018b) and result in educational deficits with a potential to impact the health of the patient. Previous experiences of the provider may affect the willingness or reluctance to introduce the topic of SRH.

A limitation of this area of research is the sparse available literature on the topic. Another limitation is the lower level of evidence (many are qualitative studies with small sample sizes) of some of the studies included in this analysis. Comfort with the topic, which has been identified as a dimension, may be a barrier to research in this area. Researchers may have the same reluctance to initiate this work as the reluctance documented in literature regarding the omission of SRH care by the CF health care team.

Implications for Practice

Women with CF have the same SRH care needs as women without CF. With a predicted life expectancy of 47.7 years (CFF, 2019a), they are living long enough to experience sexual and reproductive choices and require routine SRH care. Comprehensive health care for women includes SRH care, and the comprehensive health care for women with CF should not omit this aspect of care. With the heavy burden of care experienced by women with CF, it is important to research ways to incorporate SRH care into the routine provision of care for women with CF.

This review of literature revealed gaps in nursing knowledge and potential barriers to the provision of appropriate SRH care to women with CF. Despite evidence that women with CF want CF-specific SRH care to be provided by the CF health care team (Kazmerski, Borrero, Tuchman et al., 2016), there is also evidence that it is not included in routine delivery of care (Gage, 2012).

This review analyzed the concept of SRH in women with CF and introduced the dimensions of prioritization of care, knowledge of topic, comfort with topic, and previous experiences from the perspectives of the patient, their partner or parent, and the provider of CF health care. Analysis of this concept established the importance of this topic, and the relevance to comprehensive care of women with CF. SRH education should be provided at age-appropriate intervals, addressing developmentally sensitive topics at each interval to provide patient-centered, comprehensive CF care. Educational resources are needed to assist members of the CF health care team in delivery of this care in an effective and efficient manner. Upon completion of this literature review-based concept analysis of SRH care for women with CF, three key implications for practice are noted: (a) individuals with CF require specialized SRH care, (b)

SRH must be a component of comprehensive CF care, and (c) further work is needed to develop effective ways to provide SRH care to women with CF.

Design and Methods

Choosing a mixed methods research design over a quantitative or qualitative design for the proposed study allowed the integration of the quantitative strand with the qualitative strand to build on the complementary strengths and nonoverlapping weaknesses of each strand, providing a better understanding (Plano Clark & Ivankova, 2016) of the relationship between self-efficacy and SRH care utilization, concerns, and preferences of women with CF than either research method alone. The mixed methods research design integrates the two strands and makes inferences based on the combined strength of the integrated strands (Creswell, 2014).

Typologies of mixed methods research that support this research design as a good fit for the proposed project include complementarity, enhancement, and explanation. Complementarity increases the interpretability and meaningfulness of results by elaborating, enhancing, illustrating, and clarifying the results from one method (quantitative) with the results from the other method (qualitative) (Greene et al., 1989). This method is appropriate because the qualitative interviews illustrate, or better explain, the findings from the quantitative survey. Enhancement integrates methods to enhance interpretations of data, analysis, and results and expands the interpretation of both the quantitative and qualitative results (Collins et al., 2006). Enhancement may provide clarification as to the reason outcomes did or did not occur. The mixed methods design allows “real-life” stories garnered from the semi-structured, individual interviews to provide compelling ways to communicate quantitative findings from the survey, which enhance, or more fully explain, the findings from the survey (Collins et al., 2006).

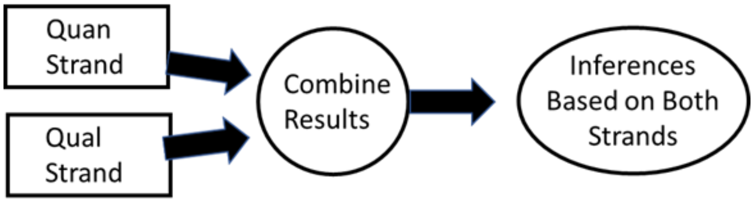
Explanation includes using one method to help explain findings generated by the other, which may further explain the results (Bryman, 2006).

Concurrent Mixed Methods Design

The specific mixed methods design selected for this study was a concurrent mixed methods study design utilizing a survey to collect quantitative data and a semi-structured interview to collect qualitative data. A concurrent design was selected based on the study goal of gaining a better understanding of the relationship of self-efficacy to utilization of SRH care services among women with CF. Utilizing a mixed methods study design provides a better and more thorough explanation of this topic than either method could if used independently. The Quan + Qual design indicates concurrent collection of both qualitative and quantitative data with equal importance assigned to each strand. Data were collected simultaneously but analyzed separately prior to integration of the findings and reciprocal interaction of the data (Rosenberg et al., 2015). Data were then merged to create a data set comprised of quantitative and qualitative data for full integration. Figure 6 is a representation of this design.

Figure 6

Design Logic for Concurrent Mixed Methods Study



Note. Adapted from Plano Clark and Ivankova (2016).

Daily CF care is complex and poses a significant burden on the individual. A daily care regimen can require an investment of up to two or more hours daily (CFF, 2020). This study's use of a concurrent mixed methods design allowed the participant to complete the survey and interview on the same day if they chose to maximize their time and decrease the potential for any increase in their burden of care, or they could complete them on separate days if that optimized their time management. The concurrent design allowed the researcher to collect both quantitative and qualitative data in a single session or at different times, as needed (Creswell & Poth, 2016).

Philosophical/Epistemological Underpinnings

Philosophical/epistemological underpinnings of mixed methods research include pragmatism, critical realism, and the transformative-emancipatory perspective (Plano Clark & Ivankova, 2016). Described as the underlying philosophy capable of informing both quantitative and qualitative research (Creswell, 2015), pragmatism is regarded by many as the best philosophical/epistemological underpinnings of mixed methods research (Denscombe, 2008). Creswell (2015) further describes pragmatism as "what works" as a philosophy for mixed methods. Pragmatism has been described as a strong foundation for mixed methods research with the research questions directing methods decisions and the importance of the inferences made from evaluating the responses (Plano Clark & Ivankova, 2016). This concept guided the selection of study methods by providing an underpinning that supports quantitative and qualitative research equally. Unlike purely quantitative research that is underpinned mainly by a philosophy of post-positivism, or purely qualitative research that may subscribe to a philosophy of interpretivism or constructivism, mixed methods research is a fusion of methodologies, and pragmatism may be the best philosophical partner (Denscombe, 2008). That is, the post-positivist philosophy of one reality and one truth approach of quantitative research would not be enough to fully answer the research question. Furthermore, the interpretivist or constructivist philosophical approaches of qualitative research, which posits that there is no such thing as a single reality, would also not answer, explain, or describe the research question fully. For these reasons, the philosophical underpinning of pragmatism, which focuses on the question to be researched and different layers, some objective and some subjective, is well suited to mixed methods research (Feilzer, 2010) and guided the selection of the research design for this study.

Chapter Summary

Gaps in the comprehensive care of women with CF exist. Despite living well into the fourth decade of life or longer, SRH care is not a component of routine care. The two reviews of literature established the following points:

1. SRH care is desired by women with CF but may not be prioritized; the providers or women with CF may experience embarrassment; the women or providers may experience knowledge deficits; and previous experiences of the women or providers may impact current behaviors.
2. Self-efficacy has been studied in other chronic illnesses and shown to improve health outcomes.
3. Research related to self-efficacy and SRH in women with CF is lacking.

Bandura’s (1977) self-efficacy construct of the Social Cognitive Theory provided the basis for the adapted model for this study. A concurrent mixed methods approach was utilized to explore and understand self-efficacy and utilization of SRH care services of women with CF more fully.

Chapter 3 presents the methods utilized for conducting this study. The data analysis plan will be discussed, and the reliability and validity of the selected instrument established.

CHAPTER 3

METHODS

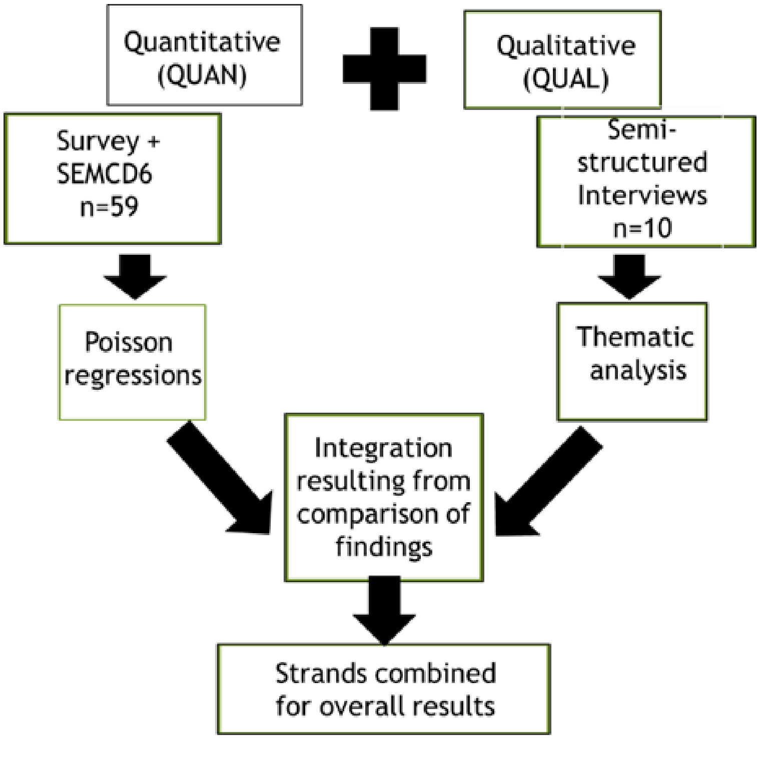
This concurrent mixed methods study aimed to explore sexual and reproductive health (SRH) in women with cystic fibrosis (CF) and examined whether a relationship exists between self-efficacy and utilization of SRH care services in women with CF. The purpose of this chapter is to present rationale for selecting a concurrent Quan + Qual (Plano Clark and Ivankova, 2016) mixed methods study with equal emphasis on the quantitative and qualitative strands of the study and to describe the methods of the study. The quantitative strand assessed self-efficacy in women with CF and statistically examined whether a relationship exists between self-efficacy and utilization of SRH care services. The qualitative strand provided a better understanding of the perspectives of women with CF related to their perceived self-efficacy, specifically in relation to utilization of SRH care services. Lastly, the integration of the findings of the quantitative and qualitative strands of the study provided a better understanding of the relationship of self-efficacy to SRH care utilization in women with CF.

Research Design

The purpose of the concurrent Quan + Qual mixed methods design is to compare or integrate the results to obtain a better understanding of the findings (Plano Clark & Ivankova, 2016). Equal priority was given to both strands in this Quan + Qual design. By giving equal priority to the quantitative and qualitative strand, different but complementary data could be analyzed side by side to provide overall results (Plano Clark & Ivankova, 2016). The mixed methods design capitalized on the strengths of each research method to provide stronger and more credible studies (Plano Clark & Ivankova, 2016). Figure 7 illustrates the process for a concurrent mixed methods study, which is one of the three design logics as described by Plano Clark and Ivankova (2016). The quantitative and qualitative strands were conducted concurrently, then results were integrated with inferences based on the merged findings from both strands.

Figure 7

Concurrent Quan + Qual Mixed Methods Study Design Procedural Diagram



Note. Adapted from Plano Clark & Ivankova (2016).

Study Setting

The study setting was an accredited CF center in an academic medical center in the southeastern United States. The CF center coordinator provided a weekly appointment list, in addition to a weekly inpatient list, of women with CF above age 25 years. Women with CF attending routine clinic appointments and meeting inclusion criteria of age 25 years or older and the ability to speak and read English were approached in the waiting room and offered the opportunity to participate in the study. All participants completed the REDCap® survey on an iPad while in clinic, or electronically with the link to the REDCap® survey e-mailed to them. Participants received $20 in cash after completing the survey.

Sampling

Sampling consisted of a subset of participants recruited for the parent study entitled *Sexual and Reproductive Health in Women with Cystic Fibrosis.* Participants were recruited via a convenience sample of women older than 25 years of age, meeting the inclusion criteria for the 10-site parent study funded by the Cystic Fibrosis Foundation (CFF). Additionally, inclusion criteria included women with CF who can speak and read English, have a diagnosis of CF, and receive comprehensive CF care at the University of Alabama at Birmingham CF clinic. The CF coordinator sent the weekly clinic schedule to the principal investigator each week. All participants who met the inclusion criteria were invited to participate in the study.

Due to the pilot study status of this research, 59 women were recruited for the quantitative strand and 10 for the qualitative strand. Quantitative sampling was limited by the parent study, and a power analysis was not conducted. The number of interviews could have been increased if data saturation had not been reached after 10 interviews. Prior to initiation of the research project, the CF center population was evaluated to ensure enough women met inclusion criteria, making the recruitment reasonable. A back-up plan was to utilize participants recruited from the other 10 sites included in the parent study. Recruitment occurred in CF clinic during routine clinic visits. The study was supported by the CF center director and coordinator, who both granted access to patients in clinic and facilitated recruitment by sending the clinic schedule to the principal investigator each week.

Ethical Issues

Conducting research in a vulnerable population such as women with CF presents specific ethical concerns. Special care was taken to protect the rights of vulnerable populations. As outlined in the Belmont Report (National Commission, 1979), the researcher considered respect for individuals, beneficence, and justice in addition to special precautions for vulnerable populations (Shamoo & Resnik, 2015). These special precautions include establishment of: (a) importance of the research, (b) a research question that can only be answered by the vulnerable population, (c) a careful analysis of the risks and benefits to the participants, and (d) an expectation that the research will provide new insights and add to the body of knowledge (Moore & Miller, 1999).

The American Psychological Association (APA) provides guidance for ethical principles and code of conduct for research studies (APA, 2020). The University of Alabama at Birmingham (UAB) Institutional Review Board (IRB) guidebook contains information about protecting the rights of the research participant, including guidance regarding special populations, informed consent, and protecting the privacy of the participant (UAB IRB, 2019). Both resources were utilized and followed carefully. A UAB course addressing ethics in research and responsible conduct of research was successfully completed by the researcher in addition to Collaborative Institutional Training Initiative (CITI) certification.

Some vulnerable groups have been excluded from research, which can adversely affect a group (Shamoo & Resnik, 2015). SRH in women with CF is such an example. Based on statistics from the CFF Patient Registry Data Report (2019b), 43.4 % of the CF population are either married or partnered, 54.9% have completed high school and some college, and 30.8% are college graduates, evidence of meeting milestones similar to their peers without CF (CFF, 2019b). These demographics establish the importance of exploring the experiences of women with CF related to SRH.

To mitigate ethical concerns, current literature established the importance of the research, gaps in comprehensive CF care, and validated that only the vulnerable population could answer the question. A careful analysis of the risks and benefits to the participants was conducted and revealed the risk of potential embarrassment related to the sensitive nature of the topic, potential breach of anonymity, and burden of time required to complete the study. To mitigate the risk of embarrassment, participants were encouraged to skip any question they found embarrassing and were instructed they could end the survey or interview at any point at which they became embarrassed or uncomfortable. To mitigate the risk of breach of anonymity, surveys were completed by participants on an iPad utilizing REDCap® software and identifying information was not linked to the survey. Interviews were conducted individually in a private room or via telephone. There are no known direct benefits to individual participants, which was explained during enrollment. The goal of this research was to provide new insights and add to the body of knowledge (Moore & Miller, 1999) regarding SRH behaviors in women with CF. To mitigate the potential burden of time to the participant, the survey and interview could be completed on the same day, or on different days. The participant selected the option best for them after receiving the study information.

Respect

Consideration of the principle of respect was established by respecting the individual’s opinions and their right to determine whether to participate in research or not (Knight et al., 2009). Informed consent was obtained from each participant. For the quantitative strand, the study was fully explained to potential participants, and a printed information sheet describing the study in detail was given to each participant. The Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6) as well as quantitative survey questions of the parent study, entitled *Sexual and Reproductive Health in Women with Cystic Fibrosis,* were loaded into REDCap® on an iPad. The first page of the survey explained the study and included a question asking the participant for their informed consent. Electronic consent was obtained in this manner and paper consent was not necessary. A record of the participant’s informed consent is contained in REDCap®. Paper surveys were not utilized in this study. Respect for participants who chose to participate, or not to participate, required that participants receive instruction that they could stop the study at any time without any negative consequences. For the qualitative strand, informed consent was obtained verbally prior to the interview and audio recorded. The audio recording was transcribed verbatim and contains the verbal, informed consent given prior to the beginning of the interview.

To avoid any potential coercion, it was explained to the participant that the researcher is not a part of their care team and choosing to participate or not participate in the study would not affect the care they received. Participants received $20 via UAB ClinCard for completing the survey and another $20 Visa gift card if they completed the interview. These compensation amounts are consistent with incentives used in other CF-related studies and not deemed coercive.

Beneficence and Nonmaleficence

Beneficence is defined in the Belmont Report as securing the well-being of the research participant and doing no harm (Knight et al., 2009). The researcher must assess the risk, if any, the participant may experience because of the study (Knight et al., 2009). The researcher must also assure the participant does not feel an expectation to participate, and that they fully understand they may stop participation at any time (Knight et al., 2009). A review of the literature revealed some potential barriers to conducting research related to sexual health topics. One barrier noted in the literature is that it may be difficult to explain equipoise to the participant, that is, that they may not perceive any benefit from the study (Ledger, 2011). Another barrier noted is the potential embarrassment the participant may feel talking about sexual health topics (Havermans, 2011). Strategies to protect the participant include protecting privacy by allowing the participant to complete the survey on the iPad in private (they could take the iPad into the exam room during their visit) and conducting interviews individually in a private room.

It was important to explain to the participant any potential harm that could possibly be encountered from the study. In this study, this may be defined as feeling uncomfortable or embarrassed discussing the subject. It was explained to each participant that they could end their participation at any time they desired. Care was taken to be particularly observant of nonverbal cues that might indicate the participant felt uncomfortable. If these nonverbal cues such as stressed facial expression or restless movements were noted, participants were reminded that they could stop at any time they liked. The information sheet given to participants included verbiage that described medical terminology in lay terms to ensure veracity. Privacy of the participant was protected by de-identifying all information. Information was protected with the secure software system REDCap®. Privacy of the interview participants in the qualitative strand was maintained by use of a pseudonym chosen by the participant, and interviews were conducted individually in a private room or via telephone as each participant selected.

Justice

Justice is the principle of fairness and refers to the burden of research and benefits, if any, to the participant (Knight et al., 2009). To ensure justice, all participants received information that, although they may not personally benefit from the study, their participation could possibly help to improve the SRH care that women with CF receive in the future. UAB IRB approval was obtained (see Appendix B) and ensures the concept of justice has been addressed. Due to COVID-19 restrictions, recruitment could not be conducted in clinic during the COVID-19 pandemic. The IRB approval was amended and approved by the UAB IRB board to allow for telephone and email recruitment (see Appendix B).Inclusion criteria, as per the parent study, were women with CF 25 years of age or older. All women meeting inclusion criteria were given equal opportunity to participate in the study. CF occurs primarily in Caucasians (Cystic Fibrosis Foundation [CFF], 2020), precluding the possibility of an ethnically diverse population, which would ordinarily be evidence of justice.

Fidelity and Responsibility

To establish fidelity and responsibility, communication was maintained with the mentor and members of the interdisciplinary CF health care team, and issues or concerns were reported promptly. Care was taken to responsibly recruit participants, fairly including all who met inclusion criteria, but communicating with the CF care coordinator regarding special circumstances, such as the appropriateness of approaching a new patient on their first clinic appointment.

Integrity

Accuracy, honesty, and truthfulness in science (APA, 2020) was maintained by careful treatment of data, including de-identified survey results and interview transcripts; explaining the purpose, potential risks, and benefits carefully to participants; and allowing ample time for the participant to ask questions and for rapport to be established between the participant and the researcher.

Informed Consent

Informed consent was obtained from each participant. For the quantitative strand, the study was fully explained to potential participants, and they were given a printed information sheet describing the study in detail. The SEMCD6 as well as quantitative survey questions from the parent study were loaded into REDCap® on an iPad. The first page of the survey explained the study and included a question asking the participant for their informed consent. Electronic consent was obtained in this manner and paper consent was not necessary. A record of the participant's informed consent is contained in REDCap®. For the qualitative strand, informed consent was obtained verbally prior to the interview and audio recorded. The audio recording was transcribed verbatim and contains the verbal, informed consent given prior to the beginning of the interview.

Data Collection

Data for the quantitative strand were collected via a survey using REDCap® software. Participants completed the survey either during their clinic appointment or later in the privacy of their home. Participants who completed the survey during clinic received $20 to compensate them for their time. Participants who wished to complete the survey at home were e-mailed a link to the survey and completed the survey at their convenience. A $20 UAB ClinCard was then mailed to the participant. The survey contained questions for the parent study as well as the SEMCD6 to assess self-efficacy. Appendix A contains a copy of this instrument.

Data for the qualitative strand were obtained via semi-structured interviews, which were audio recorded and transcribed verbatim. Participants who completed the interview received a $20 Visa gift card. See Appendix C for the interview guide.

Reliability and Validity of Instrument

Reliability is the degree of confidence that exists related to the probability that the measure performs without measurement error (Polit & Yang, 2016). Test-retest reliability can be examined to evaluate the reliability of a measure. This requires participants of the research population to take the test twice on at least two different days to determine if their scores have changed (Polit, 2016). If the scores are minimally changed, this is defined as reproducibility, and reliability is high (Polit, 2016). Parallel test reliability also necessitates administration of the test on two days but should be used with multi-item measures (Polit, 2016) and would not therefore be appropriate for the SEMCD6, which is constructed with only 6 items. Interrater and intrarater reliability incorporates two or more raters using the instrument with the same participant at the same time and comparing scores. The SEMCD6 is a 6-item measure that can be administered electronically or as a paper version; therefore, interrater or intrarater reliability testing would not be appropriate for this measure. Internal consistency can be assessed utilizing Cronbach’s alpha or a Kuder-Richardson score (Polit, 2016). Cronbach’s alpha testing was performed to assess internal consistency with alpha of .93 in this sample, indicating internal consistency and reliability of the SEMCD6 in this study.

The SEMCD6 evolved from research at the Stanford Patient Education Research Center in the early 1980s as researchers there began to develop the Chronic Disease Self-Management Program (CDSMP) to study self-efficacy (Ritter & Loring, 2014). The initial scale, Self-Efficacy Management of Chronic Disease (SEMCD) was validated, then shortened to the current 6-item scale (SEMCD6) to decrease the burden for patients of having to complete the longer version (Ritter & Loring, 2014). A Spanish version (SEMCD-S) was also created and validated. The validation testing at Stanford indicated a high test-retest reliability of $r > 0.89$.

The National Institute of Health developed the Patient-Reported Outcomes Measurement Information System® (PROMIS®) to validate and make available for research a list of reliable instruments that demonstrated acceptable psychometrics (Gruber-Baldini et al., 2017). Gruber-Baldini et al. (2017) reported the SEMCD6 has good internal consistency but did not provide Cronbach’s alpha or a Kuder-Richardson score. A study conducted in 2014 by Ritter and Loring studied the validity and reliability of the SEMCD6 and found internal consistency was high (Cronbach’s alpha, 0.88-0.95) and the scales were sensitive to change and significantly correlated with health outcomes (Ritter & Loring, 2014).

Additionally, the SEMCD6 was used in a Parkinson's disease study where Cronbach's alpha was determined for internal consistency (Dal Bello-Haas et al., 2011). The researchers evaluated test-retest reliability coefficients for all 6 measures using intraclass correlations (ICC). They tested absolute reliability using the standard error of measurement (SEM), which measures how an individual score changes with repeated measurement (Dal Bello-Haas et al., 2011). The ICC for the SEMCD6 was 0.72 and the SEM was 0.81. The researchers reported the SEMCD6 measure has moderate to excellent internal consistency and can provide reliable test-retest values in populations with Parkinson's disease (Dal Bello-Haas et al., 2011).

The SEMCD6 was also used in a 2011 CF study; however, but the article did not report any reliability testing of the instrument (Cummings et al., 2011). The study introduced a mentoring program as an intervention and evaluated the change in self-efficacy (Cummings et al., 2011). Prior to this dissertation study, the Cummings et al. (2011) research appears to be the only study that has used the SEMCD6 for patients with CF. In this dissertation study of patients with CF, the reliability of the SEMCD6 was assessed for use with this population by evaluating Cronbach's alpha for the SEMCD6.

The five domains used for creating banks of questions that resulted in the current SEMCD6 are: (a) Self-Efficacy for Managing Daily Activities, (b) Self-Efficacy for Managing Medications and Treatments, (c) Self-Efficacy for Managing Symptoms, (d) Self-Efficacy for Managing Emotions, and (e) Self-Efficacy for Managing Social Interactions (Gruber-Baldini et al., 2017). All items in this bank correlated well, with $r > 0.85$ (Gruber-Baldini et al., 2017). From this bank of questions, the SEMCD6 was created. The SEMCD6 contains 6 items related to managing: (a) fatigue, (b) physical discomfort/pain, (c) emotional distress, (d) other symptoms/health problems, (e) tasks/activities needed to manage health conditions, and (f) things other than just taking medication (Gruber-Baldini et al., 2017).

Gruber-Baldini and colleagues (2017) assessed concurrent validity using Pearson's correlations of the 6 items. The demographics and descriptives for the sample included 57% female, mean age of 53.8 with *SD* 14.7 and range of 18-89, 76% Caucasian, 21% African American, 6% Hispanic, and 3% other race. For 80% of the sample, education was above a high school level, and income was above $60,000/year for 54%. The percentage of those married was 59%, and 59% were not employed (Gruber-Baldini et al., 2017).

Convergent validity was established by correlating the SEMCD6 items with the legacy version (original SEMCD instrument), which correlated well (r >.05) with the short forms. Content validity was established by creating the PROMIS® domains, evaluating the legacy SEMCD, and creating the SEMCD6.

One test that should have been conducted was construct validity to determine whether each question measured what it was intended to measure. This was not addressed in any study. Gruber-Baldini et al. (2017) analyzed each category to see if it performed as expected, but they did not identify this as construct validity. They noted self-efficacy scores were higher with higher age and higher education, as they had expected.

Reliability and Validity of Study

Reliability and validity of the mixed methods dissertation study was assessed using the process described by Plano Clark and Ivankova (2016). Specifically, the steps included: (a) trustworthiness, (b) credibility, (c) quality, (d) inference transferability, and (e) legitimation.

Trustworthiness

Trustworthiness refers to criteria that are used to assess for quality in qualitative research and that guide researchers in producing findings that can be accepted as persuasive and credible by others. Trustworthiness was established by review of the proposed study by the dissertation committee and oversight at each phase of the study by the mentor. The study was approved by the IRB, further establishing trustworthiness. Please see Appendix A for the UAB IRB approval letter.

Credibility

Credibility is the extent to which the qualitative findings are perceived as accurately conveying the study participant’s experiences. One method of establishing credibility is data triangulation (Plano Clark & Ivankova, 2016). This study achieved credibility and therefore more credible conclusions by comparing the results of the quantitative and qualitative strands in a side-by-side table to compare findings simultaneously.

Inference Quality

Standards for evaluating the quality of conclusions are made based on research findings (Plano Clark & Ivankova, 2016). The quality of the conclusions reached was established by utilizing established methods for both the quantitative and qualitative strands and making inferences from the integrated findings of the strands. This was achieved by utilizing statistical analyses appropriate for the quantitative strand and considering the number of study participants in regard to whether power was reached and inferences could be made, and utilizing Braun and Clarke’s (2006) thematic analysis to analyze the qualitative strand in evaluating the findings and reaching inferences. Ensuring the quality of each strand establishes the quality of the integrated findings and the inference quality of the study (Plano Clark & Ivankova, 2016).

Inference Transferability

The degree to which conclusions from a mixed methods study can be applied to similar settings, contexts, and people is inference transferability. The small sample size is a limitation of this study and will be discussed in the limitations section. Due to the small sample size limited to one locale, inference transferability could not be achieved.

Legitimation

Legitimation is the process of continuous evaluation of all mixed methods procedures for consistency between the research purpose and the resulting inferences. The dissertation committee evaluated the research aims and questions for appropriateness for a mixed methods study to meet the requirements of legitimation.

Quantitative Data Analysis Plan

Participants completed the SEMCD6 and survey questions electronically via REDCap® on an iPad while attending a routine CF clinic appointment or while hospitalized. The data were cleaned manually, monitoring for duplicates and incomplete entries, and then validated for accuracy. After data were cleaned, analysis was conducted. The SEMCD6 scores and utilization of SRH services scores were the variables analyzed. Table 6 represents these variables and their measurement once at the time the survey was completed.

Table 6

Measurement Table

Concept	**Definition**	**Instrument**	**Validity/Reliability**	**Time of Measurement**
Self-efficacy	Belief or confidence in one's ability to complete a task (Bandura, 1977)	SEMCD-6	Cronbach's α 0.88-0.95	Once, at recruitment
Utilization of SRH services	Receipt of gynecological office visit, contraceptives, pap smear, or no services during the past 12 months	Survey question	Self-report	Once, at recruitment

Descriptive statistics were analyzed for the sample. SEMCD6 scores were the mean of the 6 questions per scoring criteria of the instrument. The SRH score of 0-3 was the number of SRH services a participant received in the past 12 months, indicating a participant utilized no SRH care services (score of 0), or the number of any combination of obstetrical-gynecological routine office visit, Pap smear, or contraceptives. Spearman's rho was used to assess whether a correlation exists between self-efficacy as measured by the SEMCD6 and utilization of SRH care services as measured by a SRH care utilization score.

The null hypothesis was that self-efficacy and utilization of SRH care services are independent of one another. The *p*-value guided decision-making about the null hypothesis. If the *p*-value was less than or equal to the alpha set at 0.05, the null hypothesis would be rejected, and it would be determined there is a correlation between self-efficacy and utilization of SRH care services. If the p-value was greater than 0.05, then the null hypothesis would fail to be rejected and it would be determined there is no sufficient evidence from the data for the relationship between self-efficacy and utilization of SRH care services.

In the quantitative arm, the small sample size may result in low power to obtain a significant statistical inference, so that effect size and its confidence interval will be considered to justify the results to support the initial hypothesis. In the quantitative arm, participants (*n* = 59) completed a survey including demographic data (age, education, marital status, and FEV1) in addition to the SEMCD6. The small sample size is due to this study being a part of a larger, parent study. The parent study is a 10-site study representing all geographical locations of the United States. This study is limited to one CF center in the southeastern U.S., therefore, limiting the sample size. The small sample size may lead to wide confidence intervals and inconclusive conclusions (de Winter, 2013).

Simple linear Poisson regressions were conducted to evaluate the association of utilization of SRH care and each of the predictors (age, FEV1, SEMCD6). Further, the association between SRH utilization and self-efficacy was evaluated with a multiple linear Poisson regression controlling for age and disease severity (FEV1). Risk ratios were assessed. If risk ratio is > 1, then higher levels of the predictor (e.g., self-efficacy) is associated with more SRH utilization.

Rather than a binary decision about the null hypothesis using only significance testing, an estimate of the magnitude of the effect should be assessed, particularly when the sample size is small (Schönbrodt & Perugini, 2013). The size of the true correlation and the confidence the researcher wants to have in the conclusion should also be considered in addition to null hypothesis significance testing, i.e., a small effect size may still indicate an important clinic implication (Schönbrodt & Perugini, 2013). For instance, in some research contexts, even small correlations of .10 might have meaning with significant implications (Schönbrodt & Perugini, 2013). However, when using a small sample size in a pilot, preliminary/exploratory research, the researcher must acknowledge that the results are not conclusive and need further confirmation (Forstmeier et al., 2017).

If statistical inference is not significant possibly due to the small sample size, for instance, if the p value is greater than the α (set at 0.05), it does not necessarily mean there is no association in the study population; it could be that the sample size is too small to achieve enough power to reject the null hypothesis even there exists an association. Results that do not achieve statistical significance may, however, may suggest an association if the effect and its 95% confidence interval do cover a scientifically relevant effect size (Browner et al., 1988).

In addition to statistical inference that is not significant, the researcher must guard against evaluating for probable false-positive results and exert care to avoid overfitting the model with too many variables, which is of particular significance in a small sample size (Forstmeier et al., 2017). In this study, the risk ratios and confidence intervals was assessed.

Qualitative Data Analysis Plan

Prior to analysis of data, a secure storage plan must be established (Creswell, 2007). For this study, the data analysis spiral as outlined in Creswell (2007) was used to analyze the data. The steps of the spiral are outlined below.

Managing and Organizing the Data

The de-identified voice recordings of the interviews were uploaded into an NVivo program on a secure server of the university. The computer was password protected and located in a locked, secure area. Only the research team as listed on the IRB approval had access to the files. Verbatim transcriptions remained in NVivo as they were transcribed by the researcher.

Reading and Memoing Emergent Ideas

The researcher read all the interview transcripts in their entirety and gained a sense of the whole database (Creswell, 2007). The transcripts were read thoroughly several times to gain an understanding of the interview, and several more times to understand the entire database (all the transcripts) as a whole. Writing notes or “memos” helped in the first evaluations of the data. Memos are short versions of ideas, concepts, or interpretations of the data (Creswell, 2007). This created an “audit trail” (Creswell, 2007) that can be used in evaluation of the data.

Describing and Classifying Codes into Themes

In this step, codes, themes, or dimensions were identified. A codebook was established to categorize the emerging results. This codebook helped to establish reliability among multiple coders (Creswell, 2007). The codes represented themes, relationships, and the organization of the data into these categories. Quotes were placed in the categories to establish validity of the codes. NVivo 12 software was utilized to create these codes or nodes. Verbatim transcripts were uploaded into NVivo 12, then analyzed, placing participant quotes into nodes. This allowed for the researcher to note the frequency of quotes in each node and establish emerging themes.

Developing and Assessing Interpretations

As codes and categories were established, meaning was given to the interpretations. Questions that facilitated the interpretations included (Creswell, 2007):

1. What surprising data that you did not expect to find was present?
2. What data were interesting or unusual?
3. What were the dominant interpretations?

Representing and Visualizing the Data

In this final step, data were represented by a model, figure, or a table of quotes for each category (Creswell, 2007). A table of quotes was constructed to represent the data. NVivo software was utilized to organize quotes into nodes.

Integration Data Analysis Plan

Teddlie and Tashakkori's (2009) *Integrative Framework for Inference Quality* was used in the integration data analysis of the quantitative and qualitative findings. This framework assumes that inference validity rests upon four domains of quality: (a) design suitability, (b) design fidelity, (c) design consistency, and (d) analytic adequacy (Plano Clark & Ivankova, 2016). A concurrent mixed methods design is suitable to obtain two sets of complementary data to better explain a topic (Plano Clark & Ivankova, 2016), indicating design suitability for this study. Design fidelity was demonstrated by strict adherence to both the quantitative and qualitative traditions for each strand, while design consistency is demonstrated by rigorous data collection and analysis of both the quantitative and qualitative strand. Analytic adequacy is demonstrated by rigorous analysis of both strands, as well as integration of the findings. A 2x2 table of quantitative and qualitative findings was constructed to assist in the integration of both study strands to gain an understanding of the results in the context of the individual research questions.

Chapter Summary

A concurrent mixed methods study design was utilized to best answer the research questions of the quantitative strand, the qualitative strand, and the overarching mixed methods research question. A sample of 59 women with CF ages 25 years or older completed the SEMCD6 to measure their perceived self-efficacy. Utilization of SRH care services by women with CF was measured by receipt of a routine gynecological visit in the past year, contraceptive use, or receipt of a Pap smear. Self-efficacy scores (higher score indicates higher self-efficacy) were compared to utilization of SRH care services (scored 0-3, depending on the number of SRH services utilized in the past 12 months). This study explored the relationship of self-efficacy to SRH among women living with CF. Little is known about self-efficacy in CF, or the role it may play in utilization (or lack thereof) of SRH care services by women with CF. Research in other chronic illnesses has demonstrated self-efficacy can be improved with behavioral interventions with subsequent improvement in patient outcomes. For these reasons, it is important to explore this phenomenon in women with CF.

CHAPTER 4

RESULTS

The purpose of this study was to explore self-efficacy in relation to CF-specific sexual and reproductive health (SRH) concerns, care utilization, and preferences of women with CF. This was done by utilizing a concurrent, Quan + Qual mixed methods design to gain a better understanding of the relationship of self-efficacy to utilization of SRH care services among women with CF. The quantitative research question was: *Is there an association between self-efficacy as measured by a cross-sectional survey using the Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6) and utilization of SRH care services among women with CF?* The qualitative research question was: *What are the perceptions and experiences of women with CF related to self-efficacy and utilization of SRH care services?* The overall mixed methods research question was: *How do quantitative questionnaire results and qualitative semi-structured interview results jointly explain the relationship of self-efficacy to utilization of SRH care services in women with CF?*

Quantitative Strand

The goal of the quantitative strand was to examine whether an association between self-efficacy and utilization of SRH care services among women with CF exists. Self-efficacy was measured by a cross-sectional survey using the Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6); utilization of SRH care services was measured by self-report of receipt of a routine GYN office appointment, a Pap smear, or contraceptives and scored 0-3, for the number of services participants utilized during the past 12 months.

The quantitative strand was led by the research question: Is there an association between self-efficacy and utilization of SRH care services among women with CF?

Sample Characteristics

The quantitative strand data were generated by 59 participants who were recruited in one site for the 10-site parent study entitled *Sexual and Reproductive Health in Women with Cystic Fibrosis.* The demographic and clinic characteristics were summarized in Table 7. The sample was female with a median age of 34 years (ages ranged from 25 to 65 years), mostly married (57%), mostly with at least some college education (28% with at least some college, 34% with a college degree, and 22% with a professional or graduate degree), and mostly Caucasian (95%). Participants reported their forced expired volume measured in one second (FEV1), which is an indicator of lung health. About 47% reported an FEV1 greater than 70%, 24% reported an FEV1 of 41-69%, 14% reported an FEV1 less than 40%, and 15% reported they did not know their FEV1.

Table 7

Characteristics of the Quantitative Strand Study Sample

Factor	*n* (%)
Age	
Mean (Standard deviation)	37.2 (11.6)
Median (Range)	34 (25-65)
Marital status	
Single/never married	14 (23%)
Married	34 (57%)
Separated	1 (2%)
Divorced	6 (10%)
Widowed	2 (3%)
Living with a partner	3 (5%)
Education	
Some high school or less	1 (2%)
High school graduate or GED	7 (12%)
Some college	17 (28%)
Vocational school	1 (2%)
College degree	20 (34%)
Professional or graduate degree	13 (22%)
Race/ethnicity	
Caucasian	56 (95%)
African American	2 (3%)
Asian	1 (2%)
Lung function (FEV1)	
Greater than 70% predicted	28 (47%)
41-69% predicted	14 (24%)
Less than 40% predicted	8 (14%)
Don’t know	9 (15%)

Results

Participants completed the Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6) in addition to questions regarding age and lung function. Descriptive and inferential statistics were analyzed using R version 3.4.1 (2017). The SEMCD6 was scored per guidelines established by the instrument creator (Gruber-Baldini et al., 2017). A self-efficacy score was obtained by scoring the SEMCD6 and was derived from the mean of the scores of the 6 items on the SEMCD6. These scores were the main predictor variable for analysis. The SEMCD6 scores, FEV1, age, and utilization of SRH care services were assessed for normality via histograms, and all variable data were noted to be not normal. For correlation analysis the null hypothesis (Ho) was: *There is no linear relationship between SEMCD6 scores (self-efficacy) and utilization of SRH care services.* The alternate hypothesis (Ha) was: *There is a linear relationship between SEMCD6 scores (self-efficacy) and utilization of SRH care services.*

To assess for a correlation between SEMCD6 scores and utilization of SRH care services, Spearman's rho was conducted using R version 3.4.1 (2017), revealing a positive correlation between SEMCD6 scores (self-efficacy) and utilization of SRH care services (Spearman's rho = .28, $p = .04$), indicating that higher self-efficacy (higher SEMCD6 scores) was related to higher utilization of SRH care services (higher utilization scores). The p value was 0.04, which is smaller than the alpha set at 0.05; therefore, the null hypothesis was rejected, and it was concluded there is a significant correlation between SEMCD6 scores (self-efficacy) and utilization of SRH care services. The correlation coefficient was .28, which indicates a weak positive correlation between the two variables.

A correlation matrix was constructed to display the correlation coefficients between variables. SEMCD6 scores, age, FEV1, and utilization scores were included in the Spearman's correlation analysis. Results of this are displayed in Table 8. SEMCD6 scores were moderately correlated with age (*rho* = -0.466; *p* <.001) and FEV1 (*rho* = -0.375; *p* = .005). The relationship between SEMCD6 and age is negative (*rho* = -.466), which indicates that as age increases, self-efficacy decreases. The relationship between SEMCD6 and FEV1 is negative (*rho* =-.375), which indicates that better lung function (higher FEV1 indicates better lung function) is related to worse self-efficacy. The relationship between SEMCD6 and utilization is positive (*rho* =.278; p = .04), indicating that as SEMCD6 increases, utilization increases. The relationship between age and FEV1 is positive, indicating that as age increases, FEV1 increases. The relationship between age and utilization is negative (*rho* = -.404; p = .001), indicating that as age increases, utilization decreases. The relationship between FEV1 and utilization is negative (*rho* = -.520; p = <.001), indicating that as FEV1 increases, utilization decreases.

Table 8

Correlation Matrix

Variable				
	SEMCD6	Age	Fev1	Utilization
SEMCD6	1.000			
Age	-.466 ***	1.000		
Fev1	-.375 ***	.245	1.000	
Utilization	.278	-.404 ***	-.520 ***	1.000

* *p-value* < .05 ; ** *p-value* < .01; *** *p-value* < .001

Simple and multiple linear Poisson regressions were performed using self-reported utilization of SRH care services as the outcome variable. In the model, the predictors of SEMCD6 scores, age, and FEV1 were included alone or together to assess whether any variables (SEMCD6 scores, age, or FEV1) predicted utilization of SRH care services. These results are depicted in Table 9. Model 1 simple linear Poisson regression with utilization of SRH services regressed on SEMCD6 scores suggests that those with higher SEMCD6 scores tend to be more likely to utilize SRH services (risk ratio [RR] = 1.17, 95%CI [1.00, 1.39], *p*= .0688,). Model 2 Simple linear Poisson linear regression with utilization of SRH services regressed on age indicates older participants are less likely to utilize SRH services (RR= 0.96, 95%CI [0.94, 0.98], p= .0014). Model 3 Simple linear Poisson regression of utilization of SRH services on FEV1indicates participants with a higher Fev1 are less likely to utilize SRH services (RR=0.41, 95%CI [0.21, 0.70], p = .0032).

Table 9

Simple Linear Poisson Regression

Model	Predictor	Risk Ratio	95% CI of RR	*p*-value
Model 1 (utilization of SRH services ~ SEMCD6)	SEMCD6	1.17	(1.00, 1.39)	.0688
Model 2 (utilization of SRH services ~ age)	Age	0.96	(0.94, 0.98)	. 0014
Model 3 (utilization of SRH services ~ FEV1)	Fev1	0.41	(0.21, 0.70)	. 0032

The association between utilization of SRH care services and SEMCD6 score was further analyzed using a multiple linear Poisson regression model adjusting for FEV1 and age. Table 10 displays the results of the multiple linear Poisson regressions. To see which explanatory variables (SEMCF6, Age, or FEV1) influenced the response variable (utilization of SRH services), the *p* values, risk ratios, and confidence intervals were assessed . If the *p was less than 0.05* then the variable influenced the utilization of SRH services (the response variable). Model four is the regression of utilization of SRH services on the combination of SEMCD6 + age (SEMCD6 p = .443 and Age p = *.011)*, indicating age influenced utilization of SRH care services after controlling for SEMCD6 while SEMCD6 was not significantly associated with utilization of SRH care services after controlling for age. Model five is the regression of utilization of SRH services on the combination of SEMCD6 + FEV1 (SEMCD6 p = .489 and FEV1 p = .007), indicating FEV1 influenced utilization of SRH care services after controlling for SEMCD6 while SEMCD6 was not significantly associated with utilization of SRH care services after controlling for FEV1. Model six is the regression of utilization of SRH services on the combination of SEMCD6 + FEV1 + age (SEMCD6 p = .933, FEV1 p = .011 and age p =.033), indicating after controlling for age and FEV1, the association between SEMCD6 and utilization of SRH services is no longer significant.

Table 10

Bivariate and Multivariate Poisson Regression Models

Model	Predictor	Risk Ratio	95% CI of RR	*p-value*
Model 4 (utilization of SRH services ~ SEMCD6 + age)	SEMCD6	1.071	(0.904, 1.287)	.443
	Age	0.965	(0.094, 0.992)	.0118
Model 5 (utilization of SRH services ~ SEMCD6 + FEV1)	SEMCD6	1.061	(0.903, 1.27)	.489
	Fev1	0.431	(0.218, 0.762)	.007
Model 6 (utilization of SRH services ~ SEMCD6 + FEV1 + age)	SEMCD6	0.993	(0.841, 1.193)	0.933
	Fev1	0.449	(0.223, 0.797)	0.011
	Age	0.972	(0.947, 0.998)	0.033

Qualitative Strand

The qualitative strand was led by the research question: *What are the perceptions and experiences of women with CF related to self-efficacy and utilization of SRH care services?* This strand was comprised of audio-recorded, semi-structured interviews with a subset of participants in the parent study entitled *Sexual and Reproductive Health in Women with Cystic Fibrosis*. Women with CF who participated in the cross-sectional survey of the parent study were recruited for the interviews. The qualitative strand was comprised of 10 participants who were age 25 years or older, able to speak and read English and participated in completing the cross-sectional survey of the parent study. Data saturation was obtained at 10 participants and recruitment closed. Braun and Clarke's (2006) method of thematic analysis was used and consisted of the following steps: 1) familiarizing with the data, 2) generating initial codes, 3) searching for themes, 4) reviewing themes, 5) defining and naming themes, and 6) generating the report. Codes and themes were developed independently and compared.

Results

Thematic analysis of the 10 semi-structured interviews resulted in four overarching themes and 12 subthemes. The four overarching themes were: (a) confidence, (b) sources of confidence, (c) inadequate information, and (d) discussions lacking. Within the first overarching theme “Confidence” were two subthemes. They were feeling confident, and not feeling confident. Eight of the ten women felt confident utilizing SRH care services and reported receiving SRH care in the past 12 months. Four subthemes emerged within the second overarching theme “Sources of Confidence”. They were mastery experiences, vicarious experiences, verbal persuasion, and physiological state. Women’s confidence toward SRH care utilization was attributed to communicating with other women with CF, verbal encouragement from a trusted CF healthcare team member or from a trusted family member or close friend, or from the stories of women with CF related to utilizing SRH care services. Two subthemes emerged within the third subtheme “Inadequate Information.” Women described feeling they did not have adequate SRH information during their adolescent and young adult years which is the first subtheme of the past and not having adequate information regarding SRH currently, which is the second subtheme of the present. Eight of the ten participants described feeling information provided by CF care team members about SRH was lacking due to a lack of current research. The fourth overarching theme “Discussions Lacking” revealed nine of the ten participants felt their CF care team did not initiate SRH conversations and contained four subthemes of comfort with topic, knowledge of topic, previous experiences, and prioritization of care. The themes and subthemes identified are presented in Table 11.

Table 11

Qualitative Themes and Subthemes Identified

Themes	**Subthemes**
1: Confidence	• Feeling confident • Not feeling confident
2: Sources of confidence	• Mastery experiences • Vicarious experiences • Verbal persuasion • Physiological state
3: Inadequate information	• Past • Present
4: Discussions lacking	• Comfort with topic • Knowledge of topic • Previous experiences • Prioritization of care

Theme 1: Confidence

"Confidence" is the first theme that emerged from analysis of the qualitative data. Subthemes of "Feeling Confident" and "Not Confident" also emerged. All participants (10/10) discussed their confidence toward discussing SRH with the CF healthcare team.

Feeling Confident.

Eight participants described themselves as confident when discussing SRH care concerns with their CF providers or utilizing SRH care services. One woman stated, “Oh, I feel confident with that [sharing concerns about SRH issues with the CF healthcare team] (Interview Participant 1 [IP1]). Participant 2 conveyed, “I’m very confident [about discussing SRH with the CF healthcare team],” and “They ask everything, so you just are comfortable with them and you feel confident to talk to them.” One woman felt that she was confident and described a successful and trusting relationship with her care team who she believed were knowledgeable in SRH care and were “experts”. She stated, “I think I am confident when it comes to CF-related sexual reproduction because I know they [my CF care team] are experts” (IP5), and another described her relationship with the CF healthcare team stating, “What makes me confident with my team is because they know everything about you” (IP4). Another participant continued the idea of the CF healthcare team providing holistic care and managing all aspects of care: “I don’t have a primary care doctor, and I feel like CF is connected to just my overall health, so I feel confident talking with them because they are aware of everything else that is going on related to my body” (IP9).

Not Feeling Confident.

Two participants described not feeling confident toward SRH. One woman described herself as confident with all aspects of managing her CF care except SRH: “I’m confident with everything about my CF care. I am one of those patients that does everything she is supposed to, until it comes to SRH” (IP8). Another woman attributed her lack of confidence toward SRH to lack of information: “I think for years there wasn’t any help around that [SRH], which is probably why I just don’t feel as confident now to bring up things like that to them” (IP2).

Summary of Theme 1

The theme of “Confidence” was further delineated by the subthemes of feeling confident or not feeling confident toward SRH. Participants described either their feeling of confidence toward SRH, or specifically described their lack of feeling confident toward SRH. Some women described feeling confident toward all aspects of holistic care except SRH; they felt they managed their CF care well but did not utilize SRH care. Most of the women interviewed discussed feeling confident discussing SRH with their CF healthcare team. Women described factors that contributed to this confidence, which emerged as the second overarching theme.

Theme 2: Sources of Confidence

Women described sources of confidence related to SRH. The sources were varied among women interviewed. Some women discussed one source for obtaining their confidence, while others discussed more than one source. Within the theme of sources of confidence emerged four subthemes. These four subthemes are “Mastery Experiences”, “Vicarious Experiences”, “Verbal Persuasion”, and “Physiological State”. Participants described experiences they felt contributed to their development of self-efficacy. These four subthemes related directly to Bandura’s (1977) self-efficacy construct of Social Cognitive Theory and the four sources of self-efficacy identified in his model (Bandura, 1977).

Mastery Experiences.

Two women related experiences that they felt contributed to their development of confidence toward SRH. They felt successful completion of specific tasks related to SRH care made them more confident and more willing to initiate other self-care activities. One woman described asking questions during her clinic appointment and explained, “I feel like because I have asked questions over time, I am confident” (IP5). Another felt that after a visit to her gynecologist she felt more confident with initiating conversations with her CF physician: “Being able to seek treatment from her [gynecologist] made me more confident in being able to have a discussion about it [SRH]” (IP1).

Vicarious Experiences.

Eight women described gaining self-confidence from the experiences of other women with CF. They described these experiences as “stories” of other women they heard via conversations with their CF friends, via Facebook groups, or via conversations with family members or friends. One woman described gaining confidence from the experiences of others and said that by “asking other people that have gone through it” (IP 3) she has found it easier to maneuver her own pathway. She described trusting someone’s past experiences: “If it’s something they’ve actually been through, so, then you know that it’s not really their opinion, it’s fact.” Another woman shared:

> The thing that has helped me build my confidence was seeing it modeled for me…it would be important for any doctor to model what should be done in the process of preparing for an appointment and creating a list of questions could help build confidence. (IP5)

She explained this further by saying:

> I think people's stories are key. Listen to people's stories and what has worked for them and what they have learned. I think there are stories that can oftentimes be inspiring to care teams. It can also help patients realize that they are not alone.

Another participant stated, "There is lots of research in the CF fields but even so, there's limited stories sometimes when it comes to how people work through these challenging concepts [SRH] and navigating CF" (IP5). Another participant felt the experiences of women with CF related to SRH could be helpful to others, stating, "I would say, too, if they could possibly hear some interviews, or some version of a story of this [experiences of women with CF related to SRH], it would help" (IP7). Another utilized social media to validate experiences, but not necessarily to gain information. She explained, "I'm looking for true information. I do look at anecdotal things on social media, but I am not taking that as necessarily a source of truth, more just an experiential thing for people to see like, 'Oh, are people experiencing similar things to what I am?'" (IP9).

Verbal Persuasion.

Verbal persuasion from members of the CF healthcare team, family members, or friends was described by four women as important in developing confidence toward SRH. One woman described verbal persuasion from her family, especially her mom, and stated, "My family said it's just normal to have yourself checked every year for cancer or just to make sure everything is well, so I was just taught that you are supposed to do that" (IP4). Participant 5 described verbal persuasion as encouragement from her support system, especially her mom, who guided her. She recalled:

> I feel like I have a great support system. One person of my support system accompanied me, especially early in life. It would typically be my mother. She would be asking these questions and not so much training me to make sure I'm advocating for myself but making sure that we always gather and generate a list of questions before we go to the doctor and that we have our checklist of things if there are any questions.

One participant described a member of the CF healthcare team as supportive of her pregnancy and recalled the verbal persuasion she received: "The respiratory therapist was great. She was open and I could talk to her about anything, and in fact, I told her about my pregnancy prior to telling my doctor" (IP1). She felt the verbal persuasion she received from her CF healthcare team member facilitated her development of confidence toward initiating a conversation about her pregnancy with her physician.

Physiological State.

Seven women discussed physiological state as being a priority for their CF care team when they brought up the topic of SRH, but they did not discuss physiological state being their priority. They discussed that their lung health (physiological state) was the priority of their CF care team and felt their CF care team did not want to discuss SRH. One woman recalled discussing her desire to start a family with her CF provider, and the first concern of her CF provider was, **"**to see where I stand health-wise "(IP4). One woman currently undergoing fertility treatments stated: "In the last year, I have been trying to conceive. I have been working closely with my cystic fibrosis doctor just making sure I was in the best health" (IP5). Participant six described the concerns of her CF care team about her physiological state and explained:

> "They [CF care team] worry about your health having a baby because it takes a

> whole lot more time. They don’t want it to take time away from your treatments. They don’t want your health to go down. I think if your health is in good standing, then I think they would be all for it [pregnancy] “.

One woman described the focus on physiological state by the CF care team as a barrier to younger women considering starting a family or initiating a conversation with the CF care team by saying, “I’ve talked with younger CF patients in their early twenties, one that I spoke to a couple of weeks ago. She is married and wanting to start a family, but she felt like she could not. When I talked to her, she was telling me her lung function is like in the nineties” (IP1).

Summary of Theme 2

The second theme to emerge was sources of confidence. Four main sources of confidence were mastery experiences, vicarious experiences, verbal persuasion, and physiological state. The participants’ experiences were consistent with Bandura’s (1977) sources of confidence. Women described feeling more confident after mastering the experience of scheduling their routine SRH appointments, or making contraceptive choices, or completing their Pap smear. They described experiences of friends, family, and other women with CF that helped them manage their own SRH care and the verbal encouragement they received from them that also helped them feel more confident toward meeting their own SRH care needs. Their physiological state, specifically, was discussed in relation to their CF care team’s priority for them, but not in the context of their [woman with CF] desire to start a family or in relation to their utilizing or not utilizing SRH care services.

Theme 3: Inadequate Information

The third overarching theme that was noted during the qualitative data analysis was inadequate information. This theme was subdivided into inadequate information in the "Past" and inadequate information in the "Present."

Past.

Three women felt their lack of information in their past affected their confidence. One woman felt the educational deficits were related to sparse information that was available at that time, with deficits in information she received both from her mother and her team. She stated:

> I think for years there was just a total knowledge gap. It was just blindly going in the dark. I would say that was through my teen and adult years. I do not know. None of it [SRH education/information] happened for me. Now, I feel like I could go ask anybody and I would get a ton of responses. I would say throughout my 20s, it was just a dark, just totally dark era. (IP10).

Inadequate information in the past was described as relying on books or pamphlets that did not address the topic of pregnancy in relation to CF. Lack of information in the past was described by another woman, who said, "I think it should be brought up regularly. Depending on your age. At a certain age we do not need SRH every single visit. But I wish that it had been available in my 20s and 30s" (IP3).

Present.

Three women discussed lack of information in the present in relation to the development of confidence toward SRH. This was communicated as, “There is not a lot of information out there” (IP2). One woman related her experiences entering menopause with CF and felt information is lacking: “When I asked my doctors about it [menopause and CF], they were like, well, I don’t really know anything about it. So, I have been kind of running into brick walls with that. No one seems to know what to do” (IP3). When one woman was discussing pregnancy for women with CF with a younger woman with CF, she remembered the younger woman “was shocked, she was like, ‘I didn’t know people with CF could really do this [become pregnant]’, and so I really feel like there needs to be more of a dialogue between the providers and the patients” (IP1).

Summary of Theme 3

The third emergent theme was inadequate information. This theme included subthemes of inadequate information in the past and inadequate information in the present. Some women described feeling they did not have adequate information entering adolescence but overcame this lack of information as they entered adult years. Women reported they presently did not feel there was sufficient research in the area of SRH and their current information was lacking.

Theme 4: Discussions Lacking

The fourth overarching theme that emerged from the data was that discussions regarding SRH were lacking. Within this theme, four subthemes were identified: (a) comfort with topic, (b) knowledge of topic, (c) previous experience, and (d) prioritization of care. Three women addressed the general topic of lacking discussions. Women felt the topic was not mentioned by their healthcare providers and that it should be brought up. One participant stated, “I think that should be a portion of what is being talked about, whether it be related to periods or sexual health or potential childbearing. I think these topics should be brought up ’cause, well… they have never been brought up to me” (IP1). Another participant reinforced that discussions were lacking, stating, “I am not sure they ever brought it up” (IP3), and “I’m not fearful to bring it up, but like I said, since it’s not something we talk about, I just don’t bring it up” (IP4).

Comfort with Topic.

Comfort with the topic of SRH was described by 9 out of 10 women interviewed who described feeling comfortable discussing SRH topics with their care team. One woman described feeling more comfortable if she was speaking to another woman about the topic of SRH, stating, “Usually females feel more comfortable talking about sexual and reproductive health with other females” (IP1). This was echoed by participant 5, who stated, “I felt very comfortable speaking about any of my reproductive sexual health, any of those topics with my CF doctor. I feel like she’s a woman, so that made me feel really comfortable and competent being able to share some of those concerns.” One woman described feeling uncomfortable at younger ages but described feeling “comfortable at this [later] age” (IP7). Another described feeling “generally fine” in relation to discussing general topics, including general SRH health, but feeling “nervous” when discussing “specific” SRH issues (IP8). The relationship with the CF care team was described as making the conversations more comfortable, with one participant stating, “We’ve got a great relationship and I feel like that I could probably bring up anything to him [CF provider] and he would be open to hearing me” (IP5). However, another participant felt the relationship made the conversation more uncomfortable, saying, “They’re more like family, and I don’t feel comfortable discussing this kind of stuff with my CF team” (IP1).

Knowledge of Topic.

The subtheme of knowledge of topic was discussed by 5 of the 10 women interviewed. Specifically, participants felt that there was inadequate knowledge available to women with CF on the topic of SRH due to limited research in the area and that providers might not have sufficient knowledge on SRH. This was described as, “We need to have someone that is knowledgeable to answer the questions that we need answered” (IP3). Describing SRH conversations with her team, one woman felt “since that that is not a topic we talk about very much, I sometimes wonder if they know much about that topic” (IP4), and another felt conversations related to SRH might be related to whether “they [providers] themselves had enough education in that area” (IP5).

Previous Experiences.

Four women described previous experiences, both positive and negative, that contributed to their perception that SRH discussions were lacking at routine appointments. The previous experience of “always having someone with you” [her parent] (IP4) during clinic visits was described by one participant as a barrier to honest, open conversations, and her perception was that this was the reason for the absence of discussions regarding SRH topics. Another felt that if something “negative” had occurred previously, the conversations were not likely to be brought up, summing it up by saying, “If they have a negative experience [related to discussing SRH during a routine visit] added on top of that, they might not” [bring up the topic] (IP8).

Prioritization of Care.

Six women discussed prioritization of care and their perception that the priority of care for the CF care team is lung health. This was described by the statement, “I think the main goal of clinic when you go in is lung, lung, lung, you know, and CF affects the whole body” (IP1). She further explained and expanded this idea by sharing, “Like I said, they [CF care team] only think lungs. That is the end all be all. In fact, the focus is how they [CF care team] can improve lung function in patients. But you have all these other issues that still need to be addressed. But most of the focus is set on improving your lung function” (IP1). Others described feeling that their CF care team prioritized lung health and that the CF care team did not consider them well enough for SRH concerns to be relevant. One woman explained, “I was discouraged [from talking about or considering pregnancy]. When I was younger, I was definitely discouraged [from talking about or considering pregnancy] for fear that I wouldn’t be able to carry the pregnancy to term because of lung infections or decreased lung function” (IP1). Another woman shared feeling her CF provider did not think she should consider pregnancy and stated, “I have had talks recently [with my CF physician] about what could affect me if I were to get pregnant. We discussed the dangers of it if I’m not healthy” (IP2). Participant 10 described the complexity of CF care and the need for the CF care team to prioritize care, resulting in SRH not being a priority of care and stated:

> There are too many other things for them [CF care team] to manage. I think it [SRH care] becomes less—when you look at nutrition, and social, and respiratory, and sinus, and digestion. I think there’s just so much. It’s [SRH care] not thought about in the overall sense of our care, which unless we

> bring it up or we have an issue [with SRH care].

Another felt her team was “worried about my health” and SRH was not a priority (IP3).

Summary of Theme 4

The overarching theme of “Discussions Lacking” included four subthemes: (a) comfort with topic, (b) knowledge of topic, (c) previous experiences, and (d) prioritization of care. The participants felt that discussions about SRH were missing from routine CF care and described the four subthemes as to why these discussions may be lacking during clinic visits. They observed that comfort with the topic may be related to gender of the provider or the relationship they have with the provider. The women did not feel confident that they had adequate knowledge about the topic of SRH, even questioning whether the CF care providers themselves had adequate knowledge on SRH. The women described previous experiences, both positive and negative, that impacted the likelihood that the topic of SRH would be discussed during a clinic appointment. They described that lung health is the top priority for the CF care team and SRH was not.

Integration of Quantitative and Qualitative Results

Integration of the quantitative and qualitative results produced four overall findings: (a) women with CF are confident related to SRH, (b) most women with CF utilize SRH care services, (c) a positive relationship exists between self-efficacy in women with CF and utilization of SRH care services, and (d) health (lung function) does not influence utilization of SRH care services.

Confidence

Integration of the quantitative and qualitative strand findings revealed that most of the women who participated in the study were both confident toward SRH in general and confident in utilizing SRH services. Assessed in both strands of the study, confidence was conceptually defined in both strands as belief in an individual’s ability to complete a specific task. Confidence was operationally defined and empirically measured by the SEMCD6 scores in the quantitative strand and by each participant’s verbal descriptions of having, or not having, confidence in the qualitative strand.

In the quantitative strand, analysis of the scores of the SEMCD6 revealed that most women with CF in this study were confident. The SEMCD6 median score was 7.16 with a range of 1.6 to 10. The standard deviation was 2.05. Higher scores are indicative of higher self-efficacy. Thus, most women in this study had higher than average self-efficacy scores, indicating higher than average self-efficacy (confidence).

The thematic analysis of the verbatim interview transcripts revealed that 8 out of 10 participants described feeling confident utilizing SRH care services. They stated, “I feel confident with SRH” (IP1) and “I’m very confident [toward SRH]” (IP2). Others described confidence with SRH and being very “comfortable” (IP3) with the topic.

Utilization of SRH Care Services

Integration of the quantitative and qualitative findings revealed that most women in the study utilized SRH care services in the past 12 months. Utilization of SRH care services was analyzed in both the quantitative and qualitative strands of the study. In the quantitative strand, participants answered a survey question regarding whether they had received a routine GYN office appointment, a Pap smear, contraceptives, or no SRH care services in the past year. A utilization score was created from their self-reported answers ranging from 0 (no services) to 3 (received all 3 services) in the past year. The range of scores was 0-3 with a median score of 1, a mean score of 0.75, and standard deviation of 0.86, indicating that most women in the study received at least one SRH care service in the past year.

In the qualitative strand, interview questions asked participants to describe the SRH care services they received in the past year. Responses revealed that 8 out of 10 women interviewed reported receiving SRH care in the past 12 months. One participant described receiving "just the routine stuff [GYN appointment]" (IP3). Another described receiving "yearly" services like a GYN appointment for contraceptives (IP4).

Positive Relationship

The third finding of the integration of the quantitative and qualitative strands was a positive relationship between self-efficacy and utilization of SRH care services. In the quantitative strand, self-efficacy, as measured by the SEMCD6 and utilization scores, was assessed using R version 3.4.1 (2017). Analysis revealed a positive correlation between SEMCD6 scores (self-efficacy) and utilization of SRH care services (Spearman's rho = .28, p = .04), indicating that higher self-efficacy (higher SEMCD6 scores) was positively related to higher utilization of SRH care services (higher utilization scores). Throughout the interview transcripts, women who described feeling confident also described utilizing SRH care services during the past year, suggesting a positive relationship between self-efficacy and utilization of SRH care services. They described feeling "comfortable" (IP3) and "confident" (IP2) and receiving "just the routine, GYN appointment" (IP3) and "yearly Pap smear" (IP4).

Lung Function

In the quantitative strand, participants self-reported their FEV1, which is a measure of lung function. In the Poisson regression models, which will be discussed in the next section, lung function was not the best predictor of utilization of SRH care services. See Table 9 for all models tested and the findings. In the qualitative strand, none of the women interviewed (0/10) described their lung function as being relevant to utilization of SRH care services. Lung function was the fourth integrated result and was not found to be related to utilization of SRH care services.

Joint Display to Show Integrated Findings

A 2x2 table was constructed to display the integration of the quantitative and qualitative findings and the overall mixed methods results. These results are displayed in Table 12. Integration of the quantitative and qualitative findings revealed four major overall results: (a) women with CF are confident related to SRH, (b) most women with CF utilize SRH care services, (c) a positive relationship exists between self-efficacy in women with CF and utilization of SRH care services, and (d) health (lung function) does not affect utilization of SRH care services.

Table 12

Integrated Findings Presented in a Joint Display

Quantitative Results	**Qualitative Themes**
Confidence: SEMCD6 median score = 7.16 (range 1.6-10; standard deviation = 2.05) with higher scores indicative of higher self-efficacy	Confidence: Women (8/10) described feeling confident utilizing SRH care services
Utilization of SRH care services: Utilization of SRH care services range = 0-3, median = 1, mean 0.75 (standard deviation 0.86)	Utilization of SRH care services: Women (8/10) reported receiving SRH care in the past 12 months
Relationship between self-efficacy and utilization of SRH care: A positive correlation between self-efficacy and utilization of SRH care services was analyzed (Spearman's rho = .28, *p* = .04	Relationship between self-efficacy and utilization of SRH care: Participants that described confidence with SRH also reported utilizing SRH care services in the past 12 months
Lung function (FEV1): 47% reported FEV1 greater than 70% predicted, 24% reported FEV1 of 41-69% predicted, 14% reported FEV1 less than 40% predicted, and 15% reported they did not know their FEV1	Lung function (FEV1): Sources of confidence/physiological state: Participants did not describe declining lung health or better lung health in relation to their utilization of SRH care services

Chapter Summary

This chapter presented the results of the study. The quantitative strand findings indicate that women with higher self-efficacy are more likely to utilize SRH care services. The qualitative strand findings suggest women are confident, obtain confidence via mastery experiences, vicarious experiences, and verbal persuasion, and their physiological state (specifically, lung health) does not affect their confidence. Qualitative analysis further revealed that women do not have adequate information regarding CF specific SRH topics, and that discussions regarding this topic are lacking. The integrated results answer the overarching mixed methods question: *How do quantitative questionnaire results and qualitative semi-structured interview results jointly explain the relationship of self-efficacy to utilization of SRH care services in women with CF?* The integrated findings indicate that most women with CF are confident, utilized at least one SRH care service in the last year, there is a positive correlation between self-efficacy and utilization of SRH care services, and most participants experience good lung function.

CHAPTER 5

DISCUSSION

A concurrent, Quan + Qual mixed methods design study was conducted to gain a better understanding of the relationship between self-efficacy and utilization of SRH care services among women with CF. The goal of the quantitative phase was to explore whether there was an association between self-efficacy as measured by a cross-sectional survey using the Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6) and utilization of SRH care services among women with CF. The goal of the qualitative phase was to explore the perceptions and experiences of women with CF related to self-efficacy and utilization of SRH care services. The goal of the overall study was to determine the answer to the following research question: *How do quantitative questionnaire results and qualitative semi-structured interview results jointly explain the relationship of self-efficacy to utilization of SRH care services by identifying self-efficacy in women with CF?*

Summary of Major Findings

Quantitative Results

Analysis of the SEMCD6 and utilization of SRH care scores was utilized to answer the quantitative research questions: *Is there an association between self-efficacy as measured by a cross-sectional survey using the Self-Efficacy for Managing Chronic Disease 6-item Scale*

(SEMCD6) and utilization of SRH care services among women with CF? The review of literature revealed a gap in the provision of comprehensive CF care with deficiencies in the routine provision SRH care reported (Kazmerski et al., 2018b). Higher self-efficacy is associated with improved outcomes in other chronic illnesses (Faint et al., 2017). Self-efficacy predicted treatment adherence and health-promoting behaviors (Mishali et al., 2011; Roncoroni et al., 2019), was an outcome predictor in cardiac patients (Marks et al., 2005), and was linked to sustained clinical improvements in arthritis patients (Marks et al., 2005). Research indicated that self-efficacy is modifiable as interventions have been shown to increase self-efficacy (Borimnejad et al., 2018; Kocaaslan & Kostak, 2019). Self-efficacy toward airway clearance therapy (Sherman et al., 2019) and adherence to therapies in CF has been studied (McDonald et al., 2013), but self-efficacy toward SRH care utilization has not been studied. This is the first study to analyze self-efficacy among women with CF in association with utilization of SRH care.

Quantitative analysis of the SEMCD6 and survey responses revealed that a positive correlation exists between self-efficacy and utilization of SRH care services. Participants with higher SEMCD6 scores (indicative of higher self-efficacy) had higher utilization of SRH care services. Poisson regressions indicated that self-efficacy alone is a good predictor of utilization of SRH services, and that a model with age plus FEV1 is also a good predictor of utilization of SRH care services. These findings are consistent with findings in other chronic illness and provides new knowledge about self-efficacy and utilization of SRH care services among women with CF. Establishing a positive correlation between self-efficacy and utilization of SRH care services among women with CF informs future studies about interventions designed to increase the self-efficacy of women with CF in using SRH care services to potentially improve clinical outcomes for this population.

Qualitative Results

Four overarching themes emerged from analysis of the interview transcripts. They were: (a) confidence, (b) sources of confidence, (c) inadequate information, and (d) discussions lacking. Twelve subthemes also emerged. The first overarching theme “Confidence” contained two subthemes: 1) feeling confident, and 2) not feeling confident. The second overarching theme “Sources of Confidence” contained four subthemes: 1) mastery experiences, 2) vicarious experiences, 3) verbal persuasion, and 4) physiological state. The third subtheme “Inadequate Information” contained two subthemes: 1) past, and 2) present. The fourth overarching theme of “Discussions Lacking” contained four subthemes: 1) comfort with topic, 2) knowledge of topic, 3) previous experiences, and 4) prioritization of care. The sources of confidence identified by the women interviewed are consistent with the self-efficacy construct of Bandura’s (1977) Social Cognitive Theory.

Within the first overarching theme of “Confidence”, analysis revealed that 8/10 participants interviewed described themselves as confident toward utilizing SRH care services and 7/10 received SRH care services in the past year. These findings are inconsistent with previous studies (Kazmerski et al., 2018a) that revealed SRH care is underutilized by women with CF. These inconsistent findings may be related to the small sample size, an unintentional recruitment bias wherein the most confident women were the ones that agreed to participate in the study, or the self-reported findings may be higher than actual utilization as health records were not reviewed to validate the self-report of utilization of SRH care services in the past year.

The second overarching theme “Sources of Confidence” contained four subthemes. The first of these subthemes “Mastery Experiences” is consistent with Bandura’s (1977) theory which states that “mastered” experiences contribute to the development of self-efficacy toward a particular skill. Women described feeling more confident toward utilizing SRH after “mastering” their first gynecological appointment and more confident initiating conversations with their CF care team after conversations with their gynecologist. These findings are consistent with sources of confidence toward chronic care in post heart transplantation patients where performance accomplishments boosted self-confidence (Almgren et al., 2016). Almgren et al., found that achievements act as concrete recovery markers and evidence of mastery of each care task influenced development of self-efficacy.

The second subtheme of the overarching theme “Sources of Confidence” was identified as “vicarious experiences” and is also consistent with Bandura’s (1977) research. Women described hearing about the experiences of other women with CF, reading discussions regarding SRH on social media platforms (CF Facebook groups), and hearing about the experiences of their friends and family that contributed to their self- efficacy toward utilizing SRH care. Eight of the ten women interviewed described their experiences hearing about the SRH care experiences of other women. In post heart transplantation patients, successful heart recipients served as role models for heart transplantation patients in their first 12 months post-transplant (Almgren et al., 2016). By observing post heart transplantation patients attending physiotherapy, they gained an idea of what their recovery journey might look like and gained confidence in their own ability to succeed (Almgren et al., 2016). The second subtheme “Vicarious Experiences” of the second overarching theme “Sources of Confidence” is consistent with findings in other chronic illness (Almgren et al., 2016) and establishes new knowledge regarding self-efficacy toward utilization of SRH care services among women with CF.

The third subtheme of the overarching theme “Sources of Confidence” was “verbal persuasion” and is also consistent with Bandura’s (1977) research. Women described receiving encouragement from mothers, older sisters, and friends with CF about utilizing SRH care services. Significantly, they did not bring up the CF care team as a source of verbal persuasion which will be components of the remaining two overarching themes. These rich descriptions of receiving verbal persuasion from their family and friends with CF and the subsequent development of confidence toward utilizing SRH care services is inconsistent with findings from the Almgren et al. (2016) study with post heart transplantation patients where verbal persuasion did not increase self-confidence, but rather increased anxiety when the heart recipients were unable to meet the expectations.

The fourth subtheme of the overarching theme “Sources of Confidence” was ” physiological state.” Conversely, this theme differed from Bandura’s (1977) research by not being described by the participants as a source of confidence but was described as a priority of their CF care team. Women did not describe their physiological state (lung function, overall health) in context of gaining confidence toward utilization of SRH care. They described their physiological state or lung health as a priority of their CF care team.

This is consistent with previous research that established there are no interaction effects between self-efficacy and health status on global quality of life in a sample that was 48% female (Wahl, et al., 2005). This study presents new findings on physiological state as a source of confidence, specifically in the context of SRH care among women with CF and establishes the importance of SRH education and information to women with CF, regardless of their physiological state.

This study validated that the sources of self-efficacy (mastery experiences, verbal persuasion, and vicarious experiences) for women with CF are consistent with what is currently known about sources of self-efficacy, except for “physiological state” which was not described as a source of developing self-efficacy. These findings supported what was known about sources of self-efficacy in other chronic conditions and established new knowledge about self-efficacy among women with CF. Establishment of the sources of self-efficacy is an important step toward research designed to increase the self-efficacy of women with CF toward utilization of SRH care.

The third overarching theme was identified as “Discussions Lacking” with two subthemes: 1) past, and 2) present. Participants described a lack of conversations with their CF care team about SRH. The finding that SRH discussions are lacking is consistent with other SRH research findings (Kazmerski et al., 2018a). Women described wanting to receive guidance from their CF care team regarding SRH. The two subthemes of “past” and “present” were identified from the recounts of the women interviewed of times in the past and recently where conversations about SRH were not conducted during the clinic visit. This finding validates what is known about this topic from current research (Kazmerski et al., 2018a) and may help explain why SRH care is underutilized by women with CF. Understanding the reasons SRH care is underutilized may lead to research that includes interventions designed to facilitate conversations regarding SRH during routine CF clinic appointments as a vital component of comprehensive CF care.

The fourth overarching theme was “Inadequate Information” with four subthemes identified: 1) comfort with topic, 2) knowledge of topic, 3) previous experiences, and 4) prioritization of care. Women described wanting information regarding SRH but feeling the information available to them was inadequate. They described wanting current, timely, information, but feeling it was not available. They described feeling their CF care team was not comfortable discussing the topic of SRH which led to the first subtheme of “comfort with topic.”

Women described feeling their CF care team did not have adequate knowledge of the topic of SRH (subtheme two), possibly due to lack of research available. Women described previous experiences (subtheme three) where they attempted to discuss SRH with their CF care team, but it was not well received, and these negative experiences led to them avoiding the introduction of the topic of SRH at subsequent clinic appointments. The fourth theme of "prioritization of care" stemmed from women explaining that SRH was very important to them, but they did not feel SRH was a priority of their CF care team. These findings are consistent with previous research (Brown et al., 2018) where a concept analysis of SRH identified the dimensions of SRH and established the perspectives of SRH (patient, partner and provider) wherein the perspective of the patient, partner, and provider may differ. Identification of the dimensions of SRH among women with CF is important because it may contribute to future research designed to increase SRH care utilization among women with CF. Knowledge of the dimensions of SRH important to the women with CF from their own perspectives may guide future research.

Integrated Results

Findings from the quantitative and qualitative strands were integrated to answer the overall mixed methods research question: *How do quantitative questionnaire results and qualitative semi-structured interview results jointly explain the relationship of self-efficacy to utilization of SRH care services in women with CF?* Integration of the findings of the two concurrent strands revealed that women are confident toward SRH, most utilized at least one SRH service during the past year, there is a positive relationship between self-efficacy and utilization of SRH care services, and lung function is not a major factor in relationship to utilization of SRH care services.

The first integrated result of “Women are Confident Toward SRH” contradicts previous research indicating SRH care is underutilized by women with CF (Kazmerski et al., 2018a). Elexacaftor + tezacaftor + ivacaftor (Trikafta™) is a combination therapy combining three CFTR modulators that was approved for people with CF ages 12 years and older who have at least one copy of the F508del mutation by the U.S. Food and Drug Administration on Oct. 21, 2019 (CFF, 2019a). Since the emergence of highly effective modulator therapy (elexacaftor + tezacaftor + ivacaftor), the rate of pregnancy has increased (CFF, 2019a) and perhaps explains the finding of increased utilization of SRH care services in this study. The expected finding based on the review of literature would suggest that women with CF are not confident toward SRH. This finding expands what is known about self-efficacy and SRH in women in CF and is important to establish that some women with CF are confident toward SRH and that self-efficacy can be developed toward SRH. This exploration of the perspectives of women with CF who successfully utilize SRH care services could help explain factors related to their utilization and contribute to designing research which has a goal of increasing SRH care utilization by all women with CF.

The second integrated result of “Most utilized SRH Services in the Past Year” also contradicts what is known about SRH care utilization by women with CF. Previous research established that SRH care services are underutilized by women with CF (Kazmerski et al., 2018a). Underutilization of SRH care services was established prior to the advent of highly effective modulator therapy (CFF, 2019a) and may be a factor related to increased SRH care services utilization. This finding is important because it establishes that some women with CF are utilizing SRH care services. A potential bias of this finding could be that women with higher self-efficacy were more likely to participate in this study. Exploring and defining characteristics of women that successfully utilized SRH care services could contribute to an understanding of interventions that would improve utilization of SRH care services for all women with CF.

The third integrated result of this mixed methods study is that there is a positive relationship between self-efficacy and utilization of SRH care services. This finding is new knowledge as this relationship has not been previously studied. This finding extends what is known about self-efficacy and utilization of SRH care services among women with CF. Establishment of this relationship is an important finding that demonstrates the need for future studies designed to increase self-efficacy toward SRH care services with the goal of increasing SRH care utilization of services.

The fourth integrated finding is that lung function is not major factor in relationship to utilization of SRH care services. Lung function was assessed by self-report on the survey and discussed during the interviews. In this sample, 47% reported a FEV1 greater than 70% predicted and participants did not describe declining lung health or better lung health in relation to their utilization of SRH care services. This surprising finding may be related to an unintentional recruitment bias in that recruitment occurred during routine clinic appointments and women with higher lung functions felt more well and were willing to participate in the research. This finding adds to what is known about SRH in women with CF in that women with CF do not necessarily relate their desire for SRH conversations or information to their state of health but is rather a personalized need for women who participated in the study.

Implications

Findings from this study suggest that higher self-efficacy is correlated to greater utilization of SRH care services. Literature establishes that utilization of SRH care services by women with CF is underutilized (Kazmerski et al., 2018a), This underutilization of SRH care services places these women at risk for undetected cervical cancer, or an unplanned pregnancy when their health is not optimized. By establishing a positive correlation between self-efficacy and utilization, the assumption is that increasing a woman's self-efficacy would therefore increase her utilization of SRH care services. The qualitative strand of this study explored sources of self-efficacy among women with CF. These stories of women with CF validate the sources of self-efficacy as vicarious experiences, verbal persuasion, or mastery experiences. Exploring how they described their acquisition of self-efficacy implies that interventions could be designed and initiated with the goal of increasing self-efficacy toward SRH among women with CF and subsequently increase their utilization of SRH care services. This could be accomplished via the sharing of experiences by women with high self-efficacy, verbal persuasion from members of the interdisciplinary health care team, or guidance through the process of scheduling and receiving SRH care by members of the interdisciplinary health care team. These interventions directly relate to Bandura's (1977) original sources of self-efficacy and to the ways women with CF described their personal journal to the acquisition of self-efficacy toward SRH care.

Clinical Practice

Results of this study highlight the relationship of self-efficacy to utilization of SRH care services by women with CF. Current clinical care protocols do not address self-efficacy. The SEMCD6 is not currently used in a clinical setting to assess self-efficacy of women with CF. Evaluating self-efficacy during a routine clinic appointment would provide the CF healthcare team with information to inform and guide SRH conversations.

Policy

This study provided information useful in addressing policy related to SRH care for women with CF, including the addition of self-efficacy screening during routine CF care appointments which could subsequently lead to the development of interventions designed to increase self-efficacy and to improve the utilization of SRH care services by women with CF. There are no current guidelines regarding assessment of self-efficacy and no established SRH care guidelines (CFF, 2020). SRH care is underutilized by women with CF (Kazmerski, et al., 2018a), placing them at risk for cervical cancer (Rousset-Jablonski et al., 2018) an unplanned pregnancy when health is not optimized. Self-efficacy is necessary for self-management (Parcel et al., 1994), interventions have been shown to improve self-efficacy (Bartholomew et al., 1997; McDonald et al., 2013), and interventions have been designed to improve self-efficacy (Cummings et al., 2011). It is therefore important to establish policy regarding the inclusion of SRH care and the assessment of self-efficacy into routine, comprehensive CF care.

Future Research

This study has potential to guide a pilot study exploring the feasibility and acceptability of an intervention study. Including healthy controls could provide insight into self-efficacy in healthy women without CF and determine whether there are differences, and if so, explore factors that were associated with higher or lower self-efficacy for the purpose of developing interventions to increase self-efficacy toward SRH among women with CF. As women with CF continue to live longer and desire to achieve life goals, interventions designed to improve SRH self-efficacy may improve utilization of SRH care services by women with CF.

Limitations

There were seven limitations of this study. The first limitation is related to COVID-19 restrictions. Due to COVID-19 restrictions, the last six interviews had to be conducted via telephone, which may have impacted the privacy of the participant and therefore their willingness to discuss sensitive topics. Also due to COVID-19 restrictions, the IRB had to be amended and the last 11 participants were recruited via telephone rather than the recruitment of the first 48 participants that were recruited during a routine clinic appointment. The second limitation was that the quantitative strand was restricted to using data collected as part of the parent study. The SEMCD6 was added to quantitative strand, but no additional data was collected. A third limitation is that all data were collected from a single CF center and are therefore not representative of the population. The fourth limitation is that convenience sampling was utilized, posing a potential for sampling bias, and therefore, limits representativeness of the entire population. The fifth limitation is that inclusion criteria were limited by the parent study to women aged 25 years or older, rendering the study not representative of the entire population of women with CF. The sixth limitation is that the small sample size precludes generalizability. The final limitation is that demographic data were not collected for the subset of participants completing the audio recorded, semi-structured interview during the interview process.

Strengths

Four strengths of this study were noted. The first strength is that the researcher completed IRB training, a qualitative research course, a quantitative research course, and a mixed methods course prior to conducting the study. The second strength noted was that for a validated and reliable instrument was utilized in the quantitative strand. A third strength is that peer review was provided by the dissertation committee at each phase of the research. The final strength noted was that the research was guided by a theoretical framework.

Conclusion

This study is the first concurrent mixed methods study to explore self-efficacy and SRH in women with CF. Results from this study can be used to guide development of SRH care protocols, inform future research and clinical practice, and shape SRH policy development. A future intervention study based on the model in this study could be used to further explore the development of self-efficacy and potentially improve SRH care outcomes among women with CF. Awareness of the need to reorient health care systems towards better care for chronic patients is growing (Nuno et al., 2012), and the CF health care team is uniquely positioned as an interdisciplinary health care team to focus on not only improving health care, but also improving the quality of life for women with CF and play a pivotal role in supporting their achievement of life goals.

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APPENDIX A

BANDURA’S CONSENT TO MODIFY AND USE MODEL

Re: Permission to use model

Karen S Saltzman <karen333@stanford.edu>
Thu 9/17/2020 11:46 PM

To: Brown, Janet L
<jbrown5@uab.edu>
Permission granted,
Albert Bandura

From: "Brown, Janet L" <jbrown5@uab.edu>
Date: Thursday, September 17, 2020 at 5:44 PM
To: Karen Saltzman
<karen333@stanford.edu>
Subject: Permission to use
model

Hello Dr. Bandura,

I am a PhD Candidate in the University of Alabama at Birmingham School of Nursing. I would like to request permission to adapt your model for use in a concurrent, mixed methods study in women with cystic fibrosis to explore the relationship of self-efficacy to utilization of sexual and reproductive health care services. The model below was published in 2004 in the journal Health Education & Behavior and has the following citation:

Bandura, A. (2004). Health promotion by social cognitive means. Health education & behavior, 31(2), 143-164.

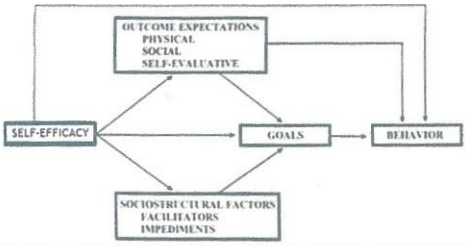

Figure 1. Structural paths of influence wherein perceived self-efficacy affects health habits both directly and through its impact on goals, outcome expectations, and perception of sociostructural facilitators and impediments to health-promoting behavior.

Here is the adaptation from the core of your model:

Thank you for your kind consideration of this request.

Sincerely,

Janet Brown MSN, RN, CPN I PhD Candidate
BSN Honors Program Graduate Teaching Assistant

Jonas Scholar htps•J/oudook.ofice.corwmaiVsearch1id/AAQkADZiYTVhNGM2LWIOMDAtNDcyYS1

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APPENDIX B

INTERVIEW GUIDE

Interviewer Name: _____________

Interview Date: ________________

Time Interview Began: ____________

Time Interview Ended: ____________

Italicized prompts are optional.

INTRODUCTION: Hello, this is Janet Brown and I am a PhD student at the University of Alabama at Birmingham. Thank you for agreeing to participate in this interview. The purpose of this interview is to talk about your experiences related to self-efficacy, or the belief that you can complete a task related to sexual and reproductive health care and any concerns about this topic that you may have. This interview will be audio recorded, and I will inform you when the recording will begin. Some questions may prompt you to tell me about your experiences. To protect your privacy, please do not use your name, or any identifying information. It is helpful if you provide a pseudonym (name that is not your own that I will use to address you during this interview). Is there a name that you would like to use throughout this interview? Answering questions is voluntary, and you may skip any question you do not choose to answer. Please feel free to add anything you would like to, or that you feel better explains your answer. There are no foreseeable risks to you associated with this project, nor are there any direct benefits. You may end this interview at any time if you should feel uncomfortable. Or we can stop the interview if you need a break, and resume when you are ready. This interview should last approximately 30 minutes. If you have any questions, you may contact me via email at jbrown5@uab.edu or 256-531-3311

Do you have any questions before we start?

I will begin recording now.

Do you consent to this interview?

At any time, please add anything you would like to explain your answer, or that you feel is important.

Let's begin by talking about your experiences regarding sexual and reproductive health care [which I will refer to as SRH for the remainder of the interview].

1. Tell me what you think of when I say the words *sexual and reproductive health?*

2. What routine care related to SRH have you sought in the past year? For example, a routine gynecological appointment, a Pap smear, or contraceptives consultation?

[prompts]:

- *What were some of the reasons affecting why you sought or did not seek care this year related to SRH?*
- *Describe factors that made this process easier or more difficult for you.*
- *Is there anything else you would like to add?*

3. Do you think an OB/GYN provider should be a part of a regular CF care team?

4. How often should SRH care topics be brought up as a part of regular CF care?

5. Do you feel like your team has ever encouraged or discouraged you from pursuing pregnancy?

6. Please describe how confident or not confident you feel about sharing your concerns with your CF healthcare team about SRH issues.

[prompts]:

- *Could you share a little about this?*
- *Do you feel confident discussing SRH care concerns with your CF healthcare team?*
- *Is there anything that made you feel more or less confident?*

7. Let's talk about things that influence your level of confidence communicating with your CF healthcare team about SRH.

[prompts]:

- *Was it easy or difficult to talk with your team about SRH issues?*
- *What made it easy or difficult?*
- *Are there factors outside of your CF team that made the process easier or more difficult?*
- *Describe things not related to your CF healthcare team that made this process easier or more difficult.*
- *Is there anything else you would like to add?*

8. Can you share your experience about bringing up a SRH topic with your CF healthcare team?

[prompt]:

-How did they receive your questions about SRH?

9. Do you have one person on your CF healthcare team you would ask SRH questions?

[prompts]:

-Who would that be?

-How did you choose that person out of everyone on the team?

10. What do you think are the biggest barriers to your CF team bringing up this topic?

11. What do you think are the biggest things that help your CF team in bringing up this topic?

12. Have you had experiences in the past which may have contributed to your confidence, or lack of confidence in seeking SRH care? Meaning, have you had experiences, either positive or negative that have made you feel more or less confident with this topic?

13. Describe to me how comfortable or not comfortable you feel about the topic of SRH in general.

14. How knowledgeable do you feel about SRH in general?

[prompts]:

- *How do you get SRH information?*
- *What are your sources of information?*
- *How do you know who to believe?*

15. How important do you think SRH is in the overall picture of your healthcare?

16. Do you think that seeking or not seeking SRH care reflects your overall approach to your general CF care? Meaning, do you think if one is confident with SRH care they are confident with all aspects of CF care?

17. Can you share what you feel is most important about any of the things we have talked about today?

18. Did these questions make you think of anything else you would like to share?

19. Recap…it seems like what I heard…

20. What are things that would help get this message to your CF healthcare team?

Thank you for agreeing to this interview. This ends the questions for this interview. Is there anything you would like to add before I end the recording? I will now end the audio recording.

May we contact you for a future related research study?

APPENDIX C

SEMCD6

SMRC
Self-Management
Resource Center

Self-Efficacy for Managing Chronic Disease 6-item Scale

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. How confident do you feel that you can keep the fatigue caused by your disease from interfering with the things you want to do?

   not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

2. How confident do you feel that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?

   not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

3. How confident do you feel that you can keep the emotional distress caused by your disease from interfering with the things you want to do?

   not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

4. How confident do you feel that you can keep any other symptoms or health problems you have from interfering with the things you want to do?

   not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

5. How confident do you feel that you can the different tasks and activities needed to manage your health condition so as to reduce your need to see a doctor?

   not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

6. How confident do you feel that you can do things other than just taking medication to reduce how much your illness affects your everyday life?

   not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

Scoring

The score for each item is the number circled. If two consecutive numbers are circled, code the lower number (less self-efficacy). If the numbers are not consecutive, do not score the item. The score for the

The score for each item is the number circled. If two consecutive numbers are circled, code the lower number (less self-efficacy). If the numbers are not consecutive, do not score the item. The score for the

scale is the mean of the six items. If more than two items are missing, do not score the scale. Higher number indicates higher self-efficacy.

Characteristics

Tested on 605 subjects with chronic disease

.

No. of items	Observed Range	Mean	Standard Deviation	Internal Consistency Reliability	Test-Retest Reliability
6	1-10	5.17	2.22	.91	NA

Source of Psychometric Data

Stanford/Garfield Kaiser Chronic Disease Dissemination Study. Psychometrics reported in: Lorig KR, Sobel, DS, Ritter PL, Laurent, D, Hobbs, M. Effect of a self-management program for patients with chronic disease. *Effective Clinical Practice*, 4, 2001,pp. 256-262.

Comments

This 6-item scale contains items taken from several SE scales developed for the Chronic Disease SelfManagement study. We use this scale now, as it is much less burdensome for subjects. It covers several domains that are common across many chronic diseases, symptom control, role function, emotional functioning and communicating with physicians. For internet studies, we add radio buttons below each number. There are 2 ways to format these items. We use the format on this document, the other is shown on the web page. A 4-item version of this scale available in Spanish.

References

Lorig KR, Sobel, DS, Ritter PL, Laurent, D, Hobbs, M. Effect of a self-management program for patients with chronic disease. *Effective Clinical Practice*, 4, 2001,pp. 256-262.

This scale is free to use without permission

Self-Management Resource Center
711 Colorado
Avenue Palo Alto
CA 94303
(650) 242-8040
smrc@selfmanagementresource.com
www.selfmanagementresource.com

APPENDIX D

IRB APPROVAL

THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM
Office of the Institutional Review Board for Human Use

470 Administration Building
701 20th Street South
Birmingham, AL 35294-0104
205.934.3789 | Fax 205.934.1301 | irb@uab.edu

APPROVAL LETTER

TO: Ladores, Sigrid L

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance # FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)

DATE: 26-Mar-2019

RE: IRB-300001842
Sexual and Reproductive Health in Adult Women with Cystic Fibrosis

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The IRB reviewed and approved the Revision/Amendment submitted on 22-Mar-2019 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

Type of Review: Exempt
Exempt Categories: 2
Determination: Exempt **Approval**
Date: 26-Mar-2019

Documents Included in Review:

- praf.190312 surveyquest.190312
- infosheet.patient.190319.clean
- interview.190322

THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM
Office of the Institutional Review Board for Human Use

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701 20th Street South
Birmingham, AL 35294-0104
205.934.3789 | Fax 205.934.1301 | irb@uab.edu

DETERMINATION LETTER

TO: Ladores, Sigrid L

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance Number FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)

DATE: 11-Mar-2019

RE: IRB-300001842
Sexual and Reproductive Health in Adult Women with Cystic Fibrosis

---

The IRB reviewed the Revision/Amendment submitted on 11-Mar-2019 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

Type of Review:	Exempt - Institutional Review Board 01 (UAB)
Determination:	Additional information required
Determination Date:	11-Mar-2019

Please respond to the items listed below. The response must be submitted through IRAP. Visit the IRAP page on the UAB IRB website for guidance on responding through IRAP. Click on the "Quick Step by Step Instructions for How to Respond to an IRB Review".

Items to Address:

1. Provide the Self-Efficacy for Managing Chronic Disease Scale. A copy was not provided with the submission.
2. The PRAF states that you want to conduct qualitative interviews with a subset of the women who volunteer. Will these be women who are currently participating in this study? How will these women be approached/contacted regarding the sub-study? Do you plan on obtaining written informed consent for the interview? If so, provide a copy of the consent document.
3. Provide a copy of the interview guide. A copy was not provided with the submission.

Project Revision/Amendment Form

Form version: November 20, 2018

In MS Word, click in the white boxes and type your text; double-click checkboxes to check/uncheck.

- **Federal regulations require IRB approval before implementing proposed changes. See Section 14 of the IRB Guidebook for Investigators for additional information.**
- **Change means any change, in content or form, to the protocol, consent form, or any supportive materials (such as the Investigator's Brochure, questionnaires, surveys, advertisements, etc.). See Item 4 for more examples.**

1. Today's Date	3/12/19

2. Principal Investigator (PI)

Name (with degree)	Sigrid Ladores PhD, RN	**Blazer ID**	sladores
Department	Family, Community and Health Systems	**Division (if applicable)**	
Office Address	1701 University Blvd., NB470L, Birmingham, AL 35294	**Office Phone**	205-934-6835
E-mail	sladores@uab.edu	**Fax Number**	205-996-7177

Contact person who should receive copies of IRB correspondence (Optional)

Name		**E-Mail**	
Phone		**Fax Number**	
Office Address (if different from PI)			

3. UAB IRB Protocol Identification

3.a. Protocol Number	IRB-30001842
3.b. Protocol Title	Sexual and Reproductive Health in Adult Women with Cystic Fibrosis

3.c. Current Status of Protocol—For active studies, check ONE box at left; provide numbers and dates where applicable; for ESU completed, skip to Item 4

☒ **Study has not yet begun** **No participants, data, or specimens have been entered.**

☐ **In progress, open to accrual** **Number of participants, data, or specimens entered:**

☐ **Enrollment temporarily suspended by sponsor**

☐ **Closed to accrual, but procedures continue as defined in the protocol (therapy, intervention, follow-up visits, etc.)**

Date closed:

Number of participants receiving interventions:

Number of participants in long-term follow-up only:

☐ **Closed to accrual, and only data analysis continues**

Date closed: **Total number of participants entered:**

4. Types of Change

Check all types of change that apply, and describe the changes in Item 5.c. or 5.d. as applicable. To help avoid delay in IRB review, please ensure that you provide the required materials and/or information for each type of change checked.

☐ **Expedited Status Update (ESU) ONLY**

For protocols under the 2018 Revised Common Rule, reviewed via the expedited procedure, any change to the protocol will be considered an ESU. Expedited studies are required to submit an ESU at least every 3 years to remain in compliance with UAB IRB POL020 & PRO150. Indicate one of the following:

☐ **Continuing (Item 3 indicates current study status)**

OR

☐ **Completed (all protocol-related data analysis is complete and no further work is being conducted)**

Total number of participants entered:

In Item 5.c., (a) include any findings or publications resulting from the research; (b) describe the storage plan: (1) how will data records be stored, (2) how will they be protected, (3) how long will data be stored, (4) where will data be stored, and (5) following storage will records be destroyed, archived, or transferred?

☒ **Protocol revision (change in the IRB-approved protocol)**

In Item 5.c., if applicable, provide sponsor's protocol version number, amendment number, update number, etc.

☐ **Protocol amendment (addition to the IRB-approved protocol)**

In Item 5.c., if applicable, provide funding application document from sponsor, as well as sponsor's protocol version number, amendment number, update number, etc.

☒ **Add or remove personnel**

In Item 5.c., include name, title/degree, department/division, institutional affiliation, and role(s) in research, and address whether new personnel have any conflict of interest. See "Change in Principal Investigator" in the IRB Guidebook if the principal investigator is being changed.

☒ **Add graduate student(s) or postdoctoral fellow(s) working toward thesis, dissertation, or publication**

In Item 5.c., (a) identify these individuals by name; (b) provide the working title of the thesis, dissertation, or publication; and (c) indicate whether or not the student's analysis differs in any way from the purpose of the research described in the IRB-approved HSP (e.g., a secondary analysis of data obtained under this HSP).

☐ **Change in source of funding; change or add funding**

In Item 5.c., describe the change or addition in detail, include the applicable OSP proposal number(s), and provide a copy of the application as funded (or as submitted to the sponsor if pending). Note that some changes in funding may require a new IRB application.

☐ **Add or remove performance sites**

In Item 5.c., identify the site and location, and describe the research-related procedures performed there. If adding site(s), attach notification of permission or IRB approval to perform research there. Also include copy of subcontract, if applicable. If this protocol includes acting as the Coordinating Center for a study, attach IRB approval from any non-UAB site added.

☐ **Add or change a genetic component or storage of samples and/or data component—this could include data submissions for Genome-Wide Association Studies (GWAS)**

To assist you in revising or preparing your submission, please see the IRB Guidebook for Investigators or call the IRB office at 934-3789.

☐ **Suspend, re-open, or permanently close protocol to accrual of individuals, data, or samples (IRB approval to remain active)**

In Item 5.c., indicate the action, provide applicable dates and reasons for action; attach supporting documentation.

☐ **Report being forwarded to IRB (e.g., DSMB, sponsor or other monitor)**

In Item 5.c., include date and source of report, summarize findings, and indicate any recommendations.

☐ **Revise or amend consent, assent form(s)**
Complete Item 5.d.

☐ **Addendum (new) consent form**
Complete Item 5.d.

☐ **Add or revise recruitment materials**
Complete Item 5.d.

☒ **Other (e.g., investigator brochure)**
Indicate the type of change in the space below, and provide details in Item 5.c. or 5.d. as applicable.
Include a copy of all affected documents, with revisions highlighted as applicable.

▶ We would like to add 6 additional questions regarding self-efficacy to the survey. These 6 questions are from the instrument, Self-Efficacy for Managing Chronic Disease (copy enclosed).

5. Description and Rationale

In Item 5.a. and 5.b, check Yes **or** No **and see instructions for** Yes **responses.**
In Item 5.c. and 5.d, describe—and explain the reason for—the change(s) noted in Item 4.

☒Yes ☐ No — **5.a. Are any of the participants enrolled as normal, healthy controls?**
If yes, describe in detail in Item 5.c. how this change will affect those participants.

☐Yes ☒ No — **5.b. Does the change affect subject participation, such as procedures, risks, costs, location of services, etc.?**
If yes, FAP-designated units complete a FAP submission and send to fap@uab.edu. Identify the FAP-designated unit in Item 5.c.
For more details on the UAB FAP, see www.uab.edu/cto.

5.c. Protocol Changes: In the space below, briefly describe—and explain the reason for—all change(s) to the protocol.

▶I would like to add Janet Brown MSN, RN, CPN, UAB School of Nursing Doctoral student, to IRB-30001842. Ms. Brown will use a portion of this research study as her dissertation. Ms. Brown's address is: UAB School of Nursing, 1701 University Blvd., NB 480, Birmingham, AL 35924-1210**.** Her role in the research includes: recruitment of participants, administration of surveys, conduct of interviews, and analysis of quantitative and qualitative data. Ms. Brown has no conflict of interest. Ms. Brown's working title of dissertation: The Role of Self-Efficacy in Sexual and Reproductive Health in Women with Cystic Fibrosis. Ms. Brown's analysis for her dissertation will not differ in any way from the purpose described in the research as approved previously by IRB.

▶We would like to amend IRB-30001842 to increase the peer nominated healthy control sample size from
15 to 50 to allow better comparisons between the women with CF (n=50) and women without CF (n=50).

▶We would also like to add the 6-item Self-Efficacy for Managing Chronic Disease Scale to the original survey. Copy of the scale is enclosed.

▶We would also like to conduct qualitative interviews with a subset of the women with CF (n=10) who volunteer to complete a semi-structured, audio-taped interview after they complete the survey. This subset of women will come from the larger group of women who complete the survey. During the participant recruitment and enrollment, the research team member will share information about the interview which will be conducted after the survey is completed, and invite participants to participate in the interview. The interview will focus on the participants' perceptions of self-efficacy related to managing their CF and will augment the quantitative data derived from the survey. A separate written informed consent for the interview is not requested as this interview topic and overall study poses no more than minimal risk to the participant. The introductory script for the interview outlines the purpose, risks, and potential benefits of participating in the interview. Answering the interview questions after the introductory script signifies informed consent. Copy of interview guide is enclosed.

5.d. Consent and Recruitment Changes: In the space below,

(a) describe all changes to IRB-approved forms or recruitment materials and the reasons for them;
(b) describe the reasons for the addition of any materials (e.g., addendum consent, recruitment); and
(c) indicate either how and when you will reconsent enrolled participants or why reconsenting is not necessary (not applicable for recruitment materials).

Also, indicate the number of forms changed or added. For new forms, provide 1 copy. For revised documents, provide 3 copies:

- **a copy of the currently approved document (showing the IRB approval stamp, if applicable)**
- **a revised copy highlighting all proposed changes with "tracked" changes**
- **a revised copy for the IRB approval stamp.**

▶

From: Denise H Ball <dhball@uab.edu>
Sent: Wednesday, May 20, 2020 12:37 AM
To: Ladores, Sigrid L <sladores@uab.edu>
Subject: Amendment - IRB-300001842

Sexual and Reproductive Health in Adult Women with Cystic Fibrosis

Dr. Ladores,
The IRB reviewed and approved the amendment to the protocol referenced above. This email will temporarily serve as your IRB approval documentation because of issues with the electronic system. Once the issue is corrected, the IRB Approval Letter will be emailed to you for your records.

Thank you,

Denise Ball | Consultant
Office of the Institutional Review Board
UAB | The University of Alabama at Birmingham
P: 205.934.3789 | dhball@uab.edu