A dissertation submitted to the
Kent State University College and Graduate School
of Education, Health and Human Services
in partial fulfillment of the requirements
for the degree of Doctor of Philosophy

by

Laura E. Santurri

August 2012
A dissertation written by
Laura E. Santurri
B.A., University of Akron, 2003
M.P.H., Case Western Reserve University, 2007
Ph.D., Kent State University, 2012

Approved by

_________________________________, Co-Director, Doctoral Dissertation Committee
Cynthia W. Symons

_________________________________, Co-Director, Doctoral Dissertation Committee
Kele Ding

_________________________________, Member, Doctoral Dissertation Committee
Tony Buffington

Accepted by

_________________________________, Director, School of Health Sciences
Lynne Rowan

_________________________________, Dean, College and Graduate School of
  Education, Health and Human Services
Daniel F. Mahony
AN ANALYSIS OF THE RELATIONSHIP BETWEEN STRESS, SELF-EFFICACY, SOCIAL SUPPORT, AND HEALTH-RELATED QUALITY OF LIFE AMONG WOMEN LIVING WITH INTERSTITIAL CYSTITIS IN THE UNITED STATES (252 pp.)

Co-Directors of Dissertation: Cynthia W. Symons, D.Ed., CHES  
Kele Ding, M.D., Ph.D.

The purpose of this study was to analyze the relationships between stress, self-efficacy, social support, and health-related quality of life among women living with interstitial cystitis (IC) in the United States (U.S.). In addition, this study examined self-efficacy as a mediator in the relationship between stress and health-related quality of life and social support as a moderator of the impact of self-efficacy on health-related quality of life in women living with IC when controlling for stress. IC is a chronic condition with the potential for substantial impact on quality of life.

Using a systematic and purposive approach, a sample of 1,387 women living with IC was recruited to complete a cross-sectional, web-based, anonymous instrument. This instrument contained 155 items, measuring health-related quality of life, social support, stress, self-efficacy, disease severity, co-morbidity, and a variety of demographic variables. Descriptive statistics, Pearson Product Moment Correlation Coefficient tests, and Linear Regression were used to analyze the data.

Findings revealed statistically significant correlations between social support, stress, self-efficacy and health-related quality of life. In addition, self-efficacy was found to be a statistically significant partial mediator of the relationship between stress and health-related quality of life. Contradictory to the theoretical and evidentiary literature,
social support was not found to be a moderator of the relationship between self-efficacy and health-related quality of life. Both qualitative and intervention research are warranted in order to better understand these relationships, as well as how to affect health-related quality of life in this population.
ACKNOWLEDGMENTS

I have been incredibly grateful for many individuals throughout this dissertation process. First, I would like to thank my dissertation committee—Drs. Cynthia Symons, Kele Ding, and Tony Buffington and my Graduate Faculty Representative and Dissertation Moderator, Dr. Kimberly Peer. With all sincerity, I could not have asked for a more supportive group of faculty. Dr. Symons—thank you for patiently helping me to write better than I ever have. Dr. Ding—thank you for your incredible responsiveness as I worked to understand my data. Dr. Buffington—thank you for constantly challenging me to think critically with meaningful and substantive questions. I also would like to thank Barbara Gordon, the Executive Director of the Interstitial Cystitis Association (ICA). Without your support, and the support of your organization, this study would not have been possible. I also would like to convey many thanks to those individuals living with IC who completed the instrument. Your willingness to share your experiences was invaluable to the success of this study.

The support of other faculty played an instrumental role in my pursuit of a doctoral degree. Drs. Carolyn Behrman and Lynn Metzger at The University of Akron—thank you from the bottom of my heart for believing in me and pushing me to go to graduate school. Thank you to Dr. Susan Flocke for giving me my first experience in public health research and to Dr. Scott Frank for giving me the opportunity to grow as a professional in academia with the Case Western Reserve University (CWRU) Master of Public Health (MPH) Program. To my second family at the CWRU MPH Program—you have no idea how grateful I am for your enduring support and flexibility as I pursued my
PhD. Kristina Knight—I could not imagine a better colleague and friend to have gone through this process with me.

To my new work family and to my supervisor and mentor—thank you. Your support and flexibility was appreciated more than you know as I finished this incredible process.

In addition to the amazing professional support that I received through this process, I am eternally grateful for the support that I received from my family. To my fiancé, Harlan Siegel—the fact that you still want to marry me after this is simply amazing. Thank you for your support, for cleaning the house and cooking dinner when all I could do was stare at my laptop, and for your patience with the many, many stacks of paper that accumulated in the computer room. I thank my parents for never expecting any less from me. To my mom—thank you for the sense of compassion and humor that got me here. To my dad (the “original” Dr. Santurri)—thank you for the strength, spirit, and perseverance that never failed me. Thank you for being a role model, for being a foundation in my life, for always quietly pushing me to work hard and not give up. Not just for you, because of you, with every step.

Finally, this would not be a real acknowledgments section without a thank you to my four-legged family. To my Roxy, Irwin, Fred, Duke, Tyler, and Judy—while you may not have been physically present through the entirety of this process, that does not mean that I did not carry you with me always. To my Hank, Marley, Nicky, and Sara—thank you for never failing to make me smile and feel at home. And to my Oliver—welcome home.
TABLE OF CONTENTS

ACKNOWLEDGMENTS .................................................................................................................. iv

LIST OF TABLES ....................................................................................................................... ix

CHAPTER

I. INTRODUCTION .................................................................................................................. 1

   Purpose of the Study ........................................................................................................ 14
   Research Questions ........................................................................................................ 14
   Definition of Terms ........................................................................................................ 15
   Basic Assumptions .......................................................................................................... 16

II. REVIEW OF LITERATURE .............................................................................................. 17

   Current Interstitial Cystitis Science and Practice ...................................................... 17
     Interstitial Cystitis (IC) .......................................................................................... 17
     Medical Community .............................................................................................. 20
     Veterinary Community .......................................................................................... 26
     National Organizations .......................................................................................... 28
   Quality of Life .............................................................................................................. 31
     Health-Related Quality of Life and Health Education and Promotion .............. 31
     Health-Related Quality of Life and Chronic Disease ........................................... 34
     Health-Related Quality of Life and IC ................................................................. 36
   Stress ............................................................................................................................... 39
     Stress and Health Education and Promotion ....................................................... 39
     Stress and Chronic Disease ................................................................................... 40
     Stress and IC ............................................................................................................. 41
   Self-Efficacy .................................................................................................................... 43
     Self-Efficacy and Health Education and Promotion ............................................ 43
     Self-Efficacy and Chronic Disease ........................................................................ 44
     Self-Efficacy and IC .................................................................................................. 46
   Social Support ............................................................................................................... 46
     Social Support and Health Education and Promotion .......................................... 46
     Social Support and Chronic Disease .................................................................... 48
     Social Support and IC ............................................................................................... 49
   Transactional Model of Stress and Coping ............................................................... 51
   Research Questions, Assumptions, and Data Analysis Approach ...................... 52
### III. RESEARCH METHODS AND PROCEDURES ....................................................... 54

- Purpose of the Study ............................................................................................. 54
- Study Procedures .................................................................................................. 54
  - Interstitial Cystitis Association ...................................................................... 54
  - Study Population and Samples ...................................................................... 55
- Instrumentation ..................................................................................................... 56
  - Sources of Scales ........................................................................................... 57
  - Operationalizing the Variables ...................................................................... 60
- Pilot Studies .......................................................................................................... 64
- Research Design and Data Collection Protocol .................................................... 69
- Research Questions ............................................................................................... 70
- Data Analysis and Test of Hypotheses ................................................................. 70

### IV. RESULTS ................................................................................................................... 72

- Purpose of the Study ............................................................................................. 72
- Data Collection: The Sample ................................................................................ 74
- Descriptive Statistics............................................................................................. 78
  - Sample Demographics ................................................................................... 78
  - Descriptive Statistics of Dependent and Independent Variables ................... 81
  - Summary of Descriptives .............................................................................. 84
- Analyses of Hypotheses ........................................................................................ 84
  - Hypothesis 1–3 .............................................................................................. 84
  - Hypothesis 4 .................................................................................................. 87
  - Hypothesis 5 .................................................................................................. 89
  - Additional Analyses ....................................................................................... 90
- Summary ............................................................................................................... 94

### V. DISCUSSION AND RECOMMENDATIONS .......................................................... 96

- Purpose of the Study ............................................................................................. 96
- Literature-Based Context ...................................................................................... 96
- Study ..................................................................................................................... 99
  - Sample ........................................................................................................... 99
  - Instrumentation and Theoretical Framework ............................................... 99
  - Analysis of Hypotheses ............................................................................... 100
- Recommendations for Further Research ............................................................. 105
- Recommendations for Health Education and Advocacy ..................................... 108
- Limitations .......................................................................................................... 110

### APPENDICES ................................................................................................................ 112

- APPENDIX A. INSTRUMENT ......................................................................... 113
- APPENDIX B. SCALE PERMISSIONS ........................................................... 141
- APPENDIX C. ICA LETTER OF SUPPORT .................................................... 148
- APPENDIX D. IRB APPROVAL AND APPLICATION ................................. 150
- APPENDIX E. STUDY INVITATION .............................................................. 197
LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. AUA Categorization of Treatment Approaches for IC</td>
<td>23</td>
</tr>
<tr>
<td>2. Null Hypotheses and Statistical Tests</td>
<td>71</td>
</tr>
<tr>
<td>3. Demographic Characteristics of Survey Participants ( (n = 1387) )</td>
<td>79</td>
</tr>
<tr>
<td>4. Additional Demographic Characteristics of Survey Participants ( (n = 1387) )</td>
<td>81</td>
</tr>
<tr>
<td>5. Description of Dependent and Independent Variables</td>
<td>83</td>
</tr>
<tr>
<td>7. Regression Coefficient Statistics of the Independent Variables in Three Multiple Linear Regression Models</td>
<td>89</td>
</tr>
<tr>
<td>8. Main Effects of Social Support and Sub-Constructs</td>
<td>92</td>
</tr>
</tbody>
</table>
CHAPTER I

INTRODUCTION

According to the Institute of Medicine (IOM) report *The Future of Public Health*, published in 1988, the 20th century marked a time of transition for the field of public health. Throughout the 18th and 19th centuries, the public health system in the United States (U.S.) focused the majority of its energy and resources on addressing epidemic plagues, including cholera and smallpox, through such measures as quarantine, the establishment of voluntary general hospitals, and perhaps most importantly, advancements in sanitation. The early 1900s, however, marked an increased understanding of bacteriology and a more scientific approach to public health practice. In addition, this century was marked by the development of the nation’s public health infrastructure. These advancements led to the control of infectious disease and increases in life span for the U.S. population (IOM, 1988).

The mid to late 20th century marked a significant reduction in the impact of acute conditions. With environmental and lifestyle factors changing, the U.S. public health system shifted from a focus on increasing years of life to, among other things, addressing chronic disease. This focus on chronic disease was placed in the context of improving quality of life (IOM, 1988). In 1985, McGinnis highlighted this shift by noting the significant public health advancements of the 20th century in preventing disease and reducing mortality. In addition, he noted the limitations of prevention, including the biological factors affecting the number of years one can live or the quantity of life. With the recognition of those limiting factors, Dr. McGinnis concluded that a goal of helping
people live longer, higher quality lives makes more sense than one that focuses solely on living longer lives (McGinnis, 1985). In 2003, McGinnis continued his reflection on the progress of the 20th century, noted by significant increases in life expectancy. Similar to his conclusions in 1985, McGinnis confirmed that “the primary paradigm shift for the 21st century will be the move from a primary focus on length of life to a primary focus on quality of life” (McGinnis, 2003a, p. 149).

Fries, Green, and Levine (1989) echoed the assertions of McGinnis (1985) by asserting that an emphasis be placed on the compression of morbidity. Specifically, this could be accomplished through addressing quality of life and the management of chronic disease. Their conclusion, “add life to your years, not years to your life,” often is repeated in the public health and health promotion literature (Fries et al., 1989).

The burden of chronic disease, and its impact on quality of life, is significant for U.S. citizens. Anderson and Horvath reported that approximately 45% of the U.S. population, or 125 million Americans, had at least one chronic condition in 2000. In addition, 21% of the U.S. population, or 61 million, had two or more chronic conditions. With the percentage of the U.S. population living with a chronic condition expected to increase over the next several decades, and with an estimated 78% of all health care dollars spent on those with chronic conditions in 2000, a shift in focus to the management and quality of care of those living with a chronic condition, as well as the prevention of chronic disease, is necessary (Anderson & Horvath, 2004). In 2010, the Centers for Disease Control and Prevention (CDC) reported that 70% of all deaths in the U.S. were attributable to chronic disease. In addition, about 25% of those with chronic disease
report one or more limitations in daily life, representing a significant impact on quality of life (CDC, 2010a).

A national emphasis on quality of life and the management of chronic disease also is reflected in the evolution of the *Healthy People* agenda. This national health promotion and disease prevention agenda has represented the nation’s health priorities since 1980. The first *Healthy People* national agenda, *Healthy People: The Surgeon General’s Report on Health Promotion and Disease Prevention* (U.S. Department of Health, Education, and Welfare, 1979) acknowledged the significant reduction in infectious disease in the U.S. Also it recognized the emerging, significant impact of chronic disease. The report noted that many of the chronic diseases affecting the nation’s health could be prevented by addressing environmental and lifestyle factors (U.S. Department of Health, Education and Welfare, 1979). This initial report, submitted by then Surgeon General Julius B. Richmond, M.D., established the foundation for the series of *Healthy People* agendas. These agendas represent national health promotion objectives, set in 10-year increments. *Healthy People 2000: National Health Promotion and Disease Prevention Objectives*, published in 1990, had three overarching goals:

1. Increase the span of healthy life for Americans,
2. Reduce health disparities among Americans, and
3. Achieve access to preventive services for all Americans (U.S. Department of Health and Human Services [USDHHS], 1990).

Within the context of those three goals, this 10-year plan identified 22 priority areas, including heart disease, stroke, and cancer (USDHHS, 1990), which represent three of the

*Healthy People 2010: Understanding and Improving Health* refined the nation’s focus on quality of life, as reflected in the first of its two main goals:

1. Increase quality and years of healthy life, and
2. Eliminate health disparities (USDHHS, 2000).

In addition to those named in Healthy People 2000, Healthy People 2010 also expanded the nation’s attention to chronic conditions by including these focus areas:

- Arthritis, Osteoporosis, and Chronic Back Conditions
- Chronic Kidney Disease
- Disability and Secondary Conditions
- Mental Health and Mental Disorders
- Respiratory Diseases (USDHHS, 2000).

The most recent of the 10-year Healthy People plans, Healthy People 2020: The Road Ahead, contains an even more refined and detailed focus on four main goals:

1. Attain high quality, longer lives free of preventable disease, disability, injury, and premature death,
2. Achieve health equity, eliminate disparities, and improve the health of all groups,
3. Create social and physical environments that promote good health for all, and
4. Promote quality of life, healthy development, and healthy behaviors across all life stages (USDHHS, 2010).

In addition, *Healthy People 2020* includes new topic areas of focus related to chronic disease, including:

- Dementias, Including Alzheimer’s Disease,
- Health-Related Quality of Life and Well-Being, and
- Older Adults (USDHHS, 2010).

The priorities of this most recent national health promotion agenda were established by a diverse group of federal agencies, including the Agency for Healthcare Research and Policy, the Centers for Disease Control and Prevention, and the National Institutes of Health. In addition, public testimony was requested in order to inform the work of contributing experts (USDHHS, 2011a). Input from public health and health promotion practitioners, in addition to the accessible goals and measurable objectives contained within this 10-year plan, encourages both the translation of science to practice and practice to science. Green (2007) noted the importance of such efforts, stating that

> The percolation and funneling approach of basic research to wide application must be met by a complementary emphasis on an outside-in examination of programs and practices that have had to proceed to meet people’s needs without the benefit of absolute certainty about efficacy. (p. 137)

Also, this national agenda represents a sustainable effort to set health goals and objectives for the U.S. and serve to direct funding and unify the field of public health and health promotion (USDHHS, 2011a).
Healthy People 2020 includes also four foundation health measures, which will be used to monitor the progress of implementing Healthy People 2020’s broad goals. These measures include general health status, health-related quality of life and well-being, determinants of health, and disparities. The professionals involved in the creation of this revised national health promotion 10-year plan recognized the assessment of health-related quality of life as an important tool for understanding the effects of chronic disease and included it for the purposes of encouraging methodological improvements in its measurement (USDHHS, 2010).

The need for focused attention on the prevention and management of chronic disease is clear and has been well-articulated in the health promotion agenda for the U.S. Currently, according to the CDC, chronic diseases such as heart disease, cancer, and stroke are accountable for more than half of death and disability in the U.S. With statistics such as these, it is understandable that these types of chronic conditions are the primary focus of attention in public health and health promotion. Consistent with public health efforts that encourage Americans to exercise regularly, eat healthier, refrain from excessive alcohol consumption, and avoid tobacco use, chronic conditions such as heart disease, cancer, and diabetes can be prevented and overall mortality reduced (CDC, 2010a). Importantly, however, the call to action by prominent health promotion professionals, including McGinnis (1985, 2003a) and Fries et al. (1989), was not focused solely on addressing mortality. The ideas of reducing morbidity and improving quality of life also were key components of their calls to action.
In this context, there are a host of chronic medical conditions that have drawn the attention of public health practitioners, health education and promotion professionals, and medical care providers. One such condition is interstitial cystitis (IC), also sometimes referred to as painful bladder syndrome, bladder pain syndrome, and chronic pelvic pain. IC is a chronic condition thought to be characterized by a deficiency of, or damage to, the inner lining of the bladder. Two types of IC are described in the medical literature—ulcerative and non-ulcerative. Small star-shaped ulcers in the lining of the bladder characterize ulcerative IC. Most IC patients (approximately 90%) will present with small ruptures in the bladder lining known as petechial hemorrhages or glomerulations. These ruptures may bleed during distension of the bladder under general anesthesia. Although petechial hemorrhaging would be expected when any bladder is stretched to capacity while the patient is under general anesthetic, an IC patient’s bladder generally will show this “tearing” at much lower volumes (600-700cc as opposed to 1000-1200cc). Individuals with very small, hard bladders and significant pain are considered to have severe IC or end-stage disease (ICA, 2011a).

Symptoms of both types of IC closely mimic those of a common urinary tract infection (UTI). The severity and range of symptoms vary from individual to individual. Most IC patients will present with one or more of the following symptoms: pain in the bladder, urethra, vagina, or testicles, pressure in the lower abdominal area, a burning sensation in the bladder or urethra, pain or discomfort with sexual intercourse, blood in the urine, an inability to empty the bladder in one attempt, bladder spasms, and urinary
frequency and urgency. While the symptoms wax and wane with time among some, others experience consistent symptoms (ICA, 2011a).

Unfortunately, symptoms of IC can exist for years before a diagnosis is made. At present, diagnosis of IC is one of exclusion and based on a detailed medical history; other diseases such as bladder cancer, urinary tract infections, and sexually transmitted diseases are ruled out. Once those diseases have been excluded, a cystoscopy with hydrodistension of the bladder under general anesthesia is done to confirm ulcers or petechial hemorrhaging associated with small bladder capacity. In more complicated cases, urodynamic testing also is used. In this procedure, the clinician can assess bladder capacity, urge to urinate, and the function of the bladder muscle. There are other in-office diagnostic tests, which are no longer as common. This includes the potassium sensitivity test, in which potassium chloride is placed into the bladder via catheter while the patient is awake and aware. If the patient feels pain, the diagnosis of IC is made. Conversely, other urologists will do the opposite by instilling local anesthetics into the bladder to determine if the patient obtains symptomatic relief (ICA, 2011a). A new method of diagnosing IC, through the analysis of blood serum samples, is being investigated. This approach utilizes infrared microspectroscopy (IRMS) to explore the presence of a biomarker in the serum. This biomarker, or unique characteristic of the serum that is associated with IC, could be used to differentiate those with IC versus those who do not have the condition. Initial research into this method has shown promise, both in the creation of a diagnostic tool and in providing new understanding into the cause of IC (Rubio-Diaz et al., 2009).
A variety of treatments are available for IC patients. The ways in which many of these treatments work are not known definitively. Also, it is true that no one treatment is effective for the majority of patients. IC patients can find some relief with antihistamines (e.g., hydroxizine), tricyclic antidepressants (e.g., amitriptyline) that increase pain tolerance, pain medications (e.g., oxycodone), instillation of medicine (e.g., DMSO, heparin, lidocaine) directly into the bladder to either “coat” the bladder lining or numb it, antispasmodics that treat overactive bladder (e.g., oxybutynin), and Elmiron (pentosan polysulfate sodium), the only FDA-approved drug to treat IC. The ingredients of Elmiron resemble those of the bladder lining. It is thought that the lining of the bladder can be regenerated with ingestion of this medication (ICA, 2011a). Physical therapy also is used to treat chronic muscle pain in the pelvic area. This muscle pain is a common result of IC and can also exacerbate symptoms, resulting in a vicious cycle of pain (Diaz-Mohedo, Baron-Lopez, & Pineda-Galan, 2011).

In addition, some clinicians have experimented with surgical interventions. Sometimes, cystoscopy with bladder hydrodistension results in temporary relief from symptoms. This procedure is conducted while the patient is under general anesthesia and involves the distension of the bladder with fluid to volumes higher than would be permitted by the patient while awake. The Interstim device, a neurostimulator implanted into the lower back that delivers electrical impulses to the sacral nerves, is FDA-approved to treat frequency/urgency. The long-term benefits of this treatment are unknown. Surgical resection of the bladder, with urine being redirected to a continent pouch or a “refashioned” bladder made from a segment of bowel, is considered a last resort. Results
of the surgery have been demonstrated to be variable with phantom pain remaining in some cases. In addition, the recurrence of IC in the new bladder made of bowel has been demonstrated (ICA, 2011a).

In the face of such inconsistent treatment outcomes, many IC patients also turn to what some medical professionals would refer to as “alternative” or “complementary” therapies to find relief. Dietary modifications with the removal of acidic or spicy foods from the diet (the “elimination diet”), fluid management in which fluid intake is increased to dilute the urine and make it less caustic to the bladder, homeopathy, and various acid-reducers such as Prelief® and Tummy Tamer® all have been considered options for the IC patient (ICA, 2011a). With the recognition that stress can exacerbate symptoms, health care providers emphasize also the importance of stress-reduction techniques. Recommended techniques include a variety of types of therapy, such as guided imagery, meditation, prayer, and the utilization of support groups (ICA, 2011a; Theoharides, 2007; Whitmore, 2002). Published literature on the efficacy of these types of treatment therapies is less than that of the more biomedical approaches to care. There is some literature, however, to support significant improvements in symptoms for those patients who engage in therapies such as hypnosis with cognitive behavioral therapy and guided imagery, acupuncture, and meditation (Anderson, Nagy, Orenberg, Morey, & Glowe, 2011; Chaiken, Blaivas, & Blaivas, 1993; Hölzel et al., 2011; Lee et al., 2011; Tugcu et al., 2010).

Currently, it is estimated that approximately 3 to 8 million women (or 3–6%) live with IC in the U.S. (Berry et al., 2011). It is estimated that approximately 1.5 million
men are living with IC in the U.S. True prevalence is unknown, as IC in men is often mistaken for other conditions, such as chronic prostatitis. Approximately 90% of the total 3–11 million individuals living with IC in the U.S. will present with the non-ulcerative version of the condition (vs. those with small, star-shaped ulcers in the bladder lining). Anyone of any age, race, or sex can get IC (ICA, 2011a).

The original epidemiologic data on IC rests on the work of Koziol’s from the early 1990s ($n = 565$ IC patients). His research revealed that the majority of the patients sampled were Caucasian (94.3%) and female (88.8%) with a mean age of 57.9 years. He also reported that 55% of the participants reported daily or constant pain, 57% described their pain as severe, 50% reported pain during sexual intercourse, 68% reported the inability to enjoy routine activities, and 70% reported a disruption in family relationships due to the disease. No explanation is provided for why the study sample was primarily middle-aged, White women (Koziol, 1994). More recent studies, including the Boston Area Community Health (BACH) survey (2002–2008) and the RAND IC Epidemiology (RICE) study (2006–2009) have contributed significantly to the understanding of IC. These studies changed the medical field’s perspective on both the prevalence and effect of the condition. Currently, another landmark epidemiologic study is underway. The Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) seeks to understand the etiology of the disease (ICA, 2011a).

To date, the etiology of IC is unknown. Importantly however, research in this area of inquiry has progressed considerably since the early 1990s. Researchers have identified specific pathologies that are thought to be unique to IC patients. These include
deficiencies in the glycosaminoglycan (GAG) layer of the bladder lining and growth inhibitors (or anti-proliferative factor [APF]) in IC patients’ urine (Keay et al., 2001). Other researchers are interested in the possibility of a dysfunction in the autonomic nervous system. It has been documented in the literature that stress can exacerbate IC symptoms (Bronstein, 2010), and that those with IC display a heightened stress response (Buffington, 2004; Twiss et al., 2009). Other hypotheses associate IC with bladder trauma (Mais et al., 2011), viral infection (Berger, 2009), inflammation (Birder, Hanna-Mitchell, Mayer, & Buffington, 2011) and autoimmune disorder (Altuntas et al., 2012). Despite these varied attributions, the consensus still remains that this condition does not represent a psychosomatic condition (ICA, 2011a).

Despite vast improvements in the knowledge of this condition, medical and public awareness of the disease is still minimal. Surprisingly, however, IC is not a new disease. In 1836, Mercier described what is thought to be the first case of IC. A description of a “spontaneous rupture of the urinary bladder secondary to ulceration” (Christmas, 1997, p. 1) was provided in Mercier’s report. In 1870, Lawson Tait reported two cases of IC. Two women, under the treatment of Sir James Simpson at the London Hospital (now the Royal London Hospital), presented with bladder pain and urinary frequency. One was “relieved” by an instillation of silver nitrate (under chloroform anesthesia) into the bladder. In 1887, Skene first used the term “interstitial cystitis” in his book Diseases of the Bladder and Urethra in Women. Hunner’s ulcer, present in approximately 10% of IC patients, is an eponymous tribute to Guy Hunner’s 1914 description of ulcerative IC (Christmas, 1997).
After these initial but few milestones, little advancement was made in etiology, diagnosis, or treatment of the condition in the following 75 years. Guesses at etiology, ranging from the spread of infection from dental abscesses to psychosomatic masochism, were offered but were discredited after further investigation. Until 1986, *Campbell’s Urology*, in its chapter on psychosomatic disorders (Ratner & Slade, 1997a), characterized IC as a disease that “may represent the end stage of a bladder that has been made irritable by emotional disturbance . . . a pathway for the discharge of unconscious hatred.” Until 1987, no federal research funds were spent on IC (Ratner & Slade, 1997a). Since the founding of the Interstitial Cystitis Association (ICA) in 1984 by Vicki Ratner, MD, a woman living with IC, significant progress has been made with federal funding. Studies such as BACH, RICE, and MAPP are direct results from increases in federal funding for IC research.

The most recent sign of progress in the medical field’s understanding of IC consists of new guidelines published by the American Urological Association in March 2011. These new guidelines include specific recommendations on the diagnosis and treatment of IC. In addition to clearly articulating the process of diagnosis, which is still based on a detailed medical history and the exclusion of other conditions, the guidelines encourage conservative therapy that accounts for patient quality of life, multimodal therapy, and effective pain management. Conservative therapies are generally those that are non-surgical and reversible. The guidelines also break potential treatments into first through sixth—“line groups.” For the first time, patient education, self-care, and stress management are now considered *first-line treatment* for IC, with priority in order over
pain medications, other oral medications, physical therapy, and bladder installations (American Urological Association [AUA], 2011). The need for biomedical research and clinical intervention is necessary in the effort to understand, treat, and eventually cure IC. Also, there is a significant need for those in the field of health education and promotion to become meaningfully engaged in assisting patients in the active management of their condition. As called for by McGinnis (1985, 2003a, 2003b) and Fries et al. (1989), these efforts should be targeted towards improving quality of life through the compression of morbidity and effective management of chronic disease.

**Purpose of the Study**

The purpose of this study was to analyze the relationships between stress, self-efficacy, social support, and health-related quality of life among women living with IC in the U.S. In addition, the study examined the influence of self-efficacy as a mediator in the relationship between stress and health-related quality of life and social support as a moderator of the impact of self-efficacy on health-related quality of life in women living with IC when controlling for stress.

**Research Questions**

The research questions for this study emerged from a literature review and center on selected variables:

*Research Question 1.* Are there significant correlations between stress, self-efficacy, or social support, and health-related quality of life in individuals living with IC?
Research Question 2. Does self-efficacy mediate the effect of stress on health-related quality of life in individuals living with IC?

Research Question 3. Does social support moderate the effect of self-efficacy on health-related quality of life in individuals living with IC, when controlling for stress?

These research questions reflect the following assumptions:

1. That stress, self-efficacy, and social support will each be significantly correlated with the dependent variable, health-related quality of life;
2. That the relationship between stress and health-related quality of life is diminished when self-efficacy is factored into the model; and
3. That the relationship between self-efficacy and health-related quality of life is stronger in those with high social support, versus those with low social support, when controlling for stress.

Definition of Terms

The following terms are used throughout this study:

Chronic condition. A condition that lasts more than one year, requires consistent medical care, and has the potential to significantly impact daily life (Hwang, Weller, Ireys, & Anderson, 2001).

Health-related quality of life. “A multi-dimensional concept that includes domains related to physical, mental and social functioning. It goes beyond direct measures of population health, life expectancy and causes of death and focuses on the impact health status has on the quality of life” (USDHHS, 2011b).
Interstitial Cystitis. “A bladder condition that consists of multiple symptoms” (ICA, 2011a).

Quality of life. “A multidimensional concept that usually includes subjective evaluations of both positive and negative aspects of life” (CDC, 2011a).

Self-efficacy. “Perceived self-efficacy refers to beliefs in one’s capabilities to organize and execute the courses of action required to produce given attainments” (Bandura, 1997, p. 3).

Social support. “The physical and emotional comfort given to us by our family, friends, co-workers, and others” (Jack, Grim, Gross, Lynch, & McLin, 2010).

Stress. The imbalance between internal or external demands placed on a person and the capabilities of that person to respond (Lazarus & Cohen, 1977).

Basic Assumptions

The following study consists of two basic assumptions:

1. It is assumed that all subjects will participate voluntarily.
2. It is assumed that all subjects will respond honestly to all items on the instrument.
The purpose of this study was to analyze the relationships between stress, self-efficacy, social support, and health-related quality of life among women living with interstitial cystitis (IC) in the United States (U.S.). In addition, the study examined the influence of self-efficacy as a mediator in the relationship between stress and health-related quality of life and social support as a moderator of the impact of self-efficacy on health-related quality of life in women living with IC when controlling for stress.

**Current Interstitial Cystitis Science and Practice**

**Interstitial Cystitis (IC)**

Interstitial cystitis (IC) is a chronic condition thought to be characterized by a deficiency of, or damage to, the inner lining of the bladder. Symptoms of IC closely mimic those of a common urinary tract infection (UTI). Most IC patients present in a clinical environment with one or more of the following symptoms: pain in the bladder, urethra, vagina, or testicles; pressure in the lower abdominal area; a burning sensation in the bladder or urethra; pain or discomfort with sexual intercourse; blood in the urine; an inability to empty the bladder in one attempt; bladder spasms; and urinary frequency and urgency. Some patients with the condition experience symptoms that change over time, or, wax and wane in severity. Other patients have more constant symptoms. The severity and range of symptoms vary from individual to individual (ICA, 2011a).
In this context, it is not surprising that symptoms of IC can exist for years before an accurate diagnosis is made. At present, diagnosis of IC is one of exclusion and is based on a detailed medical history. Other diseases such as bladder cancer, urinary tract infections, and sexually transmitted diseases have symptoms that are similar to those of IC. These conditions are ruled out in the diagnostic process. Once those diseases have been excluded, a cystoscopy with hydrodistension of the bladder under general anesthesia is done to confirm the presence of ulcers or petechial hemorrhaging associated with small bladder capacity. Individuals with IC often are unable to hold even moderate amounts of fluid in the bladder without damage to its lining (ICA, 2011a).

A variety of treatments are available for IC patients. These include more conventional therapies such as an antihistamines (i.e., hydroxizine), tricyclic antidepressants (i.e., amitriptyline) that increase pain tolerance, pain medications (i.e., oxycodone), instilments of medicine (i.e., DMSO, heparin, lidocaine) directly into the bladder to either “coat” the bladder lining or numb it, antispasmodics that treat overactive bladder (i.e., oxybutynin), and Elmiron (pentosan polysulfate sodium), the only FDA-approved drug to treat IC. The ingredients of Elmiron resemble those of the bladder lining. It is thought that the lining of the bladder can be regenerated with ingestion of this medication (ICA, 2011a). Physical therapy also is used to treat chronic muscle pain in the pelvic area, a common result of IC. This associated muscle pain also can exacerbate symptoms, resulting in a vicious cycle of pain (Diaz-Mohedo et al., 2011). The ways in which many of these treatments work are not known definitively. Also, it is true that no one treatment is effective for the majority of patients (ICA, 2011a).
In addition to conventional treatments, many IC patients also turn to what some medical professionals would refer to as “alternative” or “complementary” therapies to find relief. Dietary modifications with the removal of acidic or spicy foods from the diet (the “elimination diet”), fluid management in which fluid intake is increased to dilute the urine and make it less caustic to the bladder, homeopathy, and various acid-reducers such as Prelief® and Tummy Tamer® all have been considered options for the IC patient (ICA, 2011a). With the recognition that stress can exacerbate symptoms, health care providers also emphasize the importance of stress-reduction techniques. Recommended techniques include a variety of types of therapy, such as guided imagery, meditation, prayer, and the utilization of support groups (ICA, 2011a; Theoharides, 2007; Whitmore, 2002). Published literature on the efficacy of these types of treatment therapies is less than that of the more biomedical approaches to care. There is some literature, however, to support significant improvements in symptoms for those patients who engage in therapies such as hypnosis with cognitive behavioral therapy and guided imagery, acupuncture, and meditation (Anderson et al., 2011; Hölzel et al., 2011; Lee et al., 2011; Tugcu et al., 2010).

Currently, it is estimated that approximately 3 to 8 million women (or 3–6%) live with IC in the U.S. (Berry et al., 2011). It is estimated that approximately 1.5 million men are living with IC in the U.S. True prevalence is unknown, however, as IC in men is often mistaken for other conditions, such as chronic prostatitis (ICA, 2011a). The difference in prevalence between men and women accounts for the vast majority of IC
research involving samples of only women. Importantly however, anyone of any age, race, or sex can get IC (ICA, 2011a).

Medical Community

The diagnosis of IC is complicated, as many individuals with the condition are misdiagnosed or experience a delay in diagnosis. In addition to the complicated diagnostic process, the use of diagnostic criteria not deemed to be appropriate outside of its use in clinical trials complicates the published literature in this area. These complications make recommendations regarding diagnosis and treatment more difficult.

Guidelines published by the American Urological Association (AUA) in March of 2011 represent the medical community’s current perspective on the diagnosis and treatment of interstitial cystitis (IC). A panel of current IC clinicians, researchers, and patient advocates developed the AUA guidelines. This panel conducted a systematic review of the medical literature on IC from 1983–2009. Although exhaustive, this review yielded insufficient evidence-based data about the diagnosis of IC. This lack of evidence prompted the AUA Panel to present recommendations for making a definitive diagnosis based on clinical principles and opinions of experts in the field. Recommendations are, “directive statements that an action should or should not be undertaken” (AUA, 2011, p. 6). Clinical principles are those statements about clinical care that are agreed upon by the majority of urologists. The AUA Panel derived expert opinions, which were based on the training, education, experience, knowledge, and judgments of those panel members. These recommendations encourage clinicians to engage in a diagnostic process that includes:
1. A detailed medical history, physical examination, and exclusion of other conditions that may present similarly to IC;

2. An assessment of baseline bladder function and symptoms, including pain level; and

3. The consideration of more invasive medical tests in cases that present in a complicated manner (i.e., those that do not present with traditional symptoms; AUA, 2011).

In addition, the AUA Panel presented broad conclusions about treatment of IC. These recommendations were based also on clinical principles and expert opinions due to a lack of published literature that met the criteria for inclusion in this systematic review. First, there was a recommendation to avoid less conservative therapies, such as medications with significant side effects or irreversible surgeries, unless quality of life could be significantly affected. Second, IC symptoms can vary from individual to individual; therefore, treatment should be determined on a case-by-case basis. Third, multimodal therapy (i.e., treatment approaches that utilize multiple strategies) often is more effective than single-focused treatments. Fourth, treatments that are not effective should be stopped immediately. Fifth, pain management is a critical component to the treatment of IC, given its potential, significant impact on quality of life. Sixth, if standard IC treatments are ineffective, the diagnosis of IC should be reconsidered (AUA, 2011).

Specific treatment options can be categorized into first-, second-, third-, fourth-, fifth-, and sixth-“line groups.” These categorizations are based on, “the balance
between potential benefits to the patient, potential severity of adverse events and the reversibility of the treatment” (AUA, 2011, p. 2). First-line treatments are those that should be considered first in the treatment of IC and include patient education about IC, self-care strategies, and stress-management. Second-line treatments should be considered next, including such options as physical therapy, pain management, a variety of oral medications, and instillations of medicine directly into the bladder. Third-line treatments should be utilized after first and second-line treatments. These include distension of the bladder under anesthesia and the surgical treatment of Hunner’s ulcers, if present. Fourth-line treatments are used in more complicated cases, including the implantation of neurostimulation devices. Fifth- and sixth-line treatments are reserved for those cases in which all other treatment modalities have been exhausted. These include experimental treatments such as Botox injections directly into the bladder and major surgery involving the diversion of urine or the complete removal of the bladder (AUA, 2011). A further delineation of types of treatments in each category can be found in Table 1.

The systematic review of the published literature on treatment approaches to IC was complicated by a variety of factors. Some of those factors include:

1. patient groups that were poorly defined or were too heterogeneous,
2. sample sizes that were too small,
3. a lack of studies that included placebo-based control groups,
4. lack of long-term follow-up, and
5. a lack of consistency in outcome measures (AUA, 2011).
Table 1

*AUA Categorization of Treatment Approaches for IC*

<table>
<thead>
<tr>
<th>Category</th>
<th>Types of Treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>First-line</td>
<td>Patient education about IC; Instruction on self-care strategies; Instruction on stress-management techniques</td>
</tr>
<tr>
<td>Second-line</td>
<td>Physical therapy; Pain management; Oral medications; Instillations of medicine into the bladder</td>
</tr>
<tr>
<td>Third-line</td>
<td>Distension of the bladder under anesthesia; Surgical treatment of Hunner's ulcers, if present</td>
</tr>
<tr>
<td>Fourth-line</td>
<td>Trial of neurostimulation with potential permanent implant of a neuromodulation device</td>
</tr>
<tr>
<td>Fifth-line</td>
<td>Cyclosporine; Botox injections into the bladder</td>
</tr>
<tr>
<td>Sixth-line</td>
<td>Major surgery - diversion of urine with or without removal of the bladder</td>
</tr>
</tbody>
</table>

These factors resulted in varying levels of strength of evidence-base for each of the six treatment categories (AUA, 2011).

The AUA provides also a listing of treatment approaches that no longer should be utilized. These treatment approaches include long-term oral antibiotic use, high-pressure distension of the bladder under anesthesia, and the long-term use of systemic, oral glucocorticoids. These treatment options are considered contra-indicated due to the lack of published literature on efficacy and the evidence related to potential adverse effects (AUA, 2011).

In addition to specific recommendations regarding diagnosis and treatment, the AUA guidelines include multiple references to patient quality of life. The main premise behind the AUA treatment guidelines is stated as such: “until more definitively effective
therapies are identified, the treatment approach should be tailored to the specific symptoms of each patient in order to optimize quality of life” (AUA, 2011, p. 18). The AUA guidelines note the dramatic impact of living with the condition on patient quality of life. Issues of chronic pain, sleep and sexual dysfunction, loss of work productivity, and disruption in family life all contribute to this profound effect on quality of life (AUA, 2011).

In addition to new guidelines from the AUA, a new line of thought about the pathogenesis of IC has appeared in the published literature within the past five years. IC has high rates of co-morbidity with other similarly misunderstood conditions, such as fibromyalgia (FM), chronic fatigue syndrome (CFS), and irritable bowel syndrome (IBS; Warren et al., 2009; Warren, van de Merwe, & Nickel, 2011; Warren, Wesselman, Morozov, & Langenberg, 2011). This recognition has led researchers to two main hypotheses: (a) that the presence of other related conditions can lead to IC, or (b) that IC and conditions with which there are high rates of co-morbidity are actually, “a manifestation of a common, shared pathogenesis” (Warren, Wesselman, et al., 2011, p. 313). In other words, this clustering of syndromes may, in fact, represent one systemic problem in the body versus separate problems of multiple distinct organs.

This idea of a shared pathogenesis for a clustering of syndromes, including IC, has led clinicians and researchers to put forth ideas about what terminology to use. Traditionally, conditions such as FM, CFS, and IBS have been referred to as functional somatic syndromes (Warren, Morozov, & Howard, 2011). This means that the disability, symptoms, or morbidity associated with the condition are not directly correlated to
“demonstrable tissue abnormality” (Barsky & Borus, 1999). IC traditionally has been described as a structural syndrome, meaning that the presence of physiological differences in tissue (i.e., petechial hemorrhaging or Hunner’s ulcers) characterize the condition. It has been argued recently, however, that the type and severity of symptoms in IC is not directly correlated with the presence or severity of “tissue damage” in the lining of the bladder. This has led researchers and clinicians to cluster IC with other known functional somatic syndromes (Warren, Morozov, et al., 2011).

While the utilization of one term for all of these conditions (i.e., functional somatic syndrome) recognizes the potential shared pathogenesis, other researchers have proposed alternate terminology. Yunus (2008) proposed that the use of functional somatic syndrome is not only incorrect, but it also creates an unjust distinction between patients. While patients with structural disease “are the ‘real’ patients who deserve real care” (Yunus, 2008, p. 348), those with functional disease are viewed as, “second class patients not worthy of serious physician attention” (Yunus, 2008, p. 348). In opposition to functional somatic syndromes, Yunus proposed the term “central sensitivity syndrome” or CSS. This term, according to Yunus, accurately represents the clinical and physiological manifestations of these diseases (i.e., he argued that these syndromes do have documented “structural” abnormalities). It also accurately explains the increased sensitivity to painful stimulus (i.e., hyperalgesia), painful response to stimulus that is not normally painful (i.e., allodynia), and “after-stimulus unpleasant quality of the pain (e.g., burning, throbbing, tingling or numbness)” (Yunus, 2008, p. 343) that often characterizes these related syndromes. Overall, syndromes under the umbrella of CSS, including IC,
can be seen as “mediated by the central nervous system” (Yunus, 2008, p. 343). This
idea that IC and related conditions represent a systemic problem with the nervous system
is paralleled in the perspective from the veterinary community.

Veterinary Community

Humans are not the only animal species to be diagnosed with IC. Cats can
develop IC as well. This condition commonly is referred to as feline idiopathic cystitis
(FIC). Idiopathic cystitis literally means “inflammation of the urinary bladder of
unknown cause” (Merriam-Webster, 2012). Current veterinary research seems to
indicate FIC is more of a systemic condition involving the stress response system of the
feline. In contrast to traditional views on etiology from the human urologic medical
community, this approach broadens the lens by which this condition is viewed. This
approach suggests that the problem does not originate in the bladder itself, but that
dysfunction related to the bladder is an expression of an underlying problem with the
autonomic nervous system. It is thought that a combination of genetics and environment
can play a role in the manifestation of “sickness behaviors” in cats. These behaviors
“refer to a group of nonspecific behavioral and clinical signs including vomiting,
diarrhea, anorexia or decreased food and water intake, fever, lethargy, somnolence,
enhanced painlike behaviors, and decreased general activities, body-care activities
(grooming), and social interactions” (Buffington, 2011c, p. 516). While these types of
behaviors can result from infection, they can also result from environmental stress
(Buffington, 2011a, 2011b; Stella, Lord, & Buffington, 2011).
Just as with humans, there are limited treatment options that target the internal factors that may contribute to FIC with effectiveness. Parallel to the AUA guidelines for the care of humans, veterinarians have recommended environmental enrichment as a treatment for cats (Buffington, Westropp, Chew, & Bolus, 2006; Hostutler, Chew, & DiBartola, 2005; Westropp & Buffington, 2004). Environmental enrichment refers to the education of the pet owner about the needs of cats and the value of making changes to the environment that reduce stress for the cat. Six categories of enrichment have been identified:

1. Basic resources: Placement of food and water in an area where cats are less likely to be startled or feel trapped is important. Specific location, type of litter box, and litter also are important considerations.

2. Structural features: Cats should be provided with approved places to play and enact instinctive behaviors. This includes the provision of scratching posts, the creation of safe, secure places for the cat to rest, and the provision of toys that encourage stalking and pouncing behavior.

3. Social interactions: Cats in multiple cat households should be provided with separate space, food and water bowls, and litter boxes. This provides a way to avoid intercat aggression.

4. Human interactions: Cat owners should engage with their cat(s) in enriching ways. This includes play and grooming activities, when the cat is interested in engaging and not forced to do so.
5. Audio-visual enrichment: This can include playing the radio or television, providing a fish tank, or providing the cat with access to a window.

6. Olfactory stimulation: This includes the provision of specific types of herbs (e.g., catnip) or synthetic feline pheromones (Buffington, 2011b; Herron & Buffington, 2010).

Cat owners can be encouraged to engage in environmental enrichment by their veterinarians. Veterinarians are encouraged to enhance communication with clients by establishing rapport, being sensitive to client needs, expressing empathy, and developing trust. When communication is enhanced, the veterinarian can help the client identify ways in which the environment can be enriched for the cat(s) through the setting of clear, realistic, and measurable goals (Herron & Buffington, 2012). Strong evidence suggests that environmental enrichment is not only good for bladder symptoms in cats, but also in the reduction of other sickness behaviors (Buffington et al., 2006; Hostutler et al., 2005; Westropp & Buffington, 2004).

National Organizations

There are two national organizations whose missions are dedicated to serving the needs of humans with IC in the U.S. These include the Interstitial Cystitis Network (ICN) and the Interstitial Cystitis Association (ICA). The ICN began as a small support group in Northern California and grew to become the first website dedicated to those living with IC in 1994. It is now an Internet-based publishing company. The founder and current President of the ICN, Jill Osborne, describes her organization as a “social
advocacy” health education company whose mission is “support, encouragement, and empowerment” (Osborne, 2011).

Services provided by the ICN are categorized as educational opportunities, support services, research services, low-income advocacy, and products and supplies. Educational opportunities include a variety of patient and provider educational materials. The *IC Optimist* is a quarterly magazine distributed via mail or e-mail to both patients and providers. There is a free, bi-monthly *ICN E-Newsletter* that is distributed via e-mail. IC patients and caregivers can access more than 20 videos related to coping with IC. The ICN offers also free webinars for patients that are hosted by a variety of health care providers. Free transcripts of these webinars are posted on the website. Support services center around a diverse online community. Multiple online forums exist where members of the IC community can post questions for response. Also a live chat service is provided on the evenings of the first and third Monday of each month, from five to seven o’clock, Pacific Standard Time. These live chats center around a variety of topics related to living with IC. Research services include surveys administered by the ICN about IC, some of which have been presented at national urologic conferences. Current active surveys can be found in the ICN’s Survey Center webpage. Topics of current surveys that can be taken now include weight loss and IC and the use of medical marijuana for IC treatment. The ICN’s low-income advocacy consists of chat rooms where patients can share ideas for obtaining medications at a reduced cost. The ICN has also a Drug Assistance Center, which refers patients to programs providing medications at a reduced cost. Finally, the ICN offers a wide variety of “bladder-friendly” products,
such as seat cushions, books, herbal supplements, and personal coaching services. Personal coaching services can be purchased with Jill Osborne or a listing of health care professionals, including counselors and registered dieticians. The ICN website indicates that the company is financially underwritten and supported by a variety of corporate sponsors (Osborne, 2011).

The Interstitial Cystitis Association (ICA) was founded in 1984. The founder and President Emeritus of this organization, Vicki Ratner, MD, diagnosed herself with IC using the resources available to her during her time in medical school. Concerned about the current state of knowledge about IC, and the quality of care of IC patients, she founded the ICA. Since that time, she worked tirelessly with her staff to encourage medical research, educate health care professionals, and provide support to patients. When she retired as President of the ICA in 2007, the ICA was (and is still) the only national nonprofit organization in the U.S. dedicated to the support of those living with IC and to improving the quality of health care provided to people living with IC (ICA, 2011b).

The ICA works with the overall vision of “Conquering IC, Changing Lives,” and its mission is, “early diagnosis and optimal care with dignity for people affected by IC” (ICA, 2011b). In support of this vision and mission, the ICA provides advocacy, research, and education. Advocacy efforts consist of grassroots lobbying with legislators and government officials to raise awareness of the condition and to ensure proper attention and funding for IC research. The ICA itself funds pilot research on IC and encourages IC researchers to obtain larger, government grants. Finally, the ICA provides
educational programming to patients, caregivers, and health care providers. These efforts have led to tangible accomplishments that can be attributed primarily to the work of the ICA: (a) a strong partnership between the ICA and the Centers for Disease Control and Prevention (CDC) to raise awareness of IC, (b) National Institutes of Health (NIH) dollars dedicated to IC research, (c) the funding of essential pilot research related to the identification of disease biomarkers (i.e., diagnostic tests for IC), and (d) the shift in perspective on IC from a disease of “hysterical women” to a real physical problem (ICA, 2011b).

A Board of Directors, primarily comprised of people living with IC, governs the ICA. There also is a Medical Advisory Board consisting of health care professionals whose expertise is the care of IC patients and a staff of nine individuals. This staff includes those with a background in health communication, advocacy, administration, and business. Barbara Gordon, RD, is the current President and Chief Executive Officer of the ICA. Ms. Gordon’s expertise lies in nutrition, social work, and business (ICA, 2011b). The ICA has strong connections with the IC community in the U.S. and regularly communicates with approximately 30,000 IC researchers, clinicians, and patients (B. Gordon, personal communication, September 27, 2011).

Quality of Life

Health-Related Quality of Life and Health Education and Promotion

In 1948, the World Health Organization (WHO) Constitution defined health as, “a state of complete physical, social and mental well-being, and not merely absence of disease or infirmity” (p. 1). This was one of the first definitions of health that
acknowledged that health was more complex than a physical absence of illness. The definition of health continued to evolve and expand throughout the 20th century. More recently, the Ottawa Charter for Health Promotion suggested that health is, “a means to an end which can be expressed in functional terms as a resource which permits people to lead an individually, socially and economically productive life” (WHO, 1986, p. 1). It also stated that “health is a resource for every day life, not the object of living. It is a positive concept emphasizing social and personal resources as well as physical capabilities” (WHO, 1986, p. 1). The definition of health has expanded over the past few decades to include more than just physical wellbeing. This, coupled with an overall reduction in mortality in the U.S., led health education and promotion professionals to make a shift in assessing “the population’s health not only on the basis of saving lives, but also in terms of improving the quality of them” (CDC, 2011a).

In a broad sense, quality of life is defined as a “multidimensional concept that usually includes subjective evaluations of both positive and negative aspects of life” (CDC, 2011a). More specifically, health-related quality of life (HRQOL) is defined as a multi-dimensional concept that includes domains related to physical, mental and social functioning. It goes beyond direct measures of population health, life expectancy and causes of death and focuses on the impact health status has on the quality of life. (USDHHS, 2011b)

The concept of HRQOL has evolved since the 1980s, and it is widely recognized that there are a variety of determinants of HRQOL. Using a socio-ecological framework, these determinants can be identified at the individual, interpersonal, and community
levels. At the individual level, a person’s functional status, health behaviors, and perceptions can all influence HRQOL. Social support from family, friends, colleagues, and others is an important determinant at the interpersonal level. Finally, determinants of quality of life at the community level include environmental resources and policies (CDC, 2000; Gandek, Sinclair, Kosinski, & Ware, 2004; Kindig, Booske, & Remington, 2010; McHorney, 1999; Selim et al., 2009).

Measures of HRQOL often can be more powerful predictors of mortality and morbidity than more traditional “objective” measures of health, such as Body Mass Index (BMI; DeSalvo, Bloser, Reynolds, He & Muntner, 2006; Dominick, Ahern, Gold, & Heller, 2002). With the recognition of this, measuring HRQOL has become an important mechanism for

1. tracking the nation’s progress in achieving its health promotion goals and objectives;
2. determining the burden of disease, injury, and disability;
3. determining interventions to address health problems; and
4. determining policies and funding streams based on need (CDC, 2011a).

Since 1979, the national health promotion agenda of the U.S. has been established through a series of Healthy People publications. These agendas, set in 10-year increments, represent a sustainable effort to set health goals and objectives for the U.S. and serve to direct funding and unify the field of public health and health promotion (USDHHS, 2011c).
The most recent national health promotion agenda, *Healthy People 2020: The Road Ahead* (USDHHS, 2010), does not include any specific objectives related to HRQOL. This construct, however, is included as a foundational health measure. These measures include general health status, health-related quality of life, and well-being, determinants of health, and disparities. The professionals involved in the creation of this revised national health promotion 10-year plan recognized the assessment of health-related quality of life as an important tool for understanding the effects of chronic disease. It also was included for the purposes of encouraging methodological improvements in its measurement (USDHHS, 2011b).

**Health-Related Quality of Life and Chronic Disease**

The burden of chronic disease, and its impact on health-related quality of life, is significant for U.S. citizens. Anderson and Horvath (2004) reported that approximately 45% of the U.S. population, or 125 million Americans, had at least one chronic condition in 2000. In addition, 21% of the U.S. population, or 61 million, had two or more chronic conditions. With the percentage of the U.S. population living with a chronic condition expected to increase over the next several decades, and with an estimated 78% of all health care dollars spent on those with chronic conditions in 2000, a shift in focus to the management and quality of care of those living with a chronic condition, as well as the prevention of chronic disease, is necessary (Anderson & Horvath, 2004). In 2010, the Centers for Disease Control and Prevention (CDC) reported that 70% of all deaths in the U.S. were attributable to chronic disease. In addition, about 25% of those with chronic disease reported one or more limitations in daily life, representing a significant impact on
quality of life (CDC, 2010a). The CDC indicates that the utilization of health-related quality of life as an outcome measure in health promotion research is important for identifying particular subpopulations who have poor perceived health. Identification of these subpopulations can guide interventions with the potential for improving significantly health outcomes (CDC, 2011a).

The CDC also has reported on the impact of particular chronic diseases on quality of life. Conditions such as cardiovascular disease, arthritis, diabetes, epilepsy, cancer, and a variety of mental disorders have been associated with fewer reported healthy days, social stigma, emotional distress, and loss of function, in addition to general reductions in reported quality of life (CDC, 2003). Other studies have documented the impact of multiple chronic diseases (co-morbidities) on quality of life. One such study using a large national sample of Australians found that having multiple chronic diseases was associated with a significant negative impact on general quality of life, as well as increased psychological distress (Walker, 2007).

As the number of adults ages 65 years and older rises, the CDC has had also an increased focus on quality of life and aging. This focus on healthy aging includes the prevention of chronic disease and the minimization of the complications associated with living with a chronic disease(s). Dr. James S. Marks of the National Center for Chronic Disease Prevention and Health Promotion noted, “achieving a high quality of life is tied heavily to chronic diseases and the aging of the U.S. population” (2003, p. 2). The CDC reported that 80% of older adults have a chronic disease, and 50% have more than one. To address health-related quality of life in older adults, the CDC reported that efforts to
promote healthy behaviors, increase health education around the prevention and management of chronic disease, and raise awareness of the important role of mental health are all important (CDC, 2011b).

Since 2001, the CDC has maintained its Healthy Aging Research Network, supported by the Agency for Healthcare Research and the CDC’s Healthy Communities Program. The Healthy Aging Research Network has provided funding for eight Prevention Research Centers around the U.S. with the primary aims of (a) understanding the determinants of healthy aging and (b) putting new research results into practice. Beyond the Healthy Aging Research Network, the CDC has partnered with other agencies as well, including the Administration on Aging and the Centers for Medicare and Medicaid Services, to engage in research and the dissemination of research results around quality of life and the aging process (CDC, 2011b).

**Health-Related Quality of Life and IC**

In addition to the chronic diseases common among Americans, such as cardiovascular disease, diabetes, and arthritis, other chronic conditions that are not as well-known have been shown to be associated significantly with reductions in health-related quality of life. IC is one of these conditions. A landmark 1987 study by the Urban Institute found that the quality of life of women with IC was worse than that of women on dialysis for end-stage renal disease. Factors thought to contribute to this significantly decreased quality of life included unremitting urinary frequency and pain, the disruption of patient’s relationships with family, friends, and co-workers, the inability to stay employed, and significant sexual dysfunction (Ratner & Slade, 1997a).
In a 1997 study including 172 IC patients (96.5% of whom were women), it was found that those living with IC had statistically significantly lower health-related quality of life than the general population and those with other selected medical conditions, including arthritis and psychiatric disorders. Specific findings from this study indicated that IC patients, in comparison to the general population:

1. Had a 1.5-fold decrease in reported satisfaction with life,
2. Were twice as likely to screen positive for depression, and
3. Were six times more likely to cut back on work time due to health problems (Ratner & Slade, 1997b).

A variety of more recent studies have found associations between IC and reduced quality of life. A 2009 study surveyed 120 women living with IC related to general quality of life, depression, pain catastrophizing behavior, and sexual function. It was found that length of time with symptoms, unemployment, pain severity, and anxiety about pain were all associated with decreases in quality of life, with pain as the strongest predictor of quality of life (Tripp et al., 2009). A 2010 study compared 41 women living with interstitial cystitis with 43 women with overactive bladder. Along with statistically significant differences in social limitations, personal relationships, and sleep/energy, women with IC were found also to have significantly lower quality of life scores as compared to those with overactive bladder (Kim & Oh, 2010).

Sexual dysfunction and sleep deprivation also have been found to be statistically significantly associated with reduced quality of life among those living with IC. In a telephone-based, survey study with 1,469 women living with IC, Bogart, Suttorp, Elliott,
Clemens, and Barry (2011) found that the vast majority of IC patients had general sexual dysfunction (88%) and symptoms of sexual dysfunction related to IC (90%). This sexual dysfunction was associated with higher rates of depression. In a 2011 online survey of 407 women living with IC, it was found that sleep deprivation due to IC symptoms was significantly associated with daytime fatigue, depression, loss of work productivity, and overall reduced quality of life. One hundred percent of survey respondents reported poor sleep (Panzera, Reishtein, & Shewokis, 2011).

In addition to the psychosocial cost to individuals, IC has also an economic impact on individuals and society. Due to the lack of knowledge around the true prevalence of IC, estimating the economic burden of the condition is difficult. It is known, however, that the individual IC patient incurs direct costs related to physician visits, hospitalizations, prescription medications, and outpatient procedures. One study showed that per-person direct costs for an IC patient were greater than those of patients with diabetes, hypertension, depression, or asthma (Sairanen et al., 2009). Mean annual costs for those living with IC have been found to be 2.0 to 2.5 times greater than age-matched controls. Women with IC, on average, have higher mean annual costs as compared to men with IC (Clemens, Meenan, Rosetti, Kimes, & Calhoun, 2008; Sairanen et al., 2009). In order to understand the total annual costs associated with IC at the national level, a secondary data analysis of a variety of databases, including those from the Centers for Medicaid and Medicare and the National Center for Health Statistics, was conducted. Between 1994 and 2000, an increase in direct annual costs from $481 to $750
million was found. Between 1992 and 2001, visits to physicians increased three-fold, and hospital outpatient visits increased two-fold (Clemens et al., 2008).

**Stress**

**Stress and Health Education and Promotion**

In 2003, the World Health Organization (WHO) published a seminal work entitled, *Social Determinants of Health: The Solid Facts*, edited by Wilkinson and Marmot. This book identifies social determinants of health as the social and environmental factors that have a direct influence on population health outcomes. It provides an evidence-based argument for the role of policy change in addressing the vast health disparities seen in relation to the social determinants of health. Also, the WHO explicitly identified stress as one important social determinant of health. It is explained that chronic stress can be perpetuated through social circumstances in which an individual has little control over his or her environment and lacks needed social support. This chronic stress triggers the body’s autonomic nervous system, resulting in a chronically high heart rate and sense of alertness. This continued heightened stress response affects multiple body systems and can increase the risk of infections, cardiovascular disease, diabetes, high blood pressure, and depression, among others (WHO, 2003).

The U.S. national health promotion agenda, *Healthy People 2020: The Road Ahead*, recognizes stress as an important social determinant of health. Chronic job-related stress is explicitly connected to an increase in injuries and chronic disease in U.S. workers (USDHHS, 2011b). Workers who experience such stressors as long hours, shift work, and
lack of job security are more likely to have cardiovascular disease, digestive disorders, and work-related injury (Rosa & Colligan, 1997). During the next decade, the Office of Disease Prevention and Health Promotion is tasked with the development of specific objectives related to the social determinants of health (USDHHS, 2011b). In addition to stress as a social determinant of health, the CDC recognizes stress as an important issue in workplace safety, worksite quality of life (CDC, 2010b), and the prevention of both substance abuse and violence (CDC, 2011c).

**Stress and Chronic Disease**

Despite public health’s recognition of stress as a social determent of health, skepticism about the connection between stress and chronic disease is still present in the U.S. biomedical community. In 2007, S. Cohen, Janicki-Deverts, and Miller published an article in the *Journal of the American Medical Association (JAMA)* that sought to address this skepticism. In this article, the authors clearly described the physiological process by which chronic stress can affect an individual’s regulation of immune and inflammatory responses. While experimental studies attempting to provide causal links between stress and chronic disease are lacking, primarily for ethical reasons, the authors stated that there is plenty of “natural evidence” to suggest association. Evidence is presented showing associations between stress and depression, cardiovascular disease, HIV/AIDS, and cancer. The available literature strongly supports the hypothesis of a causal link between stress and these conditions. The authors indicated also that there is emerging evidence to suggest a strong association between stress and other types of chronic conditions, including asthma and autoimmune disorders (S. Cohen et al., 2007).
It also has been documented that chronic stress can lead to “allostatic load.” The body seeks to maintain homeostasis (or balance) in times of stress by producing stress hormones and other mediators. When stress is chronic, the body can experience “wear and tear . . . when the mediators are dysregulated, i.e., not turned off when stress is over or not turned on adequately when they are needed” (McEwen, 2007, p. 874). Allostatic load can result in alterations in brain function, which can affect other systemic processes in the body, including “neuroendocrine, autonomic, and immune systems” (McEwen, 2007, p. 895).

**Stress and IC**

In 1997, a research study exploring the association between psychological stress and the activation of bladder mast cells, which have been associated with IC pathophysiology, was conducted using a rat model at the Tufts University School of Medicine. Rats were “non-traumatically” immobilized to create a stressful situation. Researchers found that this stress exposure resulted in the activation of bladder mast cells in over 70% of the rats involved in the experiment (Spanos et al., 1997). Further research, using both mice and rat models, has shown associations between acute and/or chronic stress and bladder symptoms and the pathogenesis of IC (Cao, Boucher, Kempuraj, Donelan, & Theoharides, 2006; Robbins, DeBerry, & Ness, 2007). These types of studies do not document that rats or mice can get IC. They do, however, provide evidence that rats and mice, under stress, exhibit physiological differences in their bladders that are associated with some of the theories of IC etiology.
Until 2000, the exacerbation of IC symptoms by stress in humans had only been anecdotally reported in the IC literature. Lutgendorf, Kreder, Rothrock, Ratliff, and Zimmerman (2000) published the first empirical test of the association between stress and IC symptoms. A total of 14 women with interstitial cystitis, along with 14 age-matched controls, were placed in a laboratory setting and exposed to 25 minutes of mental stress tasks. Both groups were assessed for urinary pain and urgency pre and post the mental stress exposure. IC patients reported increases in both pain and urgency, whereas controls reported no changes after the stress exposure. These researchers reported in a later published article that IC patients had also significantly higher resting heart rates at the beginning of the study and throughout the mental stress tasks as compared to healthy controls (Lutgendorf et al., 2000; Lutgendorf, Latini, Rothrock, Zimmerman, & Kreder, 2004). In 2001, this same group of researchers asked 45 female IC patients and 31 healthy, age-matched controls, to fill in a bladder symptom and stress diary for one month. Results indicated that higher levels of daily stress were associated with increases in pain and urgency in IC patients but not in the control group. Also, it was found that the association between stress and IC symptoms was more pronounced in those with higher disease severity (Rothrock, Lutgendorf, Kreder, Ratliff, & Zimmerman, 2001). Results of these studies, in part, have led health care professionals to recommend complementary and alternative treatment options to IC patients, including stress reduction techniques (Whitmore, 2002). More recent published literature, representing results from research studies and literature reviews, continues to suggest an association
between stress and IC symptoms (Buffington, 2004, 2009; Klausner & Steers, 2004; Twiss et al., 2009).

**Self-Efficacy**

**Self-Efficacy and Health Education and Promotion**

Albert Bandura, the “father of self-efficacy,” defined this construct as, “not a measure of the skills one has but a belief about what one can do under different sets of conditions with whatever skills one possesses” (Bandura, 1997, p. 37). The construct of self-efficacy is known most widely for its inclusion in Social Cognitive Theory (SCT), as one of its theoretical constructs that attempts to account for psychological determinants of behavior. It has been incorporated over time as an important construct in other behavioral theories as well, including the Transtheoretical Model, Health Belief Model, and Theory of Planned Behavior (Brewer & Rimer, 2008). There have been a variety of studies to support the idea that self-efficacy is integral to the performance of particular behaviors, especially those that are particularly complex or difficult, including the management of chronic disease (Bandura, 1997). The construct also has been researched and found to be an important predictor of a variety of types of health behavior. These include breast cancer screening (Champion, Skinner, & Menon, 2005), the ability to follow-through with treatment options in the management of health problems (O’Hair et al., 2003), and sexual behaviors, including condom use, number of sex partners, and number of sexual encounters (Lin, Simoni, & Zemon, 2005; Steers, Elliot, Nemiro, Ditman, & Oskamp, 1996; Zak-Place & Stern, 2004).
Self-Efficacy and Chronic Disease

The construct of self-efficacy is associated with the idea of self-management of chronic disease. One of the first uses of the term “self-management” was by Creer, Renne, and Christian in their 1976 book on the rehabilitation of children with asthma. This team of health care providers saw the patient as an active participant in the treatment process (Creer et al., 1976). Since that time, the term self-management has been used consistently in reference to chronic disease management and patient education. The conceptualization of self-management is not consistent within the field. Lorig and Holman, in their 2003 article on chronic disease self-management education, presented one common approach. Using the qualitative research conducted by Corbin and Strauss (1988) on self-care of chronic illness, Lorig and Holman postulated that chronic disease self-management must be based on three tasks: medical management, role management, and emotional management. Medical management includes adhering to medical regimens or physician advice. Role management involves maintaining, changing, or creating new life roles. Emotional management involves treating the anger, fear, frustration, and depression of having a disease as part of the disease itself. There are also five major self-management skills that are thought to be integral to effective management. These include problem solving, decision-making, resource utilization, forming a patient/healthcare provider partnership, and taking action in reasonable steps. Examples of these self-management skills include:

1) understanding how to use the Internet to obtain reputable health information,

2) learning to communicate effectively with health care providers, and
3) Setting reasonable short-term goals (Lorig & Holman, 2003).

Utilizing this framework, Lorig and her team at the Stanford Patient Education Research Center (SPERC) have created a variety of chronic disease self-management programs. These programs include an in-person and online version of the basic Chronic Disease Self-Management Program (CDSMP), Arthritis Self-Management Program (ASMP), and the Diabetes Self-Management Program (DSMP), as well as in-person programming in HIV/AIDS and chronic pain. Many of the programs have been translated into Spanish, as well as other languages. These programs have been found over time to be evidence-based in producing positive health outcomes in patients who participate. These positive health outcomes have been found in participants in both the U.S. and in a variety of other countries, including Canada and England (Barlow, Williams, & Wright, 2000; Chui, Poon, Lee, & Lau, 1998; Goeppinger, Arthur, Baglioni, Brunk, & Brunner, 1989; Lorig & Holman, 2003; Lorig, Laurin, & Holman, 1984; Lorig, Sobel, et al., 1999; McGowan & Green, 1995). While the original hypothesis by Lorig and her colleagues was that increases in healthy behavior would be associated with increased health status, significant associations between these concepts were not found (Lorig, Selznick, et al., 1989). Through both qualitative and quantitative research, it was discovered that increases in self-efficacy were most strongly associated with improvements in health status (Lenker, Lorig, & Gallagher, 1984; Lorig, Chastain, Ung, Shoor, & Holman, 1989; Lorig, Gonzalez, & Ritter, 1999).
Self-Efficacy and IC

To date, there has been little published literature on the construct of self-efficacy and its relationship with coping with IC and health outcomes among IC patients. In 1998, Webster and Brennan published the results of their survey research with 138 women living with IC. Results indicated that women who had higher self-care effectiveness with behavioral and cognitive self-care strategies were more likely to have more positive health outcomes (Webster & Brennan, 1998). Two years later, results from another study with 80 female IC patients indicated that chronic pain was highly associated with depression, and that both the reported severity of pain and depression were associated with pain management self-efficacy (Rabin, O’Leary, Neighbors, & Whitmore, 2000).

Social Support

Social Support and Health Education and Promotion

A seminal work by House (1981) described social support as the “functional content of relationships” which includes four broad types of behavior: emotional support, instrumental support, informational support, and appraisal support. Examples of these types of support include the provision of love, resources, guidance, and constructive feedback (Heaney & Israel, 2008). The original work on the role of social support in health outcomes is attributed largely to John Cassel, a social epidemiologist who described social support as a protective factor against the effects of stress on overall health. Using the results from both animal and human research, he posited also that social support may play a role in the etiology of disease (Cassel, 1976). Since that time,
behavioral researchers have explored social support as a concept that both affects, and is affected by, health status (Heaney & Israel, 2008). Using the work of a variety of researchers (Berkman & Glass, 2000; Berkman, Glass, Brissette, & Seeman, 2000; Eng & Parker, 1994; Ferlander, 2007; Israel, 1982; Minkler, 2001; among others), Heaney and Israel posited that there are five pathways by which social support has an effect on health outcomes. Pathway One indicates that social support can directly affect physical, mental, and social health by meeting the basic needs of an individual, including companionship and a sense of belonging. If one feels a sense of reassurance or intimacy with others, he or she may have better outcomes, even in the face of stressors. Pathway Two indicates that social support can directly affect an individual’s coping resources, such as access to people and information. This type of access can serve to enhance an individual’s sense of self-efficacy or control over life. Pathway Three indicates that social support can affect directly an individual’s exposure to stress. For example, an individual with strong social support in the workplace may experience less job-related stress. Pathway Four indicates that social support can directly affect a community’s organizational and coping resources, such as having a sense of community competence. A strong social network in a community may serve to enhance that community’s ability to gather resources and solve problems. Finally, Pathway Five indicates that social support can affect directly individual health behaviors, such as choices around management of illness and engagement in risky health behavior. Interpersonal relationships have been shown to have an effect on such outcomes as medicine adherence, sick role behavior, and smoking cessation. In indirect ways, Pathways Two
through Five all have the potential to directly affect physical, mental, and social health (Heaney & Israel, 2008).

A variety of intervention research studies have attempted to enhance social support in order to improve health outcomes, such as the creation of mentoring relationships (Helgeson & Gottlieb, 2000), facilitation of self-help groups (Rhodes, 2002), and the identification of community health workers to enhance existing social networks (Eng & Hatch, 1991).

**Social Support and Chronic Disease**

The impact of social support on chronic disease-specific health outcomes also has been explored. Two examples include the Enhancing Recovery in Coronary Heart Disease Patients (ENRICHD) project and the Seattle-King County Healthy Homes Project (SKCHHP). The ENRICHD project, a multi-center, randomized trial, sought to increase social support in patients with coronary heart disease (CHD). The intervention group received therapy designed to assist patients with developing social networks. A subset of the intervention group also received group sessions with other patients, which provided both information and emotional support. The intervention did not result in lower rates of subsequent myocardial infarctions as compared to controls. It was found, however, that the intervention group did have significantly greater increases in social support as compared to controls. While the benefit decreased over time, some of that increase in social support remained at three-year follow-up (ENRICHD Investigators, 2001, 2003).
The SKCHHP was designed to provide instrumental, informational, and emotional social support to families with children with asthma and had more positive results as compared to the ENRICHD project. Community health workers were trained to assist families in the care of children with asthma and visited families in the high-intensity intervention group from five to nine times over the course of one year. Families in the low-intensity intervention group received only one visit from the community health workers. Children of the high-intensity intervention group were found to have a significant reduction in days with asthma-limited activities and urgent health care visits as compared to the low-intensity group. Children in the high-intensity group also reported more significant improvements in quality of life (Krieger, Takaro, Song, & Weaver, 2005).

Social Support and IC

A number of studies have found associations between social support and health outcomes in IC patients. In 2003, Rothrock, Lutgendorf, and Kreder administered questionnaires to 64 female IC patients measuring depression, quality of life, coping mechanisms, and symptom severity. Results indicated that those patients who sought instrumental social support had significantly fewer depressive symptoms than those who did not (Rothrock et al., 2003). More recently, Nickel et al. (2010) administered questionnaires to 207 female IC patients and 117 controls matched for age, partner status, and education. Among other results, a mild association between perceived social support and mental quality of life was found. A 2011 research study found also significant associations between positive spousal responses to patient pain and mental health-related
quality of life in IC patients (Ginting, Tripp, Nickel, Fitzgerald, & Mayer, 2011). In a 2003 qualitative research study, Breau and Norman found that individuals with IC were active seekers of self-care, stress management, and social support, but also that, compared to those living with other urologic conditions, were the least satisfied with the support and referral that they received for these methods of treatment by their health care providers (Breau, McGrath, & Norman, 2003).

On a related matter, it was long-hypothesized that women with IC would be more likely to report a past that included sexual abuse than women without the condition. A 2011 study explored this hypothesis. It was found that women with IC did more commonly report traumatic events from childhood than those without. It was found also that these early traumas had a modest association with patient adjustment as an adult (Nickel et al., 2011).

Finally, it is important to reiterate the unique history of IC as it relates to the social support, or lack thereof, received by those living with IC. Until the mid-1980s, women living with IC were told that their condition was “all in their head.” Advice from medical professionals often included such things as taking a vacation, dropping out of school, getting married, and/or seeing a psychiatrist in order to resolve symptoms (Ratner & Slade, 1997a). With treatment such as this from the medical community, as well as the stigma of having a condition erroneously associated with psychosomatic etiology, it would be no wonder that a perception of social support was associated with quality of life.
Transactional Model of Stress and Coping

The Transactional Model of Stress and Coping (TMSC) has its roots in the disciplines of biology and psychophysiology. It was developed to better understand the process of how individuals cope with stressful events. The TMSC posits that stressful events are made up of transactions between an individual and their environment, “in which the impact of an external stressor, or demand, is mediated by the person’s appraisal of the stressor and the psychological, social, and cultural resources at his or her disposal” (Glanz & Schwartz, 2008, p. 213). The TMSC includes the following constructs: primary and secondary appraisal, coping efforts, meaning-based coping, outcomes of coping, dispositional coping styles, and social support (F. Cohen, 1984; Folkman & Moskowitz, 2000; Lazarus & Cohen, 1977).

According to the model, a primary and secondary appraisal process occurs when an individual experiences a stressor. Primary appraisal consists of an evaluation of susceptibility and severity of the threat. Secondary appraisal consists of an evaluation of self-efficacy. The appraisal process is mediated by coping efforts and involves both problem-solving strategies and efforts to regulate emotions. The coping process is moderated by other factors, such as general ways of behaving, personality styles, general levels of optimism, and perceptions of social support (F. Cohen, 1984; Folkman & Moskowitz, 2000; Lazarus & Cohen, 1977).

The TMSC has been used as a framework for intervention research with cancer patients and their families (Northouse, Kershaw, Mood, & Schafenecker, 2005), studies that have sought to understand the role of spirituality in cancer management (Laubmeier,
Zakowski, & Bair, 2004), and intervention research with HIV-positive men (Antoni, 2003), among other populations. While there is some published research documenting associations between such concepts as stress, self-efficacy, social support, and quality of life in IC patients, to date there has been no published literature explicitly utilizing the TMSC as a framework for understanding those associations.

**Research Questions, Assumptions, and Data Analysis Approach**

The research questions for this study emerged from the literature and center on selected variables:

*Research Question 1.* Are there significant correlations between stress, self-efficacy, or social support, and health-related quality of life in individuals living with IC?

*Research Question 2.* Does self-efficacy mediate the effect of stress on health-related quality of life in individuals living with IC?

*Research Question 3.* Does social support moderate the effect of self-efficacy on health-related quality of life in individuals living with IC, when controlling for stress?

These research questions reflect the following assumptions:

1. That stress, self-efficacy, and social support will each be significantly correlated with the independent variable, health-related quality of life,

2. That the relationship between stress and health-related quality of life is diminished when self-efficacy is factored into the model, and
3. That the relationship between self-efficacy and health-related quality of life is stronger in those with high social support, versus those with low social support, when controlling for stress.

In order to examine the correlations between stress, self-efficacy, and social support with health-related quality of life, a Pearson Product Moment Correlation Coefficient test was used. Multiple regression was used to test for mediating effects. Moderation was examined using the General Linear Regression – Univariate analysis option is IBM SPSS 20.0 (Frazier, Tix, & Barron, 2004).
CHAPTER III
RESEARCH METHODS AND PROCEDURES

Purpose of the Study

The purpose of this study was to analyze the relationships between stress, self-efficacy, social support, and health-related quality of life among women living with interstitial cystitis (IC) in the United States (U.S.). In addition, the study examined the influence of self-efficacy as a mediator in the relationship between stress and health-related quality of life and social support as a moderator of the impact of self-efficacy on health-related quality of life in women living with IC when controlling for stress.

Subjects

Interstitial Cystitis Association

The Interstitial Cystitis Association (ICA) was founded in 1984. Since that time, this organization has emerged as the only national non-profit organization dedicated to IC research, education, and advocacy in the U.S. (ICA, 2011b). Since its beginning, the ICA also has established a strong IC community with whom it is connected. The ICA currently has a database containing approximately 80,000 contacts. This large database consists of almost all of the IC health care providers, researchers, patients, and caregivers with whom the ICA has been in communication. Some contacts are members of the ICA, some are not members but have made donations to support the agenda of the organization, and others represent those who have been in communication with the ICA in some way (e.g., through e-mail or phone inquiry). The ICA communicates regularly
with approximately 37.5% or 30,000 of those contacts. Further, the ICA was not able to identify with certainty which contacts represent patients versus others. The ICA also was not able to provide any specific demographic data about the contacts within their database (B. Gordon, personal communication, September 27, 2011).

**Study Population and Samples**

The study population included all individuals living with IC in the U.S. Currently, it is estimated that approximately 3 to 8 million women (or 3–6%) live with IC in the U.S. (Berry et al., 2011). It is estimated that approximately 1.5 million men are living with IC in the U.S. True prevalence is unknown, however, as IC in men is often mistaken for other conditions, such as chronic prostatitis (ICA, 2011a). The study sample frame consisted of approximately 30,000 individuals with whom the ICA was regularly in contact. This sampling frame was chosen for three reasons:

1. it was a readily available, convenient sample;
2. it included members of the ICA community throughout the U.S.; and
3. the support from an authority in the community (i.e., the ICA) was thought to enhance study participation.

All of these individuals received the study invitation e-mail from the ICA. Only those who had been diagnosed with IC by a health care provider and who were 18 years of age or older were eligible to complete the survey. This represented a purposive and systematic sampling approach, as only specific members of the ICA community were invited to participate in the study. The minimum sample size required to conduct meaningful statistical analysis was 300 subjects. This was roughly estimated
acknowledging that final regression models would include at least 15 predictor variables, and for each predictor variable, there should be at least 20 cases.

Instrumentation

A variable is defined as a “specific characteristic of the population” (Rea & Parker, 2005, p. 60). There are four types of levels of measurement scales: (a) nominal scale, (b) ordinal scale, (c) interval scale, and (d) ratio scale. Nominal variables, also referred to as categorical variables, are those in which there is no order or valuation. An example of a nominal variable is “political party preference.” Ordinal variables are also categorical in nature; however, they can be ordered or ranked. For example, the variable “level of education” (e.g., high school diploma or GED, undergraduate degree, graduate degree) can be ranked. While there is an implied order, there is no way to quantify the amount of difference between each level of education. Likert-type scales are also ordinal in nature. When a Likert-type scale has response categories that are fairly symmetrical, it is possible for it to approximate an interval scale or a continuous variable. Interval variables, often referred to as continuous variables, “indicate the exact value of each category or response” (Rea & Parker, 2005, p. 61). Examples of interval variables include weight, age in years, and temperature. Interval variables provide the most valuable information of all of the levels of measurement scales, and they can also be used to create categorical variables. Ratio variables are those that have equidistant points but also a meaningful zero point on the scale. Examples of ratio variables include age in years, income in dollars, or any item measuring years of participation (Rea & Parker, 2005). The reliability of a scale relates to the consistency of results each time it is
administered. Validity of a scale refers to its ability to measure accurately what it was created to measure (Creswell, 2009).

**Sources of Scales**

The instrument for this study consisted of 155 items. These items were organized into five scales, each of which had been developed and validated through prior research. Basic demographic questions and open-ended questions also were included (Appendix A). The five scales that were included in the instrument were the (a) RAND 36-Item Short Form Health Survey (SF-36); (b) RAND Medical Outcomes Study Social Support Survey Instrument (MOS SSSI); (c) Brief Encounter Psychosocial Instrument (BEPSI); (d) Interstitial Cystitis Self-Efficacy (ICSE) scale; and (e) O’Leary-Sant Interstitial Cystitis Symptom and Problem Questionnaire (ICSPQ). In specific, the response sets included the following: 7 open-ended items, 14 nominal items, 92 ordinal items (91 are Likert scales), and 3 ratio items. Approval to use all scales was obtained prior to data collection (Appendix B).

The first three items asked the subject to identify his or her role within the IC community (patient, health care provider, researcher, and/or other), and to confirm that he or she was 18 years of age or older. The survey window closed if a subject indicated that he or she had never been diagnosed with IC by a health care provider and/or was not 18 years of age or older. Subjects were instructed that this would happen on the first page of the instrument. Those who indicated that they had been diagnosed with IC by a health care provider and were 18 years of age or older were directed to the first scale on the instrument—health-related quality of life.
The RAND 36-Item Short Form Health Survey (SF-36) was originally created for use in the Medical Outcome Study (MOS). This was a study that took place over multiple years and multiple sites to explore patient outcomes (RAND, 2012). It consists of 36 items that measure physical functioning, role limitations caused by physical and emotional problems, social functioning, emotional well-being, energy/fatigue, pain, and general perceptions of health. Data from the original MOS on the reliability of each subscale indicated Cronbach’s alphas >= .78 (Ware & Shelbourne, 1992).

The version of the SF-36 that was used in this study consisted of 38 items. It was modified slightly from the original version in the following ways:

1. the inclusion of items that seek to understand the impact of IC on overall health-related quality of life,
2. the inclusion of items that seek to understand the impact of IC on overall health-related quality of life versus potential other chronic illnesses that a subject may have, and
3. the modification of some item language to ask specifically about the impact of IC.

The RAND Medical Outcomes Study Social Support Survey Instrument (MOS SSSI) was developed for use in a two-year study with chronic disease patients. It included 19 items measuring emotional/information support, tangible support, affectionate support, and positive social interaction. Shelbourne and Stewart examined the psychometrics of the scale and subscales and found it be reliable (all Cronbach’s
alphas $\geq .91$). Several construct validity hypotheses were also supported (Shelbourne & Stewart, 1991).

The Brief Encounter Psychosocial Instrument (BEPSI) was developed and evaluated for reliability and validity by Frank and Zyzanski (1988) in primary care patients. This six-item instrument demonstrated reliability (Cronbach’s alpha of .80), and validity was ascertained by its correlation with a variety of instruments measuring stress (Frank & Zyzanski, 1988).

Stoney, Bonfiglio, Buffington, and Woodworth (2001) adapted the Interstitial Cystitis Self-Efficacy Inventory (ICSEI), from the arthritis self-efficacy inventory that was developed by Lorig and colleague (Lorig, Chastain, et al., 1989). This instrument consisted of 21 statements related to the certainty that subjects can manage symptoms, participate in self-management activities, and continue other daily activities of living. Respondents were asked to indicate their level of certainty on a 10-point scale, with one indicating very uncertain and 10 indicating very certain. It should be noted that while this instrument has not been formally assessed for validity, it was informally assessed for construct validity and approved by both Bandura and Lorig (C.A.T. Buffington, personal communication, April 4, 2007).

To assess disease severity, the O’Leary-Sant Symptom Index and Problem Index for IC was used. This instrument was originally assessed in 1997 and determined to have good internal consistency, construct validity, and test-retest reliability (O’Leary, Sant, Fowler, Whitmore, & Spolarich-Kroll, 1997). In a 2006 study by Kushner and Moldwin,
this instrument was found to distinguish a diagnosis of IC from other diagnoses (p < .0001; Kushner & Moldwin, 2006).

**Operationalizing the Variables**

To test the hypotheses in this study, the following variables were analyzed. The dependent variable IC-specific health-related quality of life consists of eight subscales with a total of 37 items measuring physical functioning, role limitations caused by physical and emotional problems, social functioning, emotional well-being, energy/fatigue, pain, and general perceptions of health. There were 37 items with response categories that were Likert-type scales. These items represented categorical variables on an ordinal scale that approximated a continuous variable on an interval scale. One item was categorical on a nominal scale, as it asked subjects to indicate (a) Yes or (b) No to the question, “Do you have a chronic illness(es) other than IC?” Each item was recoded such that the response provided was recoded into representing the percentage of points possible for each item. All items were recoded such that a higher score represents higher perceived levels of quality of life. An average score was calculated that served as the overall IC-specific health-related quality of life index used in the analysis for the dependent variable. The average overall IC-specific health-related quality of life score could range from 0–100, with higher numbers indicative of higher perceived IC-specific health-related quality of life.

Independent variables included social support, stress, self-efficacy, disease severity, and demographic variables. Demographic variables consisted of:
A. Geographic Location: self-reported; indication of whether or not the subject lives in a state or territory in the U.S.; the selected options were (a) Yes or (b) No; categorical variable on a nominal scale.

B. Geographic Location: self-reported; if the subject indicated that they live in the U.S.; the selected options include all states and territories of the U.S.; categorical variable on a nominal scale.

C. Geographic Location: self-reported; if the subject indicated that they did not live in the U.S.; open-ended response where the subject could type in their country of residence, categorical variable on a nominal scale.

D. Type of Community: self-reported; the selected options were (a) urban, (b) suburban, or (c) rural; categorical variable on a nominal scale.

E. Age: self-reported in years; continuous variable on a ratio scale.

F. Gender: self-reported; the selected three options were (a) Female, (b) Male, or (c) Other; categorical variable on a nominal scale.

G. Ethnicity: self-reported; the selected two options were (a) Yes or (b) No; categorical variable on a nominal scale.

H. Race: self-reported; the selected six options were (a) American Indian, (b) Asian, (c) Native Hawaiian/Other Pacific Islander, (d) Black/African American, (e) White/Caucasian, or (f) Other. If the subject selected Other, they were asked to specify their race in an open text box. Categorical variable on a nominal scale.
I. Marital Status: self-reported; the selected options were (a) Married, (b) Divorced, (c) Married but Separated, (d) Widowed, (e) In a Relationship, or (f) Single; categorical variable on a nominal scale.

J. Level of Education: self-reported; the selected options were (a) Eighth grade or less, (b) Some high school, (c) High school graduate or GED, (d) Some college, (e) College graduate, or (f) Graduate degree; categorical variable on an ordinal scale.

K. Years Lived with IC: self-reported in years; continuous variable on a ratio scale.

L. Years Since Diagnosis with IC: self-reported in years; continuous variable on a ratio scale.

M. Health Problems Checklist: self-reported; the selected options were (a) Not applicable, (b) No problem, (c) Very small problem, (d) Small problem, (e) Medium problem, and (f) Big problem; categorical variable on an ordinal scale that approximates a continuous variable on an interval scale. An average of all specific items was calculated to serve as an overall score for co-morbidity. A range of possible scores was 1–6, with higher scores indicating higher perceived levels of co-morbidity severity.

Other independent variables include:

N. Social Support: self-reported; four subscales with a total of 19 items that measured emotional/information support, tangible support, affectionate support, and positive social interaction. The responses to each item consisted
of a Likert-type scale as follows: (a) None of the time, (b) A little of the time, (c) Some of the time, (d) Most of the time, or (e) All of the time. Categorical variable on an ordinal scale that approximated a continuous variable on an interval scale. All specific items were added together and an average score calculated, which served as an overall social support index used in the analysis for the independent variable. A range of possible scores was 1–5, with higher scores indicating higher perceived levels of social support.

O. Stress: self-reported; six items that measured overall stress. The responses to each item consisted of a Likert-type scale as follows: (a) Never, (b) Rarely, (c) Sometimes, (d) Often, or (e) Always. Categorical variable on an ordinal scale that approximated a continuous variable on an interval scale. An average of all items was computed, with a potential range of 0–4, and used in the analysis for the independent variable. A higher score indicated higher perceived levels of general stress.

P. IC-Specific Self-Efficacy: self-reported; 21 items that measured certainty around ability to manage IC and engage in normal, daily activities. The responses to each item consisted of a Likert-type scale with the subject choosing a number between 1–10, with 1 = Very Uncertain and 10 = Very Certain. Categorical variable on an ordinal scale that approximated a continuous variable on an interval scale. An average of all items was computed, with a potential range of 1–10, and used in the analysis for the
independent variable. A higher score indicated higher perceived levels of IC-specific self-efficacy.

Q. IC Disease Severity: self-reported; two subscales with a total of eight items that measure both symptoms and problems of IC. Three items on the symptom subscale consisted of a Likert-type scale as follows: (a) None of the time, (b) A little of the time, (c) Some of the time, (d) A good bit of the time, (e) Most of the time, or (f) All of the time. The fourth item on the symptom subscale, which asked about how often a subject gets up at night to urinate, had a Likert-type scale that consisted of (a) None, (b) One time, (c) Two times, (d) Three times, (e) Four times, or (f) Five or more times. The problem subscale consisted of a Likert-type scale as follows: (a) No problem, (b) Very small problem, (c) Small problem, (d) Medium problem, or (e) Big problem. Categorical variable on an ordinal scale that approximated a continuous variable on an interval scale. An average of all items was computed, with a potential range of 0–4.5, and used in the analysis for the independent variable. Higher scores were indicative of higher perceived disease severity.

Pilot Studies

An instrument, similar to the one described here, was piloted in 2009 under a Kent State University (KSU) Institutional Review Board (IRB) approved protocol. The instrument consisted of five scales, measuring general social support, general stress, IC-specific self-efficacy, disease severity and general health-related quality of life.
Demographic questions were included at the end of the instrument. Primary differences between the instrument piloted in 2009 and the one proposed here include:

1. the use of the four-item Centers for Disease Control and Prevention (CDC) Healthy Days scale, as opposed to the RAND SF-36;

2. the use of the Duke UNC Functional Social Support Questionnaire, as opposed to the RAND MOS SSSI;

3. the lack of demographic variable related to geographic location of the subject; and

4. the lack of open-ended questions specifically related to health-related quality of life, social support, stress, self-efficacy and disease severity.

Using a cross-sectional, web-based, self-administered survey, members of IC support groups from around the U.S. were invited to participate in the study. Of the 427 individuals who received the invitation e-mail, a total of 95 subjects accessed and completed at least a portion of the online survey, resulting in a response rate of 22.2%. Only two of the respondents indicated that they were male and were thus excluded from the study sample. Of the other 93 subjects, 11 left the survey after completing less than 25% of the questions. These 11 subjects were excluded as well, resulting in a final study sample of 82 subjects.

Of the 82 subjects, the mean age was 43.7 years, and the mean number of years living with IC was 10 years. All subjects reported that they were female and indicated having a diagnosis of IC by a health care provider. The majority of subjects reported that they were Caucasian (93.9%), non-Hispanic (93.8%), married (70.4%), and had at least
some college education (85.2%). Approximately half the sample reported that they were employed either full or part-time (53.1%). A stepwise regression model revealed that IC-specific self-efficacy ($p = .000, 42.5$%), general stress ($p = .000, 12$%), and general social support ($p = .018, 3.5$%) explained 58% of the variability in general health-related quality of life in the sample. Scale reliability analysis was conducted with all five sub-scales, and all five had Cronbach’s alphas of $> .8$. Results of this pilot study were presented at the 2011 Public Health Combined Conference, sponsored by the Ohio Public Health Association, in Columbus, Ohio.

A second pilot study was conducted in 2011 using a revised instrument. The KSU IRB approved this pilot study. The instrument included five scales measuring general health-related quality of life, general social support, general stress, IC-specific self-efficacy, and disease severity. Demographic questions were included at the end of the instrument. Primary differences between this instrument and the one proposed here include:

1. the use of the RAND SF-36 without item language asking specifically about IC-specific health-related quality of life;
2. the use of the Social Support List, as opposed to the RAND MOS SSSI;
3. the lack of demographic questions related to geographic location of the subject; and
4. the lack of open-ended questions specifically related to health-related quality of life, social support, stress, self-efficacy and disease severity.
The instrument used in the second pilot study included also questions that asked subjects to evaluate the instrument itself. These questions asked subjects for their open-ended responses related to their initial reaction to the instrument and changes that they would suggest, as well as questions related to the length of the instrument.

Using a cross-sectional, web-based, self-administered survey, members of a local IC support group were invited to participate in the study. Of the 60 individuals who received the study invitation e-mail, 14 subjects accessed and completed at least a portion of the online survey, resulting in a response rate of 23.3%. Of the 14 subjects who responded to the survey, two did not complete the demographic questions or the questions related to the evaluation of the instrument. These subjects were excluded from the final analysis, resulting in a final sample size of 12 subjects.

All 12 subjects reported that they were female and had a mean age of 46.7 years. One hundred percent of the sample identified as non-Hispanic and Caucasian. The majority of the subjects reported that they were in a relationship or married (58.4%) and had a college or graduate degree (58.3%). While the small sample limited the ability to conduct more sophisticated statistical analyses, scale reliability analysis was completed on all five scales. All had Cronbach’s alphas of > .7. Results from the open-ended responses included:

1. 25% of the subjects expressed that the survey was too long,

2. multiple subjects expressed that some of the questions in the social support scale were either redundant or not relevant,
3. two subjects indicated that it would be helpful to have places to express open-ended responses related to each category of questions,

4. two subjects expressed that a couple of the questions in the disease severity scale did not accurately reflect the different types of pain that IC patients can have, and

5. one subject suggested that an additional question be added that related to how long it had been since the subject had been diagnosed.

In response to the feedback provided by study subjects in this second pilot, a number of changes were made that resulted in the instrument proposed here. These changes include:

1. changing language in the RAND SF-36 to ask specifically about IC-related health-related quality of life;

2. the use of the RAND MOS SSSI, which is shorter and more specific to chronic disease-related social support than the Social Support List;

3. changing language in the O’Leary-Sant Symptom Index and Problem Index to allow subjects to report on pain in general (versus one specific type of pain);

4. the addition of open-ended questions after each scale to allow subjects to provide further comments;

5. the addition of demographic questions that ask subjects to identify the state or country in which they live, as well as what type of community (urban, suburban, or rural); and
6. the addition of a demographic question that asks subjects to report on how long it has been since the time of diagnosis with IC.

**Research Design and Data Collection Protocol**

The design of this study was a cross-sectional, web-based, self-administered survey. The Executive Director of the ICA, Barbara Gordon, provided a letter of support for this study on January 9, 2012 (Appendix C). This letter was incorporated into the application to the Institutional Review Board (IRB) at Kent State University (KSU), which was approved on February 3, 2012 (Appendix D). The data collection protocol was consistent with guidelines provided by the Dillman Tailored Design Method, a process for engaging in data collection via survey research (Dillman, Smyth, & Christian, 2009). The initial study invitation e-mail was sent by a representative of the ICA to contacts within the ICA community database, approximately 30,000 individuals. The ICA community database consists of IC patients, health care providers, researchers, and others. Given this, the study invitation e-mail stated clearly that the survey was to be completed only by IC patients who were over the age of 18 years. To support this process of self-selection, the instrument began with questions related to role (patient, health care provider, researcher, other) and age. This was done to rule out those who were ineligible to take the survey. It also stated clearly that the study was supported by the ICA (Appendix D).

A second, reminder e-mail was sent to the ICA community database about one and a half weeks after the initial e-mail. This reminder e-mail thanked those who had already completed the survey and reminded others that the survey was still open for
completion. A similar, third reminder e-mail was sent about three weeks after the initial study invite (Appendix D).

Once the instrument was closed for data collection, all data were exported to IBM SPSS Statistics 20.0. Initial data analysis began with data cleaning and the review of descriptive statistics for all variables. Each of the composite scores was examined further for outliers, the extent to which the distribution of data was normal, and the distribution of frequency data across key demographic variables.

**Research Questions**

The research questions for this study emerged from a literature review and center on selected variables:

*Research Question 1.* Are there significant correlations between stress, self-efficacy, or social support and health-related quality of life in individuals living with IC?

*Research Question 2.* Does self-efficacy mediate the effect of stress on health-related quality of life in individuals living with IC?

*Research Question 3.* Does social support moderate the effect of self-efficacy on health-related quality of life in individuals living with IC, when controlling for stress?

**Data Analysis and Test of Hypotheses**

Based on the research questions, this study analyzed the relationships between stress, self-efficacy, social support, and health-related quality of life among women living with IC in the U.S. In addition, this study examined self-efficacy as a mediator in the relationship between stress and health-related quality of life and social support as a
moderator of the impact of self-efficacy on health-related quality of life in women living with IC when controlling for stress. Based on the research questions, the null hypotheses that were tested in this study are illustrated in Table 2.

### Table 2

**Null Hypotheses and Statistical Tests**

<table>
<thead>
<tr>
<th>Null hypothesis</th>
<th>Statistical test</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hypothesis 1:</strong> There is no statistically significant correlation between stress and health-related quality of life.</td>
<td>Pearson Product Moment Correlation Coefficient test</td>
</tr>
<tr>
<td><strong>Hypothesis 2:</strong> There is no statistically significant correlation between self-efficacy and health-related quality of life.</td>
<td>Pearson Product Moment Correlation Coefficient test</td>
</tr>
<tr>
<td><strong>Hypothesis 3:</strong> There is no statistically significant correlation between social support and health-related quality of life.</td>
<td>Pearson Product Moment Correlation Coefficient test</td>
</tr>
<tr>
<td><strong>Hypothesis 4:</strong> The relationship between stress and health-related quality of life is not mediated by self-efficacy.</td>
<td>Regression Test</td>
</tr>
<tr>
<td><strong>Hypothesis 5:</strong> The relationship between self-efficacy and health-related quality of life is not moderated by the level of social support while controlling for the level of stress.</td>
<td>Regression Test</td>
</tr>
</tbody>
</table>
CHAPTER IV

RESULTS

Purpose of the Study

The purpose of this study was to analyze the relationships between stress, self-efficacy, social support, and health-related quality of life among women living with interstitial cystitis (IC) in the United States (U.S.). In addition, the study examined the influence of self-efficacy as a mediator in the relationship between stress and health-related quality of life and social support as a moderator of the impact of self-efficacy on health-related quality of life in women living with IC when controlling for stress.

The instrument for this study consisted of 155 items. These items were organized into five scales, each of which had been developed and validated through prior research. Demographic and open-ended items also were included (Appendix A). The five scales included in the instrument are as follows:

- The first scale was the RAND 36-Item Short Form Health Survey (SF-36), originally developed for use in the Medical Outcome Study (MOS; Ware & Shelbourne, 1992). The version of the SF-36 used in this study consisted of 38 items. This scale was modified slightly from the original version in order to reveal information about the specific impact of IC and other related chronic conditions on overall health-related quality of life. These modifications resulted in two additional items and some language modification to make the items ask specifically about the impact of IC on health-related quality of life.
Thirty-seven items represented categorical variables measured on an ordinal scale. These items approximated continuous variables on an interval scale. One item was categorical and measured on a nominal scale.

- The second scale was the RAND Medical Outcomes Study Social Support Survey Instrument (MOS SSSI). This scale was developed originally for use in a two-year study among patients with chronic disease (Shelbourne & Stewart, 1993). On this scale, 19 items measured emotional/information support, tangible support, affectionate support, and positive social interaction. All 19 items represented categorical variables measured on an ordinal scale. These items approximated continuous variables on an interval scale.

- The third scale was the Brief Encounter Psychosocial Instrument (BEPSI), which was developed originally for use with primary care patients (Frank & Zyzanski, 1988). Items on this scale asked subjects to rate their perceived level of general stress in the past month. There are six items on this scale, all categorical variables measured on an ordinal scale. These items approximated continuous variables on an interval scale.

- The fourth scale was the Interstitial Cystitis Self-Efficacy Inventory (ICSEI). This scale was adapted by Stoney et al. (2001) from the arthritis self-efficacy inventory, which was developed by Lorig and colleagues (Lorig, Chastain, et al., 1989). This scale consisted of 21 statements related to the perceived certainty among subjects that they can manage symptoms, participate in self-management activities, and continue other daily activities of living. All items
represented categorical variables measured on an ordinal scale. These items approximated continuous variables on an interval scale.

- The fifth scale was the O’Leary-Sant Symptom Index and Problem Index for IC. This scale consisted of two subscales with a total of eight items that measured both symptoms and problems of IC. All items represented categorical variables measured on an ordinal scale. These items approximated continuous variables on an interval scale.

**Data Collection: The Sample**

The study population included all individuals living with IC in the U.S. The study sample frame consisted of approximately 30,000 individuals with whom the national nonprofit, the Interstitial Cystitis Association (ICA), has regular contact. The ICA community database consists of IC patients, health care providers, researchers, and others. All of these potential subjects received an invitation to participate in the study from the ICA. Only specific members of the IC community, those who had been diagnosed with IC by a health care provider and who were 18 years of age or older, were eligible to participate in the study. To support this process of self-selection, the instrument began with items related to role (patient, health care provider, researcher, other) and age. This was done to rule out those who were ineligible to complete the instrument. This process represented a purposive and systematic sampling method.

The minimum-needed sample size was calculated to be 300 subjects. This was based on a rough estimate of 10-15 predictor variables in final regression models and the need to have at least 20 subjects per predictor variable.
The design of this study was a cross-sectional, web-based, self-administered instrument. The Executive Director of the ICA, Barbara Gordon, provided a letter of support for this study on January 9, 2012 (Appendix C). This letter was incorporated into the application to the Institutional Review Board (IRB) at Kent State University (KSU), which was approved on February 3, 2012 (Appendix D). The data collection protocol was consistent with guidelines provided by the Dillman Tailored Design Method, a process for engaging in data collection via survey research (Dillman et al., 2009).

The initial study invitation e-mail was sent by a representative of the ICA to contacts within the ICA community database on March 6, 2012 (Appendix E). Initial response to the instrument was substantial, with over 500 responses within the first 24 hours after the first study invitation went out via e-mail. During the first week of data collection, one subject contacted both the principal investigator and responsible investigator with a concern. She noted that she had completed the instrument, and since that time, had received a number of voicemails from someone claiming to be from the Quality of Life and IC Study. She indicated that she spoke with the individual once and was informed that she was eligible to receive a gift card as compensation for her time completing the instrument. When she asked the individual to identify herself, the individual immediately terminated the call. The following actions were taken in response to this event:

1. The principal investigator informed the subject immediately that no one from the study would be contacting her for follow-up and that there was no compensation for participation in the study. The subject was encouraged to
NOT provide any information about herself to anyone calling and claiming to be a representative of the Quality of Life and IC Study.

2. The principal investigator communicated with the committee member of record on the IRB form, other dissertation committee members, and the Executive Director of the ICA to discuss the event.

3. The principal investigator confirmed that no identifying contact information for that study subject was in the open-ended responses on the instrument. (The instrument does not ask for any identifying information, but a subject could theoretically type it into one of the open-ended text boxes, if they chose to do so.)

4. The principal investigator changed the password on the SurveyMonkey.com account used for data collection. It was also confirmed by a customer service representative with SurveyMonkey.com that there was no evidence of third-party access to the account.

5. The Executive Director of the ICA confirmed that the ICA’s database had not been accessed inappropriately or compromised in any way. In addition, the access password was changed.

6. The KSU IRB was informed of the incident and provided with documentation of all communication and steps taken. The KSU IRB responded immediately to the notice of the incident. They recommended that a notice be sent to the ICA community, indicating that no one from the Quality of Life and IC Study would be calling or e-mailing any individual to follow-up, and that there was
no compensation for participation in the study (Appendix F). The reminder study invitation e-mail included this notice.

Nine days after the initial study invitation e-mail, a reminder e-mail was sent to the ICA community database on March 15, 2012 (Appendix G). As of that date, approximately 800 subjects had completed the instrument. This reminder e-mail was embedded in the ICA’s monthly online newsletter as a “Top Story.” Once potential subjects clicked on the link to the “Quality of Life and IC Study,” they were brought to a message that thanked those who had already completed the instrument and reminded others that the instrument was still open for completion. The reminder stated clearly also that there was no compensation for participation in the study and that no one would be contacted by a member of the study team for the purposes of follow-up.

A final reminder regarding the instrument was sent by the ICA on March 26, 2012 (Appendix H). By that time, almost 1,200 subjects had completed the instrument. The final reminder resulted in another surge in instrument completion, with over 600 additional subjects completing the instrument between March 26, 2012, and April 1, 2012.

The dataset for final analysis for this study was pulled from SurveyMonkey.com on April 1, 2012 (n = 1917). All data were exported to IBM SPSS Statistics 20.0. Initial data analysis began with data cleaning and the review of descriptive statistics for all variables. Each of the composite scores was examined further for outliers, the extent to which the distribution of data was normal, and the distribution of frequency data across key demographic variables.
Descriptive Statistics

Sample Demographics

A total of 1,917 subjects began the instrument, and 1,583 (82.6%) completed it. The original sample of 1,583 consisted of both men/other ($n = 103, 6.5\%$) and women ($n = 1486, 93.5\%$), and subjects residing both inside ($n = 1502, 94.0\%$) and outside ($n = 96, 6.0\%$) the United States. Given the relatively small number of men and international respondents, these groups were excluded from final data analysis. The final data set consisted of 1,387 subjects.

The actual response rate to the instrument could not be calculated due to the limitations of the ICA community database. Without knowing the number of eligible individuals living with IC in that database, it was not possible to calculate the percentage of eligible individuals who chose to respond to the instrument. In the context of the minimum required number of subjects ($n = 300$), the response rate was more than needed. The response rate yielded nearly five times the number of usable responses required for meaningful statistical analysis ($n = 1387$).

Respondents reported that they lived in all 50 states. The Southeast region of the U.S. had the highest number of responses (25.9%) as compared to all other regions. The majority of the subjects reported that they lived in suburban communities (57.0%), were not Hispanic or Latino (96.8%), were White/Caucasian (94.9%), married (69.3%), and reported having a college or graduate degree (55.0%). The subjects were fairly evenly split on employment status, with 50.9% indicating they were not employed either full- or part-time.
The mean age of subjects was 49.39 years, with a range of 18–87 years. The reported mean number of years having lived with the symptoms of IC was 14.44, with a range of 0–64 years. The reported mean number of years since receiving the diagnosis of IC was 9.05. Responses to this item ranged from 0–50 years. Demographic characteristics reported by subjects whose responses were included in the data pool are depicted in Tables 3 and 4.

Two scores related to overall self-reported disease severity of IC and co-morbidity are included in demographics. The O’Leary-Sant IC Symptom Index and Problem Index was used to assess subjects’ symptoms of IC. The scale included also items related to problems associated with those symptoms. An average was taken of the eight items to calculate a total disease severity score. Potential scores ranged from 0–4.5, with higher scores indicating higher perceived levels of disease severity. A mean score was not calculated for those subjects for whom 25% or more of the 8 items were missing. These subjects \((n = 7)\) were excluded from data analysis. The mean disease severity score was 2.69, with a range of 0–4.5. The distribution for this variable was normal, with skewness of \(-.242\) and kurtosis of \(-.628\). The Health Problems Checklist was used to assess levels of co-morbidity and included 39 items that addressed a variety of symptoms. An average of all items was computed to create an overall co-morbidity score. Potential scores ranged from 1–6, with higher numbers indicating higher levels of co-morbidity. A mean score

Table 3

Demographic Characteristics of Survey Participants \((n = 1387)\)
<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1387</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Region of the U.S.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Southeast</td>
<td>356</td>
<td>25.9%</td>
</tr>
<tr>
<td>Midwest</td>
<td>307</td>
<td>22.4%</td>
</tr>
<tr>
<td>Northeast</td>
<td>293</td>
<td>21.3%</td>
</tr>
<tr>
<td>West</td>
<td>275</td>
<td>20.0%</td>
</tr>
<tr>
<td>Southwest</td>
<td>142</td>
<td>10.3%</td>
</tr>
<tr>
<td><strong>Type of Community</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suburban</td>
<td>788</td>
<td>57.0%</td>
</tr>
<tr>
<td>Rural</td>
<td>337</td>
<td>24.3%</td>
</tr>
<tr>
<td>Urban</td>
<td>257</td>
<td>18.6%</td>
</tr>
<tr>
<td><strong>Hispanic or Latino?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1321</td>
<td>96.8%</td>
</tr>
<tr>
<td>Yes</td>
<td>44</td>
<td>3.2%</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>1316</td>
<td>94.9%</td>
</tr>
<tr>
<td>Other</td>
<td>34</td>
<td>2.5%</td>
</tr>
<tr>
<td>Black/African American</td>
<td>31</td>
<td>2.2%</td>
</tr>
<tr>
<td>American Indian</td>
<td>28</td>
<td>2.0%</td>
</tr>
<tr>
<td>Asian</td>
<td>9</td>
<td>.6%</td>
</tr>
<tr>
<td>Native Hawaiian/Other Pacific Islander</td>
<td>1</td>
<td>.1%</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>955</td>
<td>69.3%</td>
</tr>
<tr>
<td>In a Relationship</td>
<td>123</td>
<td>8.9%</td>
</tr>
<tr>
<td>Single</td>
<td>122</td>
<td>8.9%</td>
</tr>
<tr>
<td>Divorced</td>
<td>114</td>
<td>8.3%</td>
</tr>
<tr>
<td>Widowed</td>
<td>35</td>
<td>2.5%</td>
</tr>
<tr>
<td>Married but Separated</td>
<td>29</td>
<td>2.1%</td>
</tr>
<tr>
<td><strong>Highest Level of Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>College Graduate</td>
<td>480</td>
<td>34.8%</td>
</tr>
<tr>
<td>Some College</td>
<td>413</td>
<td>29.9%</td>
</tr>
<tr>
<td>Graduate Degree</td>
<td>279</td>
<td>20.2%</td>
</tr>
<tr>
<td>High School Graduate or GED</td>
<td>186</td>
<td>13.5%</td>
</tr>
<tr>
<td>Some High School</td>
<td>19</td>
<td>1.4%</td>
</tr>
<tr>
<td>Eighth Grade or Less</td>
<td>2</td>
<td>.1%</td>
</tr>
<tr>
<td><strong>Employed (full- or part-time)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>698</td>
<td>50.9%</td>
</tr>
<tr>
<td>Yes</td>
<td>674</td>
<td>49.1%</td>
</tr>
</tbody>
</table>
Table 4

Additional Demographic Characteristics of Survey Participants (n = 1387)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (in years)</td>
<td>49.39</td>
<td>13.69</td>
<td>18–87</td>
</tr>
<tr>
<td>Years Lived w/IC</td>
<td>14.47</td>
<td>11.80</td>
<td>0–64</td>
</tr>
<tr>
<td>Years Since Diagnosis w/IC</td>
<td>9.05</td>
<td>8.21</td>
<td>0–50</td>
</tr>
<tr>
<td>Overall Disease Severity Score (0–4.5, higher score, higher disease severity)</td>
<td>2.69</td>
<td>.98</td>
<td>0–4.5</td>
</tr>
<tr>
<td>Overall Co-Morbidity Score (1–6, higher score, higher number of co-morbidities)</td>
<td>2.77</td>
<td>.74</td>
<td>1–5.58</td>
</tr>
</tbody>
</table>

was not calculated for subjects for whom 25% or more of the 39 items were missing.

These subjects (n = 21) were excluded from data analysis. The mean co-morbidity score was 2.77, with a range of 1.5–5.8. The distribution for this variable was normal, with skewness of .345 and kurtosis of .147.

Descriptive Statistics of Dependent and Independent Variables

The dependent variable, health-related quality of life, was measured using the RAND SF-36. This scale consisted of 35 items, which were recoded to responses ranging from 0 to 100, representing percentage of total possible score achieved. An average of each of these 35 items was computed to represent an overall health-related quality of life score. Potential scores ranged from 0 to 100, with higher scores representing higher perceived health-related quality of life. A mean score was not calculated for subjects for whom 25% or more of the 35 items were missing. These
subjects \((n = 3)\) were excluded from data analysis. A Cronbach’s alpha of .951 was calculated for this scale. The mean score for this sample was 46.98, with a range of 0–95.74. This variable was normally distributed based on skewness (-0.123) and kurtosis (-1.02) statistics.

The independent variable, social support, was measured using the RAND MOS SSSI. This scale consisted of 19 items. Based on the process used by the developers and evaluators of the scale (Shelbourne & Stewart, 1991), an average score was calculated to represent an overall social support score. Potential scores ranged from 1–5, with higher scores representing higher levels of perceived social support. A mean score was not calculated for subjects for whom 25% or more of the 19 items were missing \((n = 6)\). These subjects were excluded from data analysis. A Cronbach’s alpha of .966 was calculated for this scale. The mean score for this sample was 3.52, with a range of 1–5. This variable was normally distributed based on skewness (-0.403) and kurtosis (-0.652) statistics.

The independent variable, stress, was measured using the BEPSI, which consisted of six items. An average score was calculated to represent an overall stress score. Potential scores ranged from 0–4, with higher scores representing higher levels of perceived general stress. A mean score was not calculated for subjects for whom 25% or more of the 6 items were missing \((n = 2)\). These subjects were excluded from data analysis. A Cronbach’s alpha of .904 was calculated for this scale. The mean score for this sample was 2.35, with a range of 0–4. This variable was normally distributed based on skewness (-0.084) and kurtosis (-0.606) statistics.
The independent variable, IC-specific self-efficacy, was measured using the ICSEI. This scale consisted of 21 items. An average score was calculated to represent an overall self-efficacy score. Potential scores ranged from 1–10, with higher scores representing higher levels of perceived IC-specific self-efficacy. A mean score was not calculated for subjects for whom 25% or more of the 21 items were missing. These subjects \( n = 20 \) were excluded from data analysis. A Cronbach’s alpha of .960 was calculated for this scale. The mean score for this sample was 4.47, with a range of 1–10. This variable was normally distributed based on skewness (0.385) and kurtosis (-0.701) statistics. Table 5 summarizes the descriptive statistics on the dependent variable and each of the independent variables.

Table 5

*Description of Dependent and Independent Variables*

<table>
<thead>
<tr>
<th></th>
<th>Health-Related Quality of Life</th>
<th>Social Support</th>
<th>Stress</th>
<th>Self-Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Cases</td>
<td>1384</td>
<td>1381</td>
<td>1385</td>
<td>1367</td>
</tr>
<tr>
<td>Score Range in Theory</td>
<td>0–100</td>
<td>1–5</td>
<td>0–4</td>
<td>1–10</td>
</tr>
<tr>
<td>Actual Range</td>
<td>0–95.74</td>
<td>1–5</td>
<td>0–4</td>
<td>1–10</td>
</tr>
<tr>
<td>Mean</td>
<td>46.98</td>
<td>3.52</td>
<td>2.35</td>
<td>4.47</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>23.10</td>
<td>0.99</td>
<td>0.88</td>
<td>2.16</td>
</tr>
<tr>
<td>Skewness</td>
<td>-0.123</td>
<td>-0.403</td>
<td>-0.084</td>
<td>0.385</td>
</tr>
<tr>
<td>Kurtosis</td>
<td>-1.02</td>
<td>-0.652</td>
<td>-0.606</td>
<td>-0.701</td>
</tr>
<tr>
<td>Scale Cronbach’s Alpha</td>
<td>0.951</td>
<td>0.966</td>
<td>0.904</td>
<td>0.960</td>
</tr>
</tbody>
</table>
Summary of Descriptives

The final sample \( n = 1387 \) consisted of all females who had been diagnosed with IC by a health care provider, were 18 years of age and older, and were living in the U.S. The majority of the sample reported that they were White/Caucasian, middle-aged, non-Hispanic, married, and college-educated. Approximately half of the sample reported working part- or full-time at the time of instrument completion. On average, women in this sample reported that they had been living with IC for 15 years and were diagnosed 10 years prior to instrument completion. All continuous variables, including age (demographics), health-related quality of life (dependent variable), social support, stress, and self-efficacy (independent variables) were normally distributed based on skewness and kurtosis statistics.

Analyses of Hypotheses

Hypothesis 1–3

Null Hypothesis 1: There is no statistically significant correlation between stress and health-related quality of life.

Alternative Hypothesis 1: There is a statistically significant correlation between stress and health-related quality of life.

The relationship between stress and health-related quality of life was analyzed using a Pearson Product-Moment Correlation Coefficient test. Preliminary analyses were performed to ensure no violations of the assumptions of normality, linearity, and homoscedasticity. These preliminary analyses included the creation of a scatterplot to check for outliers, inspect the distribution of data points, and determine the direction of
the relationship between the variables. There was a strong, negative correlation between stress and health-related quality of life ($r = -0.632$, $p < 0.001$, $n = 1383$) that was statistically significant at the $p \leq .05$ level. Based on this result, null hypothesis 1 is rejected. High levels of perceived stress were associated with lower levels of perceived health-related quality of life. Table 6 summarizes the results of this Pearson Product-Moment Correlation Coefficient test.

Null Hypothesis 2: There is no statistically significant correlation between self-efficacy and health-related quality of life.

Alternative Hypothesis 2: There is a statistically significant correlation between self-efficacy and health-related quality of life.

The relationship between self-efficacy and health-related quality of life was analyzed using a Pearson Product-Moment Correlation Coefficient test. Preliminary analyses were performed to ensure no violations of the assumptions of normality, linearity, and homoscedasticity. These preliminary analyses included the creation of a scatterplot to check for outliers, inspect the distribution of data points, and determine the direction of the relationship between the variables. There was a strong, positive correlation between self-efficacy and health-related quality of life ($r = 0.796$, $p < 0.001$, $n = 1366$) that was statistically significant at the $p \leq .05$ level. Based on this result, null hypothesis 2 is rejected. High levels of perceived self-efficacy were associated with high levels of perceived health-related quality of life. Table 6 summarizes the results of this Pearson Product-Moment Correlation Coefficient test.
Null Hypothesis 3: There is no statistically significant correlation between social support and health-related quality of life.

Alternative Hypothesis 3: There is a statistically significant correlation between social support and health-related quality of life.

The relationship between social support and health-related quality of life was analyzed using a Pearson Product-Moment Correlation Coefficient test. Preliminary analyses were performed to ensure no violations of the assumptions of normality, linearity, and homoscedasticity. These preliminary analyses included the creation of a scatterplot to check for outliers, inspect the distribution of data points, and determine the direction of the relationship between the variables. There was a medium, positive correlation between social support and health-related quality of life ($r = 0.337, p < 0.001, n = 1379$) that was statistically significant at the $p \leq .05$ level. Based on this result, null hypothesis 3 is rejected. Higher levels of perceived social support were associated with higher levels of perceived health-related quality of life. Table 6 summarizes the results of this Pearson Product-Moment Correlation Coefficient test.

Statistically significant correlations between stress, self-efficacy, and social support also were found. There was a medium, negative correlation between stress and social support ($r = -0.474, p < .001, n = 1380$) with higher levels of perceived stress associated with lower levels of perceived social support. There was a strong, negative correlation between stress and self-efficacy ($r = -0.579, p < 0.001, n = 1363$) with higher levels of perceived stress associated with lower levels of perceived self-efficacy. There was a medium, positive correlation between self-efficacy and social support ($r = 0.408, p$
< 0.001, \( n = 1363 \) with higher levels of perceived self-efficacy associated with higher levels of perceived social support. Table 6 summarizes the results of these Pearson Product-Moment Correlation Coefficient tests.

Table 6

\textit{Hypotheses 1–3, Pearson Product-Moment Correlation Coefficients}

<table>
<thead>
<tr>
<th>Variable</th>
<th>Health-Related Quality of Life</th>
<th>Social Support</th>
<th>Stress</th>
<th>Self-Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health-Related Quality of Life</td>
<td>1.000</td>
<td>0.337</td>
<td>-0.632</td>
<td>0.796</td>
</tr>
<tr>
<td>Social Support</td>
<td>-</td>
<td>1.000</td>
<td>-0.474</td>
<td>0.408</td>
</tr>
<tr>
<td>Stress</td>
<td>-</td>
<td>-</td>
<td>1.000</td>
<td>-0.579</td>
</tr>
<tr>
<td>Self-Efficacy</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1.000</td>
</tr>
</tbody>
</table>

Hypothesis 4

Null Hypothesis 4: The relationship between stress and health-related quality of life is not mediated by self-efficacy.

Alternative Hypothesis 4: The relationship between stress and health-related quality of life is mediated by self-efficacy.

This hypothesis was analyzed using the Multiple Linear Regression test in four steps as guided by Frazier et al. (2004). All model tests contained the co-variates age, employment status, ethnicity, type of community, disease severity, and co-morbidity. The first linear regression model contained stress as the independent variable and health-related quality of life as the dependent variable. This model was significant at \( R^2 = 0.641 \) and \( p < 0.001 \). Stress in this model was a significant predictor of health-related
quality of life (β = -8.877, p < 0.001). The second linear regression model contained stress as the independent variable and the mediator, self-efficacy, as the dependent variable. This model was significant at $R^2 = 0.591$ and $p < 0.001$. Stress in this model was a significant predictor of self-efficacy (β = -8.877, p < 0.001). The third linear regression model contained both stress and self-efficacy as the independent variables and health-related quality of life as the dependent variable. This model was significant at $R^2 = 0.747$ and $p < 0.001$. Both stress (β = -4.264, p < 0.001) and self-efficacy (β = 5.357, p < 0.001) were significant predictors of health-related quality of life. Table 7 presents summary information resulting from the three regression models.

The Sobel Test for the Significance of Mediation (Soper, 2006) revealed a Sobel statistic of -13.245, significant at the $p < 0.001$ level, which indicates that the effect of the mediator variable was significant. The amount of the effect of the mediator variable on the dependent variable was further determined by calculating the indirect effect (Kenny, 2012). The direct effect of stress on health-related quality of life was -8.877, and the indirect effect of self-efficacy as a mediator was 4.591. Combined, the total effect of stress and self-efficacy on health-related quality of life was -13.468. Self-efficacy was found to be a statistically significant partial mediator of the relationship between stress and health-related quality of life, explaining 34.1% of the total effect of stress on health-related quality of life. Based on these results, null hypothesis 4 is rejected.
Table 7

Regression Coefficient Statistics of the Independent Variables in Three Multiple Linear Regression Models*

<table>
<thead>
<tr>
<th>Independent Variable</th>
<th>Unstandardized B Coefficient</th>
<th>Standard Error</th>
<th>Significance</th>
<th>Dependent Variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stress</td>
<td>-8.877</td>
<td>4.98</td>
<td>$p &lt; 0.001$</td>
<td>HRQOL</td>
</tr>
<tr>
<td>Stress</td>
<td>-0.857</td>
<td>0.053</td>
<td>$p &lt; 0.001$</td>
<td>Self-Efficacy</td>
</tr>
<tr>
<td>Stress</td>
<td>-4.264</td>
<td>0.487</td>
<td>$p &lt; 0.001$</td>
<td>HRQOL</td>
</tr>
<tr>
<td>Self-Efficacy</td>
<td>5.357</td>
<td>0.232</td>
<td>$p &lt; 0.001$</td>
<td></td>
</tr>
</tbody>
</table>

*All models were adjusted for age, employment status, ethnicity, type of community, disease severity, and co-morbidity.

Hypothesis 5

Null Hypothesis 5: The relationship between self-efficacy and health-related quality of life is not moderated by the level of social support while controlling for the level of stress.

Alternative Hypothesis 5: The relationship between self-efficacy and health-related quality of life is moderated by the level of social support while controlling for the level of stress.

This hypothesis was analyzed using General Linear Model procedure in SPSS. The Univariate Analysis option was used to test both the main and interaction effects of self-efficacy and social support on health-related quality of life. Health-related quality of life was the dependent variable. Self-efficacy, social support, and the interaction term between self-efficacy and social support were the model terms to be tested as
independent variables, adjusted for stress, age, employment status, ethnicity, type of community, disease severity, and co-morbidity. The model (Adjusted $R^2 = 0.788$, and $p < 0.001$) contained two significant predictors of health-related quality of life: co-morbidity ($p < 0.001$) and self-efficacy ($p = 0.003$). All other independent variables and co-variates, including the interaction term between self-efficacy and social support, were not significant at the $p \leq 0.05$ level. This result indicated that social support is not a moderator of the relationship between self-efficacy and health-related quality of life, when controlling for stress. Therefore, null hypothesis 5 is retained, and its alternative hypothesis is rejected.

**Additional Analyses**

The potential of social support as a moderator of the relationship between self-efficacy and health-related quality of life was explored further by using social support sub-scales as independent variables. The overall social support scale contains four subscales, as defined by its developers: emotional/informational support, tangible support, positive interaction support, and affectionate support. Scores were computed for each of these subscales, per the instructions of the scale developers (Shelbourne & Stewart, 1991), by taking the average of each item of the subscale (range 1–5). The relationships between each of the social support sub-constructs and health-related quality of life were analyzed using the Pearson Product-Moment Correlation Coefficient test. Each sub-construct was positively correlated with health-related quality of life at the $p < 0.001$ level (emotional/informational support—0.317, tangible support—0.220, positive interaction support—0.231, and affectionate support—0.356). Each of these subscale
scores was analyzed using the General Linear Model procedure in SPSS. The Univariate Analysis option was used to assess the main and interaction effects of self-efficacy and emotional/information support, tangible support, positive interaction support, and affectionate support on health-related quality of life. This was done using four separate models, each controlling for stress, age, employment status, ethnicity, type of community, disease severity, and co-morbidity. Each model contained all social support sub-constructs but only one interaction term between one of the sub-constructs and self-efficacy. None of the interaction-terms were found to be significant at the $p \leq 0.05$ level, even though each of the models was significant (Adjusted $R^2 = 0.729$, $p < 0.001$; Adjusted $R^2 = 0.712$, $p < 0.001$; Adjusted $R^2 = 0.718$, $p < 0.001$; and Adjusted $R^2 = 0.704$, $p < 0.001$, respectively). Since no sub-construct of social support was found to be a moderator of the relationship between self-efficacy and health-related quality of life, social support in general is indeed not a statistically significant moderator in this test.

To understand the impact of social support on health-related quality of life, adjusting for other independent and control variables, the main effects of social support or each of its sub-constructs were analyzed in two separate linear regression models. In both models, health-related quality of life was the dependent variable. Social support or its four sub-constructs were the independent variables with stress, self-efficacy, age, employment status, ethnicity, type of community, disease severity, and co-morbidity as co-variates. The tests found that social support in general, as well as three of the four sub-constructs, were all significant predictors of health-related quality of life in the two models ($R^2 = 0.748$, $p =< 0.001$, and $R^2 = 0.750$, $p < 0.001$, respectively).
Emotional/informational support was not a significant predictor of health-related quality of life ($p = 0.915$). Regression statistics of each social support variable in these models are shown in Table 8.

Table 8

*Main Effects of Social Support and Sub-Constructs*

<table>
<thead>
<tr>
<th>Independent Variable(s)</th>
<th>Unstandardized B Coefficient</th>
<th>Standard Error</th>
<th>Significance</th>
<th>Dependent Variable</th>
<th>$R^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social Support</td>
<td>-0.888</td>
<td>0.382</td>
<td>$p = .020$</td>
<td>HRQOL</td>
<td>0.748</td>
</tr>
<tr>
<td>Emotional/Information Support</td>
<td>0.046</td>
<td>0.429</td>
<td>$p = 0.915$</td>
<td>HRQOL</td>
<td>0.750</td>
</tr>
<tr>
<td>Tangible Support</td>
<td>-1.158</td>
<td>0.357</td>
<td>$p &lt; 0.001$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Affectionate Support</td>
<td>-1.698</td>
<td>0.497</td>
<td>$p &lt; 0.001$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive Interaction Support</td>
<td>2.031</td>
<td>0.530</td>
<td>$p &lt; 0.001$</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*All models were adjusted for stress, self-efficacy, age, employment status, ethnicity, type of community, disease severity, and co-morbidity*

It is worth noting that multicollinearity diagnostics were performed in both model tests. There were no tolerance values $> 0.2$ and no VIF statistics $> 10$ found for any social support variables. In an attempt to test for construct validity of the social support scale, the 19 items of the RAND MOS SSSI were subjected to Principal Components Analysis (PCA). Prior to performing PCA, the suitability of data for factor analysis was assessed. Inspection of the correlation matrix revealed the presence of coefficients of 0.3 and above. The Kaiser-Meyer-Oklin value was 0.956, exceeding the recommended value.
Bartlett’s Test of Sphericity (Bartlett, 1954) reached statistical significance, supporting the factorability of the correlation matrix. PCA revealed the presence of three components with eigenvalues exceeding one, explaining 62.7%, 11.4%, and 8.2% of the variance respectively. The screeplot revealed a clear break after the second component. Based on Catell’s scree test (1966), it was determined that two components should be kept for further analysis.

The two-component solution explained 74% of the variance, with Component 1 contributing 62.7% and Component 2 contributing 11.3%. Oblimin rotation was performed, with both components showing strong loadings. Eleven variables loaded on Component 1, and eight variables loaded on Component 2. Component 1 consisted of items from the tangible support, positive interaction support, and affectionate support subscales (as defined by the developers of the RAND MOS SSSI; Shelbourne & Stewart, 1991). Component 2 consisted of all items on the emotional/informational support subscale. Scores for each of these components were computed using the average of item responses. Each component was positively correlated with health-related quality of life at the $p < 0.001$ level (Component 1 – 0.307, Component 2 – 0.317).

Each of these components was analyzed using the General Linear Model procedure in SPSS. The Univariate Analysis option was used to assess the main and interaction effects of self-efficacy and each component on health-related quality of life. This was done using two separate models, each controlling for stress, age, employment status, ethnicity, type of community, disease severity, and co-morbidity. Each model contained both components but only one interaction term between one of the components
and self-efficacy. None of the interaction-terms were found to be significant at the $p \leq 0.05$ level, even though each of the models was significant ($\text{Adjusted } R^2 = 0.723, p < 0.001; \text{Adjusted } R^2 = 0.756, p < 0.001$).

In summary, additional analyses were conducted to further explore the social support variable for two purposes: (a) to determine if there was any chance that social support could be a moderator between self-efficacy and health-related quality of life when the social support total score has failed to provide evidence, and (b) to determine if social support, either represented by a total score or by four subscales, was a significant predictor of health-related quality of life when competing with self-efficacy and stress, adjusted for other control variables. Further data analysis yielded consistent results that social support was not a moderator in this sample but a significant yet medium strong predictor of health-related quality of life. This additional analysis also has revealed a new question that cannot be easily answered: why is there a negative correlation between social support and health-related quality of life, as the negative beta coefficients have suggested? By carefully examining the construct of the social support variable(s) via Principle Components Analysis and the regression model building process, the negative relationship is in contrast to the positive relationship between self-efficacy and health-related quality of life, at least in current sample of 1,387 women living with IC in the U.S.

**Summary**

In this chapter, five proposed hypotheses were subjected to statistical analyses. Pearson Product-Moment Correlation Coefficient, Multiple Linear Regression, and
General Linear Regression tests were used to examine these hypotheses. Findings from this analysis revealed that stress, self-efficacy, and social support were each statistically significantly associated with health-related quality of life. These findings confirm that as stress increased, health-related quality of life decreased. As self-efficacy increased, health-related quality of life increased. As social support increased, health-related quality of life increased. Significant associations also were found between stress and self-efficacy, stress and social support, and self-efficacy and social support. As stress increased, both self-efficacy and social support decreased. As self-efficacy increased, social support increased.

Findings from further analysis revealed that self-efficacy was a statistically significant partial mediator of the relationship between stress and health-related quality of life. When self-efficacy was entered into the linear regression model, it diminished the direct impact of stress on health-related quality of life. The indirect effect of self-efficacy as a partial mediator explained approximately 34.1% of the impact of stress on health-related quality of life.

Findings from this analysis revealed that social support nor any of its sub-constructs were statistically significant moderators of the relationship between self-efficacy and health-related quality of life, when controlling for stress.
CHAPTER V
DISCUSSION AND RECOMMENDATIONS

Purpose of the Study

The purpose of this study was to analyze the relationships between stress, self-efficacy, social support, and health-related quality of life among women living with interstitial cystitis (IC) in the United States (U.S.). In addition, the study examined the influence of self-efficacy as a mediator in the relationship between stress and health-related quality of life and social support as a moderator of the impact of self-efficacy on health-related quality of life in women living with IC when controlling for stress.

Literature-Based Context

In 2004, Anderson and Horvath indicated that approximately 45% of the U.S. population, or 125 million Americans, had at least one chronic condition. In addition, 21% of the U.S. population, or 61 million, had two or more chronic conditions (Anderson & Horvath, 2004). In 2010, the Centers for Disease Control and Prevention (CDC) updated these figures by reporting that 70% of all deaths in the U.S. were attributable to chronic disease. The CDC noted also that approximately 25% of those with chronic disease report one or more limitations in daily life, representing a significant impact on quality of life (CDC, 2010a).

In light of this documented burden of chronic disease in the U.S., an expanded focus on quality of life, as opposed to solely quantity of life, has been seen. McGinnis (1985, 2003a, 2003b) noted the limits of prevention and the importance of helping people
live longer, higher quality lives. In his words, “the primary paradigm shift for the 21st
century will be the move from a primary focus on length of life to a primary focus on
quality of life” (McGinnis, 2003a, p. 149). Fries et al. (1989) echoed the assertions of
McGinnis (1985) by asserting that an emphasis be placed on the compression of
morbidity. Specifically, these authors asserted that the compression of morbidity could be
accomplished through addressing quality of life and the management of chronic disease.
Their conclusion, “add life to your years, not years to your life,” often is repeated in the
public health and health promotion literature (Fries et al., 1989, p. 483).

A national emphasis on quality of life and the management of chronic disease also
is reflected in the evolution of the Healthy People agenda. This national health
promotion and disease prevention agenda has represented the nation’s health priorities
since 1980. Currently, Healthy People 2020: The Road Ahead, contains explicit goals
related to helping U.S. citizens attain high quality, longer lives and health-related quality
of life as a foundational measure. Professionals involved in the creation of this revised
national health promotion 10-year plan recognized the assessment of health-related
quality of life as an important tool for understanding the effects of chronic disease and
included it for the purposes of encouraging methodological improvements in its
measurement (USDHSS, 2010).

In the context of a national focus on chronic disease and quality of life, there is a
host of chronic medical conditions that have drawn the attention of public health
practitioners, health educators/promoters, and medical care providers. One such
condition is interstitial cystitis (IC), a chronic condition traditionally thought to be
characterized by a deficiency of, or damage to, the inner lining of the bladder. Symptoms mimic those of a common urinary tract infection and include urinary urgency, frequency, and pain. While there are a multitude of hypotheses around etiology, the diagnosis is one of exclusion; there is no cure, and no treatments that are effective in the majority of patients (ICA, 2011a).

The impact of IC on patients can be profound. A landmark 1987 study by the Urban Institute found that the quality of life of women with IC was worse than that of women on dialysis for end-stage renal disease. Factors thought to contribute to this significantly decreased quality of life included unremitting urinary frequency and pain; the disruption of patient’s relationships with family, friends, and co-workers; the inability to stay employed; and significant sexual dysfunction (Ratner & Slade, 1997a). More recent research has confirmed these findings: Individuals living with IC can experience pain, significant disruption in sleep, sexual dysfunction, and inability to work, all resulting in significant decreases in health-related quality of life (Bogart et al., 2011; Kim & Oh, 2010; Panzera et al., 2011; Ratner & Slade, 1997b; Tripp et al., 2009).

The most recent sign of progress in the medical field’s understanding of IC consists of new guidelines published by the American Urological Association (AUA) in March 2011. These new guidelines include specific recommendations on the diagnosis and treatment of IC. For the first time, patient education, self-care, and stress management are now considered first-line treatment for IC, with priority in order over pain medications, other oral medications, physical therapy, and bladder installations. In addition to specific recommendations regarding diagnosis and treatment, the AUA
guidelines include multiple references to patient quality of life. The main premise behind the AUA treatment guidelines is stated as such: “until more definitively effective therapies are identified, the treatment approach should be tailored to the specific symptoms of each patient in order to optimize quality of life” (AUA, 2011, p. 18). The AUA guidelines note the dramatic impact of living with the condition on patient quality of life. Issues of chronic pain, sleep and sexual dysfunction, loss of work productivity, and disruption in family life all contribute to this profound effect on quality of life (AUA, 2011).

Study

Sample

This study utilized a systematic and purposive approach to sampling from the community of the only national nonprofit organization in the U.S. dedicated to those living with IC, the Interstitial Cystitis Association (ICA). The ICA community consists of roughly 30,000 patients, caregivers, researchers, and clinicians, among others (B. Gordon, personal communication, September 27, 2011). Those living with the condition, and who were 18 years of age and older, were invited to complete a web-based, anonymous, cross-sectional instrument. Analyses were conducted on data collected between March 6, 2012, and March 31, 2012.

Instrumentation and Theoretical Framework

The instrument used in this study consisted of 155 items and five scales measuring the constructs of health-related quality of life, social support, stress, self-efficacy, and disease severity. In addition, the instrument contained demographic
items and open-ended questions at the end of each section. The theory that was the foundation of this study was the Transactional Model of Stress and Coping (TMSC). According to the model, a primary and secondary appraisal process occurs when an individual experiences a stressor. Primary appraisal consists of an evaluation of susceptibility and severity of the threat. Secondary appraisal consists of an evaluation of self-efficacy. The appraisal process is mediated by coping efforts and involves both problem-solving strategies and efforts to regulate emotions. The coping process is moderated by other factors, such as general ways of behaving, personality styles, general levels of optimism, and perceptions of social support (F. Cohen, 1984; Folkman & Moskowitz, 2000; Lazarus & Cohen, 1977).

Analysis of Hypotheses

Five hypotheses were tested in this study. They included analyses of the relationships between social support, stress, self-efficacy, and health-related quality of life; self-efficacy as a mediator of the relationship between stress and health-related quality of life; and social support as a moderator of the impact of self-efficacy on health-related quality of life, when controlling for stress.

Hypotheses 1–3. Null Hypothesis: There is no statistically significant correlation between stress and health-related quality of life.

Findings from the Pearson Product Moment Correlation Coefficient test revealed that stress had a statistically significant, negative correlation with health-related quality of life. This led to the rejection of null hypothesis 1. As stress increased, health-related quality of life decreased.
Stress has been recognized as an important social determinant of health (USDHHS, 2011b; WHO, 2003). There is a multitude of evidence that suggests that stress can have profound physiological effects on the human body (S. Cohen et al., 2007; McEwen, 2007). IC-specific literature indicates that stress can exacerbate symptoms, specifically pain and urinary urgency (Buffington, 2004, 2009; Lutgendorf et al., 2000; Lutgendorf et al., 2004; Klausner & Steers, 2004; Twiss et al., 2009). In addition, other research literature has noted the significant negative correlation between stress and health-related quality of life in those living with IC (Nickel et al., 2010). Given this, the resulting large, negative correlation between stress and health-related quality of life in this study was not surprising.

Null Hypothesis: There is no statistically significant correlation between self-efficacy and health-related quality of life.

Findings from the Pearson Product Moment Correlation Coefficient test revealed that self-efficacy had a statistically significant, positive correlation with health-related quality of life. This led to the rejection of null hypothesis 2. As self-efficacy increased, health-related quality of life increased.

The limited published literature on self-efficacy and IC supports the findings of this study. Higher self-care effectiveness has been associated with positive health outcomes (Webster & Brennan, 1998). Higher pain management self-efficacy also has been associated with mental health status and severity of pain (Rabin et al., 2000). In addition to the IC-specific literature, there is substantial literature suggesting that self-efficacy is an important mechanism by which positive health outcomes can be
obtained in those living with chronic disease (Lenker et al., 1984; Lorig, Gonzalez, et al., 1999; Lorig, Chastain, et al., 1989).

Null Hypothesis: There is no statistically significant correlation between social support and health-related quality of life.

Findings from the Pearson Product Moment Correlation Coefficient test revealed that social support had a statistically significant, positive correlation with health-related quality of life. This led to the rejection of null hypothesis 3. As social support increased, health-related quality of life increased.

The positive correlation between social support and health-related quality of life also is not surprising given the existing literature. Heaney and Israel (2008) posited five pathways in which social support can impact health outcomes. Although four of the five pathways represent indirect pathways of influence, all five represent ways in which social support can positively impact health outcomes like health-related quality of life (Heaney & Israel, 2008). Intervention research has found that increases in social support can result in increased health-related quality of life in those living with chronic disease (Krieger et al., 2005). IC-specific literature has also documented associations between social support and positive outcomes, including decreases in depressive symptoms (Rothrock et al., 2003) and increases in mental quality of life (Nickel et al., 2010; Ginting et al., 2011).

**Hypothesis 4.** Null Hypothesis: The relationship between stress and health-related quality of life is not mediated by self-efficacy.
A three-step linear regression test and the Sobel Test for Significance of Mediation revealed that self-efficacy was a statistically significant partial mediator of the relationship between stress and health-related quality of life. This led to the rejection of null hypothesis 4. When self-efficacy is entered into the regression model, the impact of stress on health-related quality of life is decreased.

The existing but limited literature on self-efficacy and IC indicates that it can positively influence health outcomes (Rabin et al., 2000; Webster & Brennan, 1998). Other literature is suggestive of self-efficacy as the mechanism by which positive outcomes can be increased in those living with chronic disease (Lenker et al., 1984; Lorig, Gonzalez, et al., 1999; Lorig, Chastain, et al., 1989). In addition to the literature addressing the direct impact of self-efficacy, there also is substantial evidence to suggest that self-efficacy is a mediator between stress and health outcomes (Benight & Harper, 2002; F. Cohen, 1984; Folkman & Moskowitz, 2000; Lazarus & Cohen, 1977; Roddenbery & Renk, 2010; Wissing et al., 2011). This finding is significant for the IC community. If stress can have a significant impact on health-related quality of life in women living with IC, and self-efficacy can mediate that impact, an additional mechanism of improving outcomes is revealed. In addition to assisting patients with stress management, helping to empower patients to have a stronger sense of control over managing their condition also can serve to improve health-related quality of life.

**Hypothesis 5.** Null Hypothesis: The relationship between self-efficacy and health-related quality of life is not moderated by the level of social support while controlling for the level of stress.
The General Linear Model – Univariate Analysis option in SPSS was used to explore social support as a moderator of the relationship between self-efficacy and health-related quality of life. Results of the model indicated that social support was not a moderator (i.e., the interaction between social support and self-efficacy was not a significant predictor of health-related quality of life). Additional analyses were conducted to explore the social support variable. Despite breaking the overall score into sub-scores, based on instructions from the developers of the scale and on results from factor analysis, the conclusion that social support was not a moderator remained accurate. This led to the acceptance of null hypothesis 5. Results of further regression modeling and factor analysis revealed also a valid variable—normally distributed, no outliers, correlated to other variables with moderate strength, a significant predictor of the dependent variable, and well-constructed.

It was surprising that social support was not revealed to be a moderator of self-efficacy and health-related quality of life. This finding is contradictory to Heaney and Israel’s model (2008), which specifically indicates that social support can enhance an individual’s self-efficacy and have an indirect impact on health outcomes. It also is contradictory to the TMSC, which posits that social support is a moderator of the impact of self-efficacy on health outcomes (F. Cohen, 1984; Folkman & Moskowitz, 2000; Lazarus & Cohen, 1977).

Social support’s main effect on health-related quality of life, as tested by linear regression, was statistically significant but minimal. Also noteworthy is the negative unstandardized beta coefficients associated with social support overall and two of the
four social support sub-constructs in that linear regression model. Social support and each of its sub-constructs were positively associated with health-related quality of life according to Pearson Product Moment Correlation testing. These beta coefficients, however, imply that when social support increases, health-related quality of life decreases. This finding is contradictory to IC-specific literature documenting the positive impact of social support on outcomes (Ginting et al., 2011; Nickel et al., 2010; Rothrock et al., 2003). As opposed to providing implications for treatment of women living with IC, this finding suggests that further research is warranted.

**Recommendations for Further Research**

Findings from this study suggest the need for further research. Three potential areas of expanded research include:

1. **Further Quantitative Research:** A refined instrument should be implemented in a more representative sample of people living with IC in the U.S. Focused effort should be made to recruit subjects from outside of the ICA community. Those individuals who are members of the ICA community may differ from those who are not. Both men and minorities also should be targeted for recruitment in future studies. The low number of male subjects led them to be excluded from this study’s data analysis. There also were a relatively low number of non-White subjects in this sample. The experiences of men and minorities living with this condition may be quite different than those who are represented here (White, non-Hispanic, married, well-educated women).
2. Qualitative Research: An extensive amount of qualitative data was obtained through the administration of this instrument. Each section of the instrument asked subjects to provide further narrative information on each construct of interest (health-related quality of life, social support, stress, self-efficacy, and disease severity). Although not analyzed and interpreted here, this data may prove to provide context for, and understanding of, the quantitative results obtained (Creswell, 2009). Answers to questions around why and how stress, self-efficacy, and social support are positively correlated with health-related quality of life may be provided. Ways in which self-efficacy reduces the effect of stress on health-related quality of life may be elucidated. More importantly, the qualitative data may provide a better understanding of the relationship between social support and health-related quality of life. Further qualitative research may be recommended after the current qualitative data is analyzed and interpreted. For instance, semi-structured, in-depth interviews or focus groups could be conducted to understand better the role of social support in outcomes. Results from qualitative research could lead to the refinement of the instrument (Creswell, 2009).

3. Intervention Research: It is clear that stress can significantly affect outcomes in those living with IC. It also is clear that self-efficacy can mediate that impact. Evidence-based interventions that are known to increase self-efficacy should be implemented with people living with IC. For example, the Chronic Disease Self-Management Program (CDSMP) is an evidence-based program
known to improve outcomes in those living with chronic disease by increasing self-efficacy (Lenker et al., 1984; Lorig, Gonzalez, et al., 1999; Lorig, Chastain, et al., 1989). The CDSMP can be implemented in both face-to-face and online formats and is led by peer facilitators (as opposed to professional health care providers). The multiple formats in which the program can be offered, and the ability of the program to be led by lay individuals, makes it easier to implement by a variety of organizations. For example, organizations that serve individuals who cannot travel easily can offer the program via the Internet. Similarly, organizations who have limited finances can choose to offer a program led by volunteer lay individuals as opposed to paying health care providers to do so (Stanford Patient Education Research Center [SPERC], 2012). Intervention research, which utilizes comparison groups, can assess changes in self-efficacy and health-related quality over time as compared to standard care.

In addition to a focus on outcomes, it is crucial that those who engage in intervention research focus also on implementation context and process. In order to understand how and why a particular intervention has or has not been effective, it is useful to understand the environment in which it was implemented. A process evaluation also can help to elucidate if the intervention was implemented as intended. More sustainable programming for those living with IC in the U.S. may be obtained through an understanding
of contextual and process factors that lead to intervention success, or lack thereof (The National Research Implementation Network, 2012).

**Recommendations for Health Education and Advocacy**

At a minimum, perceptions of stress and self-efficacy can have a significant impact on perceptions of health-related quality of life. In addition, the American Urological Association (AUA) indicates that the primary focus of IC treatment should be improving quality of life through self-care, stress management, and patient education (2011). Arguably, the findings from this study, and the recommendations of the AUA, indicate care for those living with IC that is outside the scope of treatment that urologists typically provide. Health education and promotion (HEDP) professionals are well suited to answer at least some of these “calls to action” through two primary mechanisms:

- **Education:** HEDP professionals are uniquely qualified to engage in the assessment of the IC community and in the planning, implementation, and evaluation of evidence-based programming for those living with IC (National Commission on Health Education Credentialing, Inc. [NCHEC], 2008). HEDP professionals can be called upon to assess unique communities of those living with IC to understand needs. Based on factors associated with outcomes in this population, specific programming can be identified (e.g., evidence-based programs that emphasize effective self-care of chronic disease, stress management, and enhance self-efficacy). HEDP professionals can then engage in plans for implementation, implementation of program activities, and the evaluation of those programs. In the absence of a cure and
truly effective medical treatments for IC, evidence-based, health education programming, with the overall goal of improving health-related quality of life in those living with IC, is of incredible importance.

- Advocacy: HEDP professionals also are uniquely qualified in conveying effective messages and engaging in health advocacy using evidence-based strategies (NCHEC, 2008). As health education programming is identified as effective in those living with IC, this success will need to be conveyed to the health care community. HEDP professionals must be willing to speak up regarding the utility of these strategies in order receive the human and financial support required for their sustainability. Collaboration and communication with other health care professionals also is imperative for ensuring that individuals living with IC receive appropriate treatment from the medical community. For example, HEDP professionals should advocate strongly for their profession to be represented at annual conferences of national organizations, such as the American Urological Association. When it comes to the care of those living with IC, community-based approaches (e.g., evidence-based health education programming) deserve as much attention as the next potential pharmaceutical treatment.

Overall, the human medical community has much to learn from the progress of the veterinary community in the treatment of IC. The veterinary community has researched and implemented successfully environmental enrichment for felines living with this condition. Strategies designed to reduce stress and uncertainty in a cat’s
environment, which can be employed to substantially reduce sickness behaviors, are now being taught to clients (Buffington et al., 2006; Hostutler et al., 2005; Westropp & Buffington, 2004). This holistic approach to care has done more to improve the quality of life of cats with this condition than all of the traditional medical treatments employed to improve symptoms in humans (C.A.T. Buffington, personal communication). Perhaps with a similar approach and strong advocacy, the human health care community can achieve similar success.

Limitations

- First, limitations of the ICA community database would not allow for a randomized sample of community members. The sample in this study was a type of convenience sample, which could also have led to sample selection bias.

- Second, the other national IC organization, the Interstitial Cystitis Network (ICN), was not part of this study. Subjects were not recruited from their membership, and it is possible that ICA members are significantly different than ICN members.

- Third, the demographics of the final data set used in this analysis were fairly homogenous. The majority of the sample reported being White, non-Hispanic, well-educated, and married. The final data set also did not include men. Results could not be used to generalize to the broader IC population in the U.S.

- Fourth, results were based on self-reported data and were subject to error. Self-reported data is subject to issues of bias, particularly recall bias. Subjects may also have introduced error into the study by providing socially desirable responses that were not accurate in reality.
• Fifth, only individuals with access to a computer and the Internet were able to complete the instrument, which could have resulted in sample selection bias.

• Sixth, this study represented cross-sectional survey research. It is not possible to derive causation from any study results, only associations.

• Finally, the actual response rate to the instrument could not be calculated due to the limitations of the ICA community database. Without knowing the number of eligible individuals living with IC in that database, it was not possible to calculate the percentage of eligible individuals who chose to respond to the instrument.
APPENDICES
APPENDIX A

INSTRUMENT
Appendix A

Instrument

### Quality of Life & IC Study

#### 1. Introduction to the Survey

Thank you for your interest in participating in the "Quality of Life & IC Study." You are eligible to complete this survey if you have been diagnosed with interstitial cystitis (IC) at some point in your life, and you are 18 years of age or older.

The purpose of this study, which consists of a one-time, online anonymous survey, is to gain a better understanding of the types of things that impact quality of life in people living with IC. This survey asks questions about your perceptions of quality of life, social support, stress, your ability to do the things that you need/want to do in life, disease symptoms and severity, and basic demographics. The survey is short and takes no more than 30 minutes to complete. The survey is anonymous, as it does not ask for any identifying information.

This study is being conducted by Laura Santuri, MPH, CPH, a doctoral candidate in Health Education and Promotion at Kent State University (KSU) and with the support of the Interstitial Cystitis Association (ICA). In addition to being an IC patient for the past 14 years, Ms. Santuri has also been involved in IC support group leadership and patient advocacy for the past decade, as well as IC research (through her academic) for the past eight years. Her research efforts are guided by her dissertation committee, which consists of faculty from both KSU and The Ohio State University.

There are no risks in participating in this study that are greater than those encountered in everyday life, and you would be subject to no penalties or consequences if you decide not to participate. You may also stop answering questions and withdraw from the study at any time without penalty. Your completion of this survey is your consent to participate in the study.

If you would like to obtain additional information about the study, please contact:

Laura Santuri, MPH, CPH
17576 Auburn Road
Chagrin Falls, Ohio, 44023
lsanturi@kent.edu (e-mail)
330-672-1600 (phone)

OR

Kele Ding, MD, PhD
142 Nixon Hall
Kent State University
Kent, Ohio 44242
kding@kent.edu (e-mail)
330-672-5888 (phone)

Information about KSU’s rules for research can be obtained by contacting the IRB at 330-672-2704.

Thank you for your time and consideration. Your participation in this study may help us to have a better understanding of what it is like to live with IC.

If you are ready to take the survey, please click "Next."
### Quality of Life & IC Study

#### 2. Study Eligibility

These questions will determine if you are eligible to take the survey. If it is determined that you are not eligible to take the survey (i.e. you have not been diagnosed with IC and/or you are not 18 years of age and older), the survey will automatically close.

**1. Have you been diagnosed with interstitial cystitis (IC) by a health care provider at some point in your life?**

- [ ] Yes
- [ ] No
<table>
<thead>
<tr>
<th>Quality of Life &amp; IC Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Study Eligibility (con’t)</td>
</tr>
<tr>
<td>* 2. Are you 18 years of age or older?</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
Quality of Life & IC Study

4. Study Eligibility (con’t)

*3. You have indicated that you have not been diagnosed with interstitial cystitis (IC) by a health care provider. If this is not correct, and you have been diagnosed with IC, please click the "Prev" button to change your answer to the previous question. If it is the case that you are not an IC patient, please take a second to indicate your role in the IC community. Please select all that apply.

- [ ] Health Care Provider
- [ ] Researcher
- [ ] Other

Other (please specify):
Quality of Life & IC Study

5. Quality of Life

The following questions will ask you about your overall health, as well as your physical and mental health.

4. Would you say that, in general, your current health is:
   - Excellent
   - Very Good
   - Good
   - Fair
   - Poor

5. Compared to one year ago, how would you rate your health in general now?
   - Much better than one year ago
   - Somewhat better than one year ago
   - About the same
   - Somewhat worse than one year ago
   - Much worse than one year ago

6. If there has been a change in your health in the past year, how much of that change is related to your IC?
   - I have not had a change in my health in the past year
   - None of the change is related to IC
   - A small amount of the change is related to IC
   - A moderate amount of the change is related to IC
   - A significant amount of the change is related to IC
   - All of the change is related to IC

7. Do you have a chronic illness(es) other than IC?
   - Yes
   - No
Quality of Life & IC Study

6. Quality of Life (con't)

8. If there has been a change in your health in the past year, how much of that change is related to another chronic illness(es) that you have?

- I have not had a change in my health in the past year
- None of the change is related to my other chronic illness(es)
- A small amount of the change is related to my other chronic illness(es)
- A moderate amount of the change is related to my other chronic illness(es)
- A significant amount of the change is related to my other chronic illness(es)
- All of the change is related to my other chronic illness(es)

9. The following items are about activities you might do during a typical day. Does your IC now limit you in these activities? If so, please indicate how much.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Yes, limited a lot</th>
<th>Yes, limited a little</th>
<th>No, not limited at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifting or carrying groceries</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Climbing several flights of stairs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Climbing one flight of stairs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bending, kneeling, or stooping</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking more than one mile</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking several blocks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking one block</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Quality of Life & IC Study

**7. Quality of Life (con’t)**

The following questions will ask you about your overall health, as well as your physical and mental health.

**10. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your IC?**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut down the amount of time you spent on work or other activities</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Accomplished less than you would like</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Were limited in the kind of work or other activities</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Had difficulty performing the work or other activities (for example, it took extra effort)</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

**11. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious) that were brought on by your IC?**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut down the amount of time you spent on work or other activities</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Accomplished less than you would like</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Didn’t do work or other activities as carefully as usual</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

**12. During the past 4 weeks, to what extent has your IC interfered with your normal social activities with family, friends, neighbors, or groups?**

- [ ] Not at all
- [ ] Slightly
- [ ] Moderately
- [ ] Quite a bit
- [ ] Extremely
Quality of Life & IC Study

13. How much IC-related pain have you had during the past 4 weeks?
   - None
   - Very mild
   - Mild
   - Moderate
   - Severe
   - Very severe

14. During the past 4 weeks, how much did your IC pain interfere with your normal work (including both work outside the home and housework)?
   - Not at all
   - A little bit
   - Moderately
   - Quite a bit
   - Extremely
Quality of Life & IC Study

8. Quality of Life (con't)

The following questions will ask you about your overall health, as well as your physical and mental health.

15. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes the closest to the way you have been feeling.

How much of the time during the past 4 weeks...

<table>
<thead>
<tr>
<th>Did you feel full of pep?</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Have you been a very nervous person?</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Have you felt so down in the dumps that nothing could cheer you up?</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Have you felt calm and peaceful?</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Did you have a lot of energy?</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Have you felt downhearted and blue?</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Did you feel worn out?</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Have you been a happy person?</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Did you feel tired?</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Has your physical problems or emotional problems interfered with your social activities, like visiting with friends, relatives, etc.?</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
</table>

16. How TRUE or FALSE is each of the following statements for you?

<table>
<thead>
<tr>
<th></th>
<th>Definitely true</th>
<th>Mostly true</th>
<th>Don't know</th>
<th>Mostly false</th>
<th>Definitely false</th>
</tr>
</thead>
<tbody>
<tr>
<td>I seem to get sick a little easier than other people</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I am as healthy as anybody I know</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I expect my health to get worse</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My health is excellent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
17. Is there anything else that you would like to share about IC and your quality of life?
## 9. Social Support

The next set of questions will ask you about how often social support is available to you, if you need it.

18. **People sometimes look to others for companionship, assistance, or other types of support. How often is each of the following kinds of support available to you, if you need it? Select one answer on each line.**

<table>
<thead>
<tr>
<th>Kind of Support</th>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Someone you can count on to listen to you when you need to talk</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to give you information to help you understand a situation</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to give you good advice about a crisis</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to confide in or talk to about yourself or your problems</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone whose advice you really want</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to share your most private worries and fears with</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to turn to for suggestions about how to deal with a personal problem</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone who understands your problems</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to help you if you were confined to bed</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to take you to the doctor if you needed it</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to prepare your meals if you were unable to do it yourself</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to help you with daily chores if you were asked</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
Quality of Life & IC Study

10. Social Support (con’t)

The next set of questions will ask you about how often social support is available to you, if you need it.

19. People sometimes look to others for companionship, assistance, or other types of support. How often is each of the following kinds of support available to you, if you need it? Select one answer on each line.

<table>
<thead>
<tr>
<th>Kind of Support</th>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Someone who shows you love and affection</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Someone to love and make you feel wanted</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Someone who hugs you</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Someone to have a good time with</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Someone to get together with for relaxation</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Someone to do something enjoyable with</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Someone to do things with to help you get your mind off things</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

20. Is there anything else that you would like to share about your IC and social support?
### Quality of Life & IC Study

#### 11. Stress

The following questions will ask you about stress in your life.

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>21. In the past month, how often have you felt overwhelmed by the demands placed on you in your life?</td>
<td>Never, Rarely, Sometimes, Often, Always</td>
</tr>
<tr>
<td>22. In the past month, how often have you felt frustrated trying to live up to your own expectations and standards?</td>
<td>Never, Rarely, Sometimes, Often, Always</td>
</tr>
<tr>
<td>23. In the past month, how often have you felt that your needs as a person were being left unmet?</td>
<td>Never, Rarely, Sometimes, Often, Always</td>
</tr>
<tr>
<td>24. In the past month, how often have you felt uncertain or apprehensive about your future?</td>
<td>Never, Rarely, Sometimes, Often, Always</td>
</tr>
<tr>
<td>25. In the past month, how often have you felt that there were problems in your life that could just not be solved?</td>
<td>Never, Rarely, Sometimes, Often, Always</td>
</tr>
<tr>
<td>26. In the past month, how often have you felt that there were so many everyday hassles and crises that you lost track of the things that were really important to you?</td>
<td>Never, Rarely, Sometimes, Often, Always</td>
</tr>
<tr>
<td>27. Is there anything else that you would like to share about your IC and stress?</td>
<td>Blank box for comments</td>
</tr>
</tbody>
</table>
## 12. Self-Efficacy

The following questions will ask you about how the symptoms of interstitial cystitis (IC) affect you.

For each of the questions, please indicate the number which corresponds to your certainty that you can now perform the following tasks (with 1 = Very Uncertain and 10 = Very Certain).

### 28. As of now, how certain are you that you can (with 1 = Very Uncertain and 10 = Very Certain):  

<table>
<thead>
<tr>
<th>Question</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decrease your IC symptoms quite a bit?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continue most of your daily activities?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keep IC symptoms from interfering with your sleep?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Make a small to moderate reduction in your IC symptoms by using methods other than taking extra medication?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Make a large reduction in your IC symptoms by using methods other than taking extra medication?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Quality of Life & IC Study

## 13. Self-Efficacy (continued)

The following questions will ask you how you feel about your ability to control your IC.

For each of the following questions, please indicate the number that corresponds to the certainty that you can now perform the following activities or tasks (with 1 = Very Uncertain and 10 = Very Certain).

### 29. As of now, how certain are you that you can (with 1 = Very Uncertain and 10 = Very Certain):

<table>
<thead>
<tr>
<th>Activity</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control your fatigue?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjust your activities to remain active without aggravating your IC?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do something to help yourself feel better if you are feeling blue?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manage your IC symptoms during daily activities?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manage your IC symptoms so that you can do the things that you enjoy doing?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deal with the frustration of IC?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Quality of Life & IC Study

### 14. Self-Efficacy (continued)

The next questions ask you about how confident you are about performing certain activities.

For each of the following questions, please indicate the number that corresponds to your certainty that you can perform the tasks as of now (with 1 = Very Uncertain and 10 = Very Certain). Please consider what you routinely do, not what would require a single extraordinary effort.

#### 30. As of now, how certain are you that you can (with 1 = Very Uncertain and 10 = Very Certain):

<table>
<thead>
<tr>
<th>Task</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work as much as you would like?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintain your social life?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Travel away from home for a weekend?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enjoy sexual intercourse?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have uninterrupted sleep for longer than three hours?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise as you did in the past?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eat the foods that you like to eat?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Take care of family responsibilities?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Go longer than 3 hours before emptying your bladder during the day?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Go longer than 3 hours before emptying your bladder during the night?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 31. Is there anything else that you would like to share about your IC and self-efficacy?
### Quality of Life & IC Study

#### 15. IC Symptoms

The following questions will ask you about your IC symptoms.

**32. Please answer the questions below related to your IC symptoms.**

**During the past month (4 weeks):**

<table>
<thead>
<tr>
<th>Question</th>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>A good bit of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>How often have you felt the need to urinate with little or no warning?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Have you had to urinate less than 2 hours after you finished urinating?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Have you experienced pain, burning, or discomfort due to your IC?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

**33. During the past month (4 weeks), how often did you most typically get up at night to urinate?**

- ○ None
- ○ One time
- ○ Two times
- ○ Three times
- ○ Four times
- ○ Five or more times
### Quality of Life & IC Study

#### 16. IC Problems

The following questions will ask you about problems you may or may not have with your IC.

34. Please answer the following questions related to the problems associated with your IC symptoms.

**During the past month (4 weeks):**

<table>
<thead>
<tr>
<th>Problem Description</th>
<th>No problem</th>
<th>Very small problem</th>
<th>Small problem</th>
<th>Medium problem</th>
<th>Big problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>How much of a problem has frequent urination during the day been for you?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much of a problem has getting up at night to urinate been for you?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much of a problem has the need to urinate with little warning been for you?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much of a problem has pain, burning, or discomfort due to your IC been for you?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

35. Is there anything else that you would like to share about your IC and your symptoms?
17. Demographics

The following questions will ask you to tell us a little bit more about yourself.

36. Do you live in a state or territory of the United States?

- Yes
- No
<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>37. In what U.S. state or territory do you live?</td>
</tr>
</tbody>
</table>


38. In what country do you live?

39. Please describe to the best of your ability the type of community in which you live by choosing one of the following options - urban, suburban or rural.

People who live in urban areas often live in cities, where buildings are closer together and built higher. There is generally a form of public transportation available.

People who live in suburban areas often live in the outskirts of cities and commute to work. Buildings are further apart and lower than in cities. The population is lower than that of cities.

People who live in rural areas live in areas where there is more land, and the population is lower. Buildings are usually further apart than in suburban areas.

  - Urban
  - Suburban
  - Rural

40. How old are you (in years)?

41. What is your gender?

  - Male
  - Female
  - Other

42. Are you Hispanic or Latino?

  - Yes
  - No
Quality of Life & IC Study

43. What do you consider to be your race? Please select all that apply.

☐ American Indian
☐ Asian
☐ Native Hawaiian/Other Pacific Islander
☐ Black/African American
☐ White/Caucasian
☐ Other

44. If Other, please specify:

[Blank space for specification]
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>45. What is your marital status?</td>
<td>Married, Divorced, Married but separated, Widowed, In a Relationship, Single</td>
</tr>
<tr>
<td>46. What is the highest level of education that you've completed?</td>
<td>Eighth grade or less, Some high school, High school graduate or GED, Some college, College graduate, Graduate degree</td>
</tr>
<tr>
<td>47. Are you currently employed (either full-time or part-time)?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>48. How long, in years, have you had symptoms of interstitial cystitis (IC) or painful bladder syndrome (PBS)? Please round to the nearest whole number.</td>
<td>123</td>
</tr>
<tr>
<td>49. How long, in years, has it been since you were diagnosed with interstitial cystitis (IC) or painful bladder syndrome (PBS)? Please round to the nearest whole number.</td>
<td>456</td>
</tr>
</tbody>
</table>
21. Demographics (con’t)

The next question asks you to identify other health problems that you may have, in addition to your IC. This is a longer question, but you’re almost done with the survey.

**50. For each of these symptoms below, please indicate how much each of these has bothered you during the past month (4 weeks). If you have not experienced a particular symptom, please select “Not Applicable.”**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Not applicable</th>
<th>No problem</th>
<th>Very small problem</th>
<th>Small problem</th>
<th>Medium problem</th>
<th>Big problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>Muscle pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immune deficiency</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue/tiredness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thinking or remembering problem</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muscle weakness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain/cramps in abdomen</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Numbness/fainting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insomnia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain in upper abdomen</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nervousness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chest pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blurred vision</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dry mouth</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Itching</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wheezing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raynaud's Syndrome</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hives/welts</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ringing in ears</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heartburn</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral ulcers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Page 24
<table>
<thead>
<tr>
<th>Quality of Life &amp; IC Study</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss/change in taste</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seizures</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dry eyes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shortness of breath</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loss of appetite</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sun sensitivity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hearing difficulties</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Easy bruising</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hair loss</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other (please specify)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality of Life &amp; IC Study</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>22. Demographics (con’t)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>51. Is there anything else that you would like to share about yourself and your experience living with IC?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

Page 26
Quality of Life & IC Study

23. Thank You!

Thank you so much for taking the time to complete this survey. If you have any further comments that you would like to share, please do so below. When you are done with the survey, click "Done" below.

52. Further Comments:
APPENDIX B

SCALE PERMISSIONS
Appendix B

Scale Permissions

Terms and Conditions for Use | RAND

Terms and Conditions for Using the 36-Item Short Form Health Survey

RAND hereby grants permission to use a "RAND-36-item Short Form Health Survey," in accordance with the following conditions, which shall be assented to as a consequence of accepting and using this document:

1. Changes to the health survey may be made without written permission of RAND. However, all such changes shall be clearly identified as having been made by the recipient.

2. The user of this health survey accepts full responsibility, and agrees to indemnify and hold RAND harmless, for any loss of any translation of the health survey, in any language or in any form, errors, omissions, misinterpretations, or consequences thereof.

3. The user of this health survey accepts full responsibility, and agrees to indemnify and hold RAND harmless, for any consequences resulting from the use of this health survey.

4. The user of the 36-item health survey will provide a credit line when printing and distributing this document, acknowledging that it was developed at RAND as part of the Medical Outcomes Study.

5. No further written permission is needed for use of this health survey.

http://www.rand.org/health/surveys_tools/mos/mos_core_36item_terms.html 1/28/2012
Laura Santurri, MPH

From: Scott H Frank <shf2@case.edu>
Sent: Thursday, February 16, 2012 11:50 AM
To: 'Laura Santurri, MPH'
Subject: RE: dissertation question

Please consider this formal permission to use the Brief Encounter Perceived Stress Instrument in your dissertation research.

sf

Scott Frank, MD, MS
Director, Master of Public Health Program
Department of Epidemiology and Biostatistics
Department of Family Medicine
10900 Euclid Avenue
Cleveland, Ohio 44106-4945
Office (216) 368-3725
Fax (216) 368-2286

Laura Santurri, MPH [mailto:les24@case.edu]
Sent: Thursday, February 16, 2012 10:42 AM
To: Scott H Frank
Subject: dissertation question

Scott,

I would like to formally request approval to utilize the Brief Encounter Psychosocial Instrument (BEPSI) in the instrument that I am using for my dissertation. Would this be acceptable?

Thanks!

Laura Santurri, MPH, CPH
Administrative Director
Master of Public Health Program
Case Western Reserve University
10900 Euclid Avenue, W-G74
Cleveland, Ohio 44106-4945
(216)368-3128 - phone
(216)368-2286 - fax
lsan@case.edu - e-mail

Doctoral Candidate
Health Education and Promotion
College and Graduate School of Education, Health, and Human Services
Kent State University
Hi Laura,

Yes, you absolutely have my permission to use it in any way you find helpful, without attribution. I developed it many (maybe 15?) years ago based on guidelines made available by Kate Lorig & Al Bandura. I shared it with them for critique, and they agreed that, without knowing anything about IC, it was reasonable worded. I then "face validated" it by sharing it with some IC patients (I can't remember how many, maybe 10-15?) who thought it captured the concept adequately. What I did NOT do is any test-retest validation, or determine if it might be sensitive to change in condition with disease activity or therapy. I am not suggesting that you do this unless you think it is important for your research.

I've long thought that the concept of SE might be useful for patients with central sensitivity syndromes (CSS) like IC because I see them as a "fragile population" in the learning sense of the term - they want to help themselves get better but have no SE that they can. (I recognize that this is a gross generalization and simplification, and mean no offense by my lazy use of language).

We made another instrument to query other CSS and pelvic issues that I can send you from work tomorrow if you are interested in looking at it.

Best regards,

Tony

C. A. Tony Buffington, DVM, PhD, DACVN
Professor of Veterinary Clinical Sciences
The Ohio State University Veterinary Medical Center

Dr. Buffington,

I would like to formally request permission to utilize your IC Self-Efficacy Instrument on the instrument that I am using for my dissertation. Is this acceptable?

Thank you!
P.S. Getting close – I should be sending you a full proposal in the next couple of weeks. I actually just got IRB-approval for my dissertation protocol as well.

Laura Santurri, MPH, CPH  
Administrative Director  
Master of Public Health Program  
Case Western Reserve University  
10900 Euclid Avenue, W-674  
Cleveland, Ohio 44106-4945  
(216)368-3128 - phone  
(216)368-2286 - fax  
laura.santurri@case.edu - e-mail

Doctoral Candidate  
Health Education and Promotion  
College and Graduate School of Education, Health, and Human Services  
Kent State University
Laura Santurri, MPH

From: Buffington, Tony <Tony.Buffington@cvm.osu.edu>
Sent: Monday, February 20, 2012 8:14 AM
To: Laura Santurri, MPH
Subject: RE: Santurri Dissertation Proposal

Thanks Laura,
I look forward to reading this! When will you have the refs? (I find it helpful to have them when I read such material). I also got a vmail message from Grannum Sant confirming that the OLS is in the public domain and can be freely used.

Cheers for now,
Tony

C. A. Tony Buffington, DVM, PhD, DACVN
The Ohio State University Veterinary Medical Center
The Indoor Pet Initiative

"The only thing harder than taking advice is not giving it."

---

From: Laura Santurri, MPH [mailto:less24@case.edu]
Sent: Sunday, February 19, 2012 5:51 PM
To: SYMONS, CYNTHIA; kdinng@kent.edu; Buffington, Tony
Subject: Santurri Dissertation Proposal

Drs. Symons, Ding, & Buffington,

Please find attached chapters 1-3 of my dissertation proposal. These include all requested revisions to date. I have also attached the four appendices, which are mentioned in chapter three. I apologize that I’m not sending my references with this email – I am still cleaning those up (I’ve been merging my Mendeley and EndNote libraries) and will get my reference list to you as soon as possible.

If you have any requested revisions prior to the proposal meeting, please let me know – this is my number one priority right now.

Thank you!

Laura Santurri, MPH, CPH
Administrative Director
Master of Public Health Program
Case Western Reserve University
10900 Euclid Avenue, W-G74
Cleveland, Ohio 44106-4945
(216)368-3128 - phone
(216)368-2286 - fax

1
APPENDIX C

ICA LETTER OF SUPPORT
Appendix C

ICA Letter of Support

Dissertation Committee
Health Education and Promotion
Kent State University
Kent, Ohio

January 6, 2011

Dear Committee Members,

On behalf of the Interstitial Cystitis Association (ICA), I am pleased to offer this letter of support for the dissertation research of Laura Santurri, MPH, CPH, on the effect of social support and self-efficacy on the impact of stress on health-related quality of life in people living with interstitial cystitis (IC).

As the only nonprofit association dedicated solely to improving the quality of healthcare and lives of people living with IC, the ICA is excited about the opportunity to work with Laura on her dissertation by sending out study invitation emails to the IC community with which the ICA is connected. This approach allows Laura to benefit from the reach of our targeted patient network while permitting the ICA to abide by our policy of not selling or disseminating patient data.

We are grateful for the opportunity to work with Laura on this research and look forward to her sharing useful trending information about our membership, as well as suggestions about the type of health education and support that could be provided by the ICA to the more than four million people affected by this chronic, life-altering bladder condition.

Please let me know if I can be of additional assistance.

Sincerely,

Barbara Gordon, RD
Executive Director, Interstitial Cystitis Association
bgordon@ichelp.org

Interstitial Cystitis Association, 1760 Old Meadow Road, Suite 500, McLean, VA 22102
www.ichelp.org
Appendix D

IRB Approval and Application

Laura Santurri, MPH

From: KIEHL, LAURIE <kiehl@kent.edu>
Sent: Friday, February 03, 2012 10:41 AM
To: laura.santurri@case.edu
Cc: DING, KELE
Subject: IRB approval for Protocol application #12-053 - please retain this email for your records

RE: Protocol #12-053 entitled "Quality of Life & IC Study"

I am pleased to inform you that the Kent State University Institutional Review Board has reviewed and approved your Application for Approval to Use Human Research Participants as Level I/Exempt research. This application was approved on February 2, 2012. Your research project involves minimal risk to human subjects and meets the criteria for the following category of exemption under federal regulations:

- Exemption 2: Research involving the use of educational tests, surveys, interviews, or observation of public behavior.

***Submission of annual review reports is not required for Level I/Exempt projects.***

If any modifications are made in research design, methodology, or procedures that increase the risks to subjects or include activities that do not fall within the approved exemption category, those modifications must be submitted to and approved by the IRB before implementation. Please contact the IRB administrator to discuss the changes and whether a new application must be submitted. It is important for you to also keep an unstamped text copy (i.e., Microsoft Word version) of your consent form for subsequent submissions.

Kent State University has a Federal Wide Assurance on file with the Office for Human Research Protections (OHRP); PIW Number: 0003853.

If you have any questions or concerns, please contact me by phone at 330-672-2704 or by email at Pwashko@kent.edu.

Respectfully,
Kent State University Office of Research Compliance
224 Cartwright Hall | fax 330.672.2658

Kevin McCreary | Research Compliance Coordinator | 330.672.8058 | kmccrea1@kent.edu
Laurie Kiehl | Research Compliance Assistant | 330.672.0837 | likiehl@kent.edu
Paulette Washko | Manager, Research Compliance | 330.672.2704 | Pwashko@kent.edu

For links to obtain general information, access forms, and complete required training, visit our website at www.kent.edu/research.
KENT STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD
APPLICATION FOR APPROVAL TO USE HUMAN RESEARCH SUBJECTS

Move through this document using TAB or mouse. DO NOT USE THE ENTER KEY. Please type all information.
HANDWRITTEN FORMS WILL NOT BE ACCEPTED. To check a box, double-click in the box.
Submit completed form with signatures and all required attachments to the IRB RESEARCHER associated with your
Department or College, or to: Office of Research Safety and Compliance, Research and Graduate Studies, 137 Cartwright
Hall. Fax: 330-576-2744.

Project Title: Quality of Life & LC Study

Principal Investigator:
Name: Laura Santurri, MPH, CPH
Address: 17576 Auburn Road; Chagrin Falls, Ohio 44023
Phone: 330-600-1630
Status: □ Faculty PROJECT: □ Faculty Research
□ Doctoral Student □ Student Dissertation
□ Graduate Student □ Student Thesis
□ Undergraduate Student □ Course Requirement: (Course #: )
□ Other: (Specify: )

KSU Faculty Co-Investigator(s) (Use additional sheet if necessary)
Name: Department:
Address: Email:
Phone:
Status: □ Faculty □ other (Specify:)
□ Doctoral Student □ Graduate Student
□ Undergraduate Student

Faculty Advisor (If PI is a student)
Name: Kele Ding, MD, PhD
Address: 1350 S. 2nd St., Ft. Worth, TX 76104
Phone: 330-672-0688
Department: Health Education & Promotion
Email: kding@kent.edu

Protocol Funding: □ Not-applicable □ Pending □ Awarded Federal: □ Yes □ No
Funding Agency: N/A
If funded or pending, attach detailed information regarding proposal (including title).

Estimated Project Duration: Starting Date: 2/1/2012 (But not before approval is obtained)
Ending Date: 2/1/2013

IRB IRB USE ONLY

<table>
<thead>
<tr>
<th>IRB Reviewer Determination</th>
<th>IRB Administration Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I = Exempt Category</td>
<td>Approved Level I = Exempt Category</td>
</tr>
<tr>
<td>Level II = Expedited Category</td>
<td>Approved Level II = Expedited Category</td>
</tr>
<tr>
<td>Level III = Full Board Review</td>
<td>Disapproved</td>
</tr>
</tbody>
</table>

Primary Reviewer: Date
Secondary Reviewer: Date
Administrator, IRB: Date
Chair, IRB: Date

Full Board Review Action: Approved □ Contingent Approval □ Tabled □ Disapproved
Meeting Date: Date

AGENDA Date
Contact persons
E-mail approval
Date
E-mail notice of revised review
Date
IRB NUMBER:

Part I: Please answer the following questions by checking the correct response.

☐ Yes ☐ No 1. Will participants be identifiable to anyone other than the researchers through records, responses, or identifiers linked to the participants?

☐ Yes ☐ No 2. Could participants be at risk of criminal or civil liability, damage to employability or to financial standing, or undue embarrassment, if responses become known outside this research project?

☐ Yes ☐ No 3. Does research deal with sensitive aspects of participants' behavior, such as illegal conduct, drug use, sexual behavior, use of alcohol, or potential harm to self or others?

☐ Yes ☐ No 4. Does research involve the study of existing data? (If yes, please specify.)

☐ Yes ☐ No 5. Does the research involve audio, video, digital, or image recordings of participants? (If yes, please specify.)

☐ Yes ☐ No 6. Are participants free to withdraw at any time without penalty?

☐ Yes ☐ No 7. Is there deception of participants? (If so, answer questions in Part VII, #35-44)

☐ Yes ☐ No 8. Does the research deal with participants under the age of 18?

☐ Yes ☐ No 9. Will identifiable medical information be collected?

10. Does the research deal with any of the following vulnerable populations:

☐ Yes ☐ No Legally incompetent adults ☐ Yes ☐ No Traumatized or Comatose

☐ Yes ☐ No Cognitively/Mentally impaired ☐ Yes ☐ No Economically disadvantaged

☐ Yes ☐ No Physically challenged ☐ Yes ☐ No Terminally ill

☐ Yes ☐ No Pregnant woman ☐ Yes ☐ No Prisoners

11. Does the project involve: (If yes, also answer question #20 on page 4.)

☐ Yes ☐ No Administering drugs ☐ Yes ☐ No Medical devices

☐ Yes ☐ No Administering alcohol ☐ Yes ☐ No Invasive procedures

☐ Yes ☐ No Administering nutritional supplements ☐ Yes ☐ No Drawing blood

☐ Yes ☐ No Taking tissue samples ☐ Yes ☐ No Giving injections

12. Are you collecting any portion of your data online? ☐ Yes ☐ No

13. Are you requesting a waiver of any elements of the consent process? ☐ Yes ☐ No

(If yes, answer questions in Part VIII, #48-44.)

Part II: Summary of Research

14. Describe the purpose and significance of the proposed research. Include background information and the specific objectives of the study. Summarize the major hypotheses. (Use non-technical language that can be understood by someone outside the disciplines.)

The purpose of this study will be to analyze the relationships between stress, self-efficacy, social support, and health-related quality of life among individuals living with interstitial cystitis (IC). In addition, this study will examine self-efficacy as a mediator in the relationship between stress and health-related quality of life and social support as a
moderator of the impact of self-efficacy on health-related quality of life in individuals living with IC with moderate to high stress.

The research questions associated with this study are guided by the Transactional Model of Stress and Coping (Lazarus & Folkman, 1977) and are:

1. Are there significant associations between stress, self-efficacy, social support, and health-related quality of life in individuals living with IC?

2. Does self-efficacy mediate the impact of stress on health-related quality of life in individuals living with IC?

3. In those with moderate to high stress, does social support moderate the effect of self-efficacy on health-related quality of life in individuals living with IC?

Interstitial cystitis (IC) is a chronic condition of the bladder characterized by symptoms similar to that of a common urinary tract infection - urinary urgency, frequency, and pain. It has an unknown etiology, diagnosis of exclusion, and a variety of treatments, none of which are effective for the majority of patients. Common approaches to the treatment of this condition include multimodal therapy and complementary or alternative modes of care (Interstitial Cystitis Association [ICA], 2011). Current guidelines from the American Urological Association (AUA) emphasize patient education, self-care, and stress-management (AUA, 2011).

The severity of IC differs from patient to patient; however, it can have a significant impact on health-related quality of life. Symptoms can impact the daily functioning of IC patients and have consequences for physical, emotional, social, and occupational aspects of health (Wagner, Shea, & Sant, 1997; Ratbrock, Langendorf & Kelder, 2003). Current literature suggests that such things as social support, stress, and self-efficacy have significant relationships with health (Bandura, 1977; Breaux & Norman, 2003; Breslin, 2010). In the absence of a cure or fully effective treatments for IC, it is hoped that this study will lead to an understanding of alternate mechanisms for positively impacting the health-related quality of life of IC patients.

References - see Appendix A.

15.) Describe the study design, research methods and procedures. (Please append copies of the consent form and all measures, including interview questions and self-report questionnaires, to this form.) What are the qualifications of the individuals who will be collecting the data?

This study represents a cross-sectional, survey research design and will involve a population sample of patient members of the Interstitial Cystitis Association (ICA). All individuals in the ICA database (for whom an e-mail address is available) will be e-mailed an invitation letter (see Appendix B) to participate in the study by a staff member of the ICA. The invitation letter will include a link to an anonymous, online survey via SurveyMonkey.com. Any person who has been diagnosed with IC and who is 18 years and older, will be eligible to participate in the study. Other than those requirements, there are no other inclusion/exclusion criteria.

When participants visit the survey link, they will be informed of the purpose of the study, that it is anonymous and completely voluntary, and that they can withdraw at any time without penalty. They will be consented through this "verbal script" (see Appendix C), since a written-informed consent form would be the only record linking the subject to the research.

Questions on the survey instrument (see Appendix D) will ask the subject about their perceptions of quality of life, social support, stress, self-efficacy, disease severity, and demographics. An option to provide open-ended comments is also provided after each section in the survey and at the end of the survey.

The survey will be open for approximately one month, and a reminder about the survey will be sent by an ICA staff member at the beginning of the third week of survey administration (see Appendix E). When survey administration closes, data will be exported from SurveyMonkey.com to IBM SPSS 20.0 for analysis. The data analysis protocol will begin with data cleaning and simple descriptive statistics for assessing missing cases, outliers, and the distribution of the data. Some variables will need to be computed (scores from each instrument) or recoded (scores may need to be converted to categorical variables, such as low, medium, and high). Simple correlations, independent samples t-tests, and Chi-square analyses will be used to assess for associations between variables. More complex regression modeling will be used to assess the mediators and moderators of the impact of stress on health-related quality of life.

Study results will be disseminated via dissertation defense, manuscript publication, presentation at national conferences, and a report provided to the ICA.
IRB NUMBER: __________

This study will be lead by Laura Santurri, MPH, CPH, a doctoral candidate in Health Education and Promotion at Kent State University. In addition, being an IC patient for the past 14 years, Ms. Santurri has also been involved in IC support group leadership and patient advocacy for the past decade, as well as IC research (through her dissertation) for the past eight years. She is also considered an IC Champion & Advocate for the Interstitial Cystitis Association (ICA) and will be serving as a patient expert at an upcoming NIDDK conference. Her dissertation efforts are guided by the co-chairs of her committee, including Cynthia Symons, PhD, CHES, and Renee Ding, MD, PhD. In addition, her outside committee member, CA. Tony Buffington, DVM, PhD from The Ohio State University, is an NIH-funded IC researcher.

Part III: Research Participants

16.) Briefly describe the characteristics of your population(s). Describe the ethnic background, sex, age, state of health, and the criteria for inclusion or exclusion of participants. (Include rationale for use of special classes of participants such as pregnant women, children, institutionalized mentally disabled, prisoners, or those whose ability to give voluntary informed consent may be in question.) If your population is all one gender or ethnic group, please explain.

This study represents a population sample approach and will consist of all patient members of the ICA for whom an email address is available. Any person who has been diagnosed with IC, and who is 18 years and older, will be eligible to participate in the study. Other than those requirements, there are no other inclusion/exclusion criteria.

17.) Indicate the anticipated sample size.

Given the number of variables of interest, it is hoped (and anticipated) that the final sample size will be at least 200 subjects.

18.) Explain the recruitment process. State how potential participants will be identified and who will make the initial contact. Explain how you will ensure that recruitment and selection of participants is equitable. (Please include all recruitment materials, including scripts, flyers, and advertisements as attachments to this form.)

All patient members of the ICA (for whom an e-mail address is available) will be e-mailed an invitation letter (see Appendix E) to participate in the study by a staff member of the ICA. The invitation letter will include a link to an anonymous, online survey via SurveyMonkey.com. The ICA has a database of 30,000 IC patients, health care providers, and researchers. The study invitation e-mail will be clear that the survey is meant for patients only, and the first question on the survey itself will ask the respondent to identify their role. If they indicate something other than being an IC patient, they will be diverted from the actual survey to another page explaining the survey is for patients only. The survey will be open for approximately one month, and a reminder about the survey will be sent by an ICA staff member at the beginning of the third week of survey administration (see Appendix E).

Part IV: Risks/Benefits

19.) Identify any expected or potential risks or discomforts (including physical, psychological, social, or legal) to which participants may be exposed as a result of participation in the research project (beyond those encountered in everyday life).

There are no potential physical or social risks to which participants will be exposed. While psychological risk is possible, due to answering questions that address issues such as quality of life, social support, stress, self-efficacy, and disease severity, the risk is minimal and not beyond those encountered in everyday life.

a.) What safeguards will you use to protect the participants from these risks, as well as to protect their rights, welfare, and privacy? (Must provide a response; never answer "N/A")

Participants will be informed that they can stop answering questions and withdraw from the study at any time without penalty or consequence.

20.) Describe the anticipated benefits to individual subjects and to society expected to be gained from this project. (This should include any direct benefits to the participants as well as any generalizable gain in knowledge. If there are not direct benefits to individual subjects, state that.)

With a better understanding of the relationships between the perceptions of quality of life, social support, stress, and self-efficacy, we may find new ways of positively intervening in the lives of people living with IC. While participants may not gain any direct benefit by participating in this study, the information that they provide may lead to interventions that could potentially benefit both them and others living with the condition, in a direct manner.

21.) Describe the qualifications of the person administering drugs, alcohol, or nutritional supplements, or drawing blood, taking tissue samples, or giving injections.
IRB NUMBER: __________

Please note:

i. Persons doing venipuncture must provide a copy of their certification to draw blood and proof that they completed a blood-borne pathogens training course.

ii. Inserting various catheters and lines can only be inserted and accessed by licensed/registered/certified medical personnel such as physicians, RNs, and EMTs. Proof of certification is required.

iii. Arterial blood sampling can only be carried out in an appropriate medical facility such as a hospital, clinic, or the KIU Health Center. The procedure can only be carried out by qualified personnel under the direct supervision of a licensed physician.

N/A

22.) Describe any form of compensation to participants. (i.e., money, extra credit, etc. If money, extra credit, or grade is given to students who participate in the project, what opportunity for extra credit or grade is provided to students who choose not to participate?)

Please note:

a. If the research participation affects the course grade (e.g., extra credit), then alternative opportunity for course credit is needed.

b. For multi-phase projects, compensation should not be contingent upon completion of the whole project. Rather, some compensation should be given for each phase of the project. The nature of the compensation should be stated in the consent form.

Participants will not be compensated for their participation in the study.

23.) Research participants will be informed of the risks and benefits through:

☐ Consent form (Include with application)
☐ Verbal script (include with application)
☐ Parental Consent form for parents/guardians (required for children 16 of age and younger)
☐ Assent form (in addition to Parental Consent form for children 12 years of age and younger)

Part V: Informed Consent (You must include a copy of the informed consent document with application materials.

Visit the IRB website for more information about informed consent documents.)

24.) Describe the consent process. Explain when and where consent will be obtained and identify who will be obtaining informed consent.

When participants visit the survey link, they will be informed of the purpose of the study, that it is anonymous and completely voluntary, and that they can withdraw at any time without penalty. They will be consented through this "verbal script" (see Appendix C), since a written-informed consent form would be the only record linking the subject to the research.

25.) If you will be using children under 18, explain in detail how you will obtain parental consent and assent (for children under 12) or consent (for children 12 to 16). If assent/consent will be obtained orally, supply a script of what you will say and how you will give the children the opportunity to agree to participate or decline.

N/A

26.) Explain how the possibility of coercion or undue influence will be minimized in the consent process (e.g., if employer is approaching employees, instructors are approaching students, physicians are approaching patients, if compensation is involved, etc.).

The verbal script will make clear that participation is completely voluntary and that they may withdraw at any time without penalty or consequence.

Part VI: Privacy and Confidentiality of Records

27.) Will this study use or disclose protected health information from a covered entity (a covered entity is a Doctor, Clinic Dentist, Pharmacy, Health Clinic etc... that sends transactions electronically) as defined in the Health Insurance Portability and Accountability Act (HIPAA)?

☐ Not Applicable
☐ Applicant will use a HIPAA Authorization (specify type below)
☐ Form provided by covered entity
☐ Form created by applicant
☐ Applicant requests IRB waiver of Authorization
IRB NUMBER: 

28.) Where will the signed consent forms be kept? (Consent forms must be kept in a secured location on campus, not in a private home or office.) If the study does not involve consent forms, answer "N/A":
N/A

29.) Describe specifically how you will maintain the confidentiality of the data.
The online survey is completely anonymous, and there will be no way for participants to be identified by either the research team or anyone else.

30.) How will the data/results of the research be disseminated?

☐ Thesis
☒ Dissertation
☒ Public presentation
☐ Other: Specify: Written report to Interstitial Cystitis Association
☒ Publication
☐ Course Requirement: Course #:

31.) How will the data be stored after study completion? Please be specific as to the retention or destruction of audio/video data or cell lines.

Anonymous survey data will be stored on the principal investigator's password-protected desktop computer.

32.) a. If the participants' personal files (sheelc, medical, etc.) will be read, where are the files kept (name the place, e.g., doctor's office, hospital, clinic, etc.) and who will gather the information?
N/A

b. Has permission been obtained to gather this information? (Attach documentation)
N/A

c. Do the participants (and/or their parents or guardians) know that these files will be read? If no, explain.
N/A

33.) a. Will individual results or other data be disseminated to the participants (and/or their parents or guardians)?
While aggregated data will be provided back to the Interstitial Cystitis Association (ICA) via a formal, written report, and will be disseminated via publication, presentation, and dissertation defense, no individual data will be provided to anyone.

b. If so, explain the qualifications of the person(s) interpreting the results.
N/A

34.) Does the proposed study involve deception? ☒ No ☐ Yes (Please complete Part VII)

Part VII: Projects Involving Deception

35.) Describe the type of deception being used. Consider in your answer both deception by omission (an important aspect of the research is withheld from the subject) and deception by commission (the subject is misled about the true purpose of the research).

36.) Why is deception a necessary and unavoidable component of the experimental design? (Does the deception improve the internal or external validity of the study?)

37.) Has this research protocol (involving deception) been previously used? If "Yes," please provide information on any actual harms to the participants and reactions of the participants to the use of deception in this research.

38.) What alternative procedures were considered that did not involve deception and why were those alternatives rejected?

39.) Since deception precludes informed consent by the subject prior to participation:
IRB NUMBER:

28.) Where will the signed consent forms be kept? (Consent forms must be kept in a secure location on campus, not in a private home or office. If the study does not involve consent forms, answer "N/A."
N/A

29.) Describe specifically how you will maintain the confidentiality of the data.
The online survey is completely anonymous, and there will be no way for participants to be identified by either the research team or anyone else.

30.) How will the data/results of the research be disseminated?
☐ Thesis
☒ Dissertation
☒ Public presentation
☐ Other: Specify: Written report to Interstitial Cystitis Association

☒ Course Requirement: Course #:

31.) How will the data be stored after study completion? Please be specific as to the retention or destruction of audio/video data or cell lines.
Anonymous survey data will be stored on the principal investigator's password-protected desktop computer.

32.) a. If the participants' personal files (sick, medical, etc.) will be read, where are the files kept (name the place, e.g., doctor's office, hospital, clinic, etc.) and who will gather the information?
N/A

b. Has permission been obtained to gather this information? (Attach documentation)
N/A

c. Do the participants (and/or their parents or guardians) know that these files will be read? If no, explain.
N/A

33.) a. Will individual results or other data be disseminated to the participants (and/or their parents or guardians)?
While aggregated data will be provided back to the Interstitial Cystitis Association (ICA) via a formal, written report, and will be disseminated via publication, presentation, and dissertation defense; no individual data will be provided to anyone.

b. If so, explain the qualifications of the person(s) interpreting the results.
N/A

34.) Does the proposed study involve deception?
☒ No
☐ Yes (Please complete Part VII)

Part VII: Projects Involving Deception

35.) Describe the type of deception being used. Consider in your answer both deception by omission (an important aspect of the research is withheld from the subject) and deception by commission (the subject is misled about the true purpose of the research).

36.) Why is deception a necessary and unavoidable component of the experimental design? (Does the deception improve the internal or external validity of the study?)

37.) Has this research protocol (involving deception) been previously used? If "Yes," please provide information on any actual harms to the participants and reactions of the participants to the use of deception in this research.

38.) What alternative procedures were considered that did not involve deception and why were these alternatives rejected?

39.) Since deception precludes informed consent by the subject prior to participation:
a.) How will participants be debriefed?

b.) Who will debrief them?

c.) Will the debriefing of participants be:

☐ Immediate (immediately following the experimental session in which deception occurs)
☐ Delayed
☐ Full (all deceptive aspects of the study will be revealed)
☐ Partial (some deceptive aspects of the study will remain unexplained)

40.) If debriefing is delayed, why is delayed debriefing necessary and whom will debriefing occur?

41.) If debriefing is partial, why is the partial debriefing necessary? Why is unexplained deception necessary? Would the subject be harmed in any way by full debriefing?

41.) Even if the subject is partially debriefed during the study, will full debriefing occur later?

42.) Does the presence of deception increase the risk of harm to the subject?

43.) Is the respondent free to withdraw his/her data after being fully debriefed? (e.g., form like audio/video taping).
Part VIII: Request for Waiver of Elements of Informed Consent

43.) Are you requesting a waiver of the documented informed consent form for each participant? Yes No

Please indicate the justification for requesting this waiver:

☐ The only record linking the subject to the research would be the signed consent document and the principal risk of the research would be breach of confidentiality.

☐ The research involves only minimal risk to the subjects and involves no procedures for which written consent is normally required outside of the research context (e.g. anonymous surveys of adults).

Note: Participants must still be provided with a written statement regarding the research that contains the required elements of informed consent. Refer to the Informed Consent Template on our website for more information.

44.) Are you requesting a waiver or alteration of any of the other required elements of informed consent? Yes No

(A waiver may, on occasion, approve a consent process that alters some or all of the required elements of informed consent or waive the requirement for informed consent. The following criteria must be met: 1) the research involves no more than minimal risk, 2) waiver or alteration will not adversely affect the rights and welfare of subjects, 3) the research could not practically be carried out without waiver or alteration, and 4) when appropriate, the subjects will be provided with additional pertinent information after participation.)

a) Provide justification for the waiver.
   If this study were to use a written informed consent form, it would be the only record linking the participant to the research and the principal risk of the research would be breach of confidentiality. The research involves only minimal risk to the participants and involves no procedures for which written consent is normally required outside of the research context. This study consists of anonymous surveys of adults.

b) Indicate why the proposed research presents no more than minimal risk to participants.
   There are no potential physical or social risks to which participants will be exposed. While psychological risk is possible, due to answering questions that address issues such as quality of life, social support, stress, self-efficacy, and disease severity, the risk is minimal and not beyond those encountered in everyday life.

c) Explain whether or not a waiver of written informed consent would adversely affect the rights and welfare of participants.
   This waiver of written informed consent would not adversely affect the rights and welfare of participants - it actually serves to protect their anonymity, given that a written informed consent form would be the only record linking the participant to the research.

d) Explain why it would be impracticable to carry out the research without a waiver or alteration of informed consent.
   The primary purpose of requesting a waiver of the written informed consent process is to protect the anonymity of study participants. A written informed consent form would be the only record linking the participant to the research.

e) How will pertinent information be provided to participants, if appropriate, at a later date?
   The verbal consent script will instruct participants to contact a member of the research team should they have any questions at any point about the study.

Part IX: Conflict of Interest

45.) Do the researchers conducting this protocol have any potential conflicts of interest? Yes No

Conflicts of interest may include financial or personal interest, or any condition in which the investigator's judgment regarding a primary interest may be affected by a secondary interest. Examples include speaking and consultation fees, travel expenses, stock options, royalties, company ownership or equity, etc.)

☐ Yes ☐ No (If yes, conflict of interest must be disclosed)
IRB NUMBER: 

**Investigator Assurance**

I certify that the information provided in this application is complete and correct. I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human research subjects, the conduct of the study, and the ethical performance of the project.

I agree to comply with all Kent State University policies and procedures on research involving human subjects (KSU policy #3342-3-02.2), as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research. I agree that:

- The project will be performed by qualified personnel, according to the IRB approved protocol.
- Approval from the Institutional Review Board will be obtained prior to implementing any changes to the protocol.
- If the project involves approval/perturbation from other institutions, the research will not begin until perturbation has been obtained from these institutions.
- Legally effective informed consent will be obtained from human subjects if applicable, and documentation of informed consent will be retained in a secure environment for three years after termination of the project.
- Injuries, adverse events, and/or unanticipated problems involving risks to subjects or others will be reported in writing to the Kent State University IRB promptly, and no later than within 5 working days of the occurrence.
- A Continuing Review and Progress Report will be completed and submitted before the review deadline, as determined by the IRB appropriate to the degree of risk (but not less than once per year). All protocols are approved for a maximum period of one year. Research must stop at the end of the approval period unless the protocol is re-approved for another term.
- All research staff, employees, and students assisting in the conduct of the research will be informed of their obligations and responsibilities in the above commitments.

I further certify that the proposed research will not begin until approval has been obtained. A signed approval letter from the Office of Research Safety and Compliance communicates IRB approval.

Signature of Principal Investigator: [Signature] Date: 1-5-12

Signature of Co-Investigator: 

Date: 

**Faculty Advisor Assurance**

I have reviewed and approved the research project described in this application. I agree to meet with the student on a regular basis to monitor study progress and assure that the well-being of subjects is adequately safeguarded. I agree to be available to assist the student investigator should any problems arise in the study.

Signature of Faculty Advisor: [Signature] Date: 1-9-12
**IRB NUMBER:**

Kent State University Institutional Review Board
Application for Approval to Use Human Research Subjects

**CHECKLIST:** THE FOLLOWING MATERIALS MUST BE SUBMITTED WITH THE APPLICATION FOR APPROPRIATE REVIEW (Note: all items may not be necessary for the specific application)

Double click on the box, a window will appear asking if it should be checked or unchecked

<table>
<thead>
<tr>
<th>CHECK IF NECESSARY:</th>
<th>FORMS SUBMITTED:</th>
<th>APPENDIX LETTER OR NUMBER (IF NOT NECESSARY, MARK &quot;N/A&quot;):</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>Completed Application (including signatures)</td>
<td>References - Appendix A</td>
</tr>
<tr>
<td>□</td>
<td>Recruitment script and materials</td>
<td>Appendices B &amp; E</td>
</tr>
<tr>
<td>□</td>
<td>Surveys, questionnaires, interview questions</td>
<td>Appendix D</td>
</tr>
<tr>
<td>□</td>
<td>Data collection materials</td>
<td>N/A</td>
</tr>
<tr>
<td>□</td>
<td>Informed Consent Documents</td>
<td>Appendix C</td>
</tr>
<tr>
<td>□</td>
<td>Audio/Visual Consent Forms</td>
<td>N/A</td>
</tr>
<tr>
<td>□</td>
<td>Assent Statement/Script (for children &lt; 18, will also need parental consent form)</td>
<td>N/A</td>
</tr>
<tr>
<td>□</td>
<td>Debriefing Script</td>
<td>N/A</td>
</tr>
<tr>
<td>□</td>
<td>Approval from other institutions</td>
<td>Appendix F</td>
</tr>
<tr>
<td>□</td>
<td>Signed Investigator Assurance</td>
<td></td>
</tr>
<tr>
<td>□</td>
<td>Training Verification/CITI certificate</td>
<td>Appendix G</td>
</tr>
</tbody>
</table>
Appendix A

References


Interstitial Cystitis Association (ICA). (2011). What is interstitial cystitis (IC)? Retrieved from


Appendix B

Dear Member of the ICA Community,

The purpose of this e-mail is to invite those who are living with interstitial cystitis (IC) to participate in the “Quality of Life & IC Study.” To be eligible to complete the survey, you must have been diagnosed with IC at some point in your life, and you must be 18 years of age or older.

The purpose of this study, which consists of a one-time, online anonymous survey, is to gain a better understanding of the types of things that impact quality of life in people living with IC. The survey asks questions about your perceptions of quality of life, social support, stress, your ability to do the things that you need/want to do in life, disease symptoms and severity, and basic demographics. The survey is short and takes no more than 30 minutes to complete. The survey is anonymous, as it does not ask for any identifying information.

This study is being conducted by Laura Santurri, MPH, CPH, a doctoral candidate in Health Education and Promotion at Kent State University (KSU) and with the support of the Interstitial Cystitis Association (ICA). In addition to being an IC patient for the past 14 years, Ms. Santurri has also been involved in IC support group leadership and patient advocacy for the past decade, as well as IC research (through her academics) for the past eight years. Her research efforts are guided by her dissertation committee, which consists of faculty from both KSU and The Ohio State University.

There are no risks in participating in this study that are greater than those encountered in everyday life, and you would be subject to no penalties or consequences if you decide not to participate. You may also stop answering questions and withdraw from the study at any time without penalty.

If you are ready to take the survey, please click the following link:
https://www.surveymonkey.com/s/85268RTD

If you would like to obtain additional information about the study, please contact:

Laura Santurri, MPH, CPH
17576 Auburn Road
Chagrin Falls, Ohio, 44023
lsanturri@kent.edu (e-mail)
330-608-1830 (phone)

OR

Kele Ding, MD, PhD
142 Nixon Hall
Kent State University
Kent, Ohio 44242
kding@kent.edu (e-mail)
330-672-0688 (phone)
Appendix B

Information about KSU’s rules for research can be obtained by contacting the IRB at 330-672-2704.

Thank you for your time and consideration. Your participation in this study may lead us to have a better understanding of what it is like to live with IC.
Appendix C

Thank you for your interest in participating in the “Quality of Life & IC Study.” You are eligible to complete this survey if you have been diagnosed with Interstitial Cystitis (IC) at some point in your life, and you are 18 years of age or older.

The purpose of this study, which consists of a one-time, online anonymous survey, is to gain a better understanding of the types of things that impact quality of life in people living with IC. This survey asks questions about your perceptions of quality of life, social support, stress, your ability to do the things that you need/want to do in life, disease symptoms and severity, and basic demographics. The survey is short and takes no more than 30 minutes to complete. The survey is anonymous, as it does not ask for any identifying information.

This study is being conducted by Laura Santurri, MPH, CPH, a doctoral candidate in Health Education and Promotion at Kent State University (KSU) and with the support of the Interstitial Cystitis Association (ICA). In addition to being an IC patient for the past 14 years, Ms. Santurri has also been involved in IC support group leadership and patient advocacy for the past decade, as well as IC research (through her academics) for the past eight years. Her research efforts are guided by her dissertation committee, which consists of faculty from both KSU and The Ohio State University.

There are no risks in participating in this study that are greater than those encountered in everyday life, and you would be subject to no penalties or consequences if you decide not to participate. You may also stop answering questions and withdraw from the study at any time without penalty. Your completion of this survey is your consent to participate in the study.

If you would like to obtain additional information about the study, please contact:

Laura Santurri, MPH, CPH
17576 Auburn Road
Chagrin Falls, Ohio, 44023
lsanturri@kent.edu (e-mail)
330-608-1830 (phone)

OR

Kele Ding, MD, PhD
142 Nisso Hall
Kent State University
Kent, Ohio 44242
kding@kent.edu (e-mail)
330-672-0888 (phone)

Information about KSU’s rules for research can be obtained by contacting the IRB at 330-672-2704.

Thank you for your time and consideration. Your participation in this study may lead us to have a better understanding of what it is like to live with IC.

If you are ready to take the survey, please click "Next."
1. Introduction to the Survey

Thank you for your interest in participating in the "Quality of Life & IC Study." You are eligible to complete this survey if you have been diagnosed with interstitial cystitis (IC) at some point in your life, and you are 18 years of age or older.

The purpose of this study, which consists of a one-time, online anonymous survey, is to gain a better understanding of the types of things that impact quality of life in people living with IC. This survey asks questions about your perceptions of quality of life, social support, stress, your ability to do the things that you need/want to do in life, disease symptoms and severity, and basic demographics. The survey is short and takes no more than 30 minutes to complete. The survey is anonymous, as it does not ask for any identifying information.

This study is being conducted by Laura Santurri, MPH, CPH, a doctoral candidate in Health Education and Promotion at Kent State University (KSU) and with the support of the Interstitial Cystitis Association (ICA). In addition to being an IC patient for the past 14 years, Ms. Santurri has also been involved in IC support group leadership and patient advocacy for the past decade, as well as IC research (through her academic) for the past eight years. Her research efforts are guided by her dissertation committee, which consists of faculty from both KSU and The Ohio State University.

There are no risks in participating in this study that are greater than those encountered in everyday life, and you would be subject to no penalties or consequences if you decide not to participate. You may also stop answering questions and withdraw from the study at any time without penalty. Your completion of this survey is your consent to participate in the study.

If you would like to obtain additional information about the study, please contact:

Laura Santurri, MPH, CPH
17576 Auburn Road
Chagrin Falls, Ohio, 44023
lsanturri@kent.edu (e-mail)
330-808-1630 (phone)

OR

Kell Ding, MD, PhD
142 Noble Hall
Kent State University
Kent, Ohio 44242
kdling@kent.edu (e-mail)
330-672-0666 (phone)

Information about KSU's rules for research can be obtained by contacting the IRB at 330-672-2704.

Thank you for your time and consideration. Your participation in this study may lead us to have a better understanding of what it is like to live with IC.

If you are ready to take the survey, please click "Next."
<table>
<thead>
<tr>
<th>2. Study Eligibility</th>
</tr>
</thead>
</table>

These questions will determine if you are eligible to take the survey. If it is determined that you are not eligible to take the survey (i.e., you have not been diagnosed with IC and/or you are not 18 years of age and older), the survey will automatically close.

**1. Have you been diagnosed with interstitial cystitis (IC) by a health care provider at some point in your life?**

- [ ] Yes
- [ ] No
<table>
<thead>
<tr>
<th>Quality of Life &amp; IC Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
</tr>
<tr>
<td><strong>2. Are you 18 years of age or older?</strong></td>
</tr>
<tr>
<td>☐ Yes</td>
</tr>
<tr>
<td>☐ No</td>
</tr>
</tbody>
</table>
**Quality of Life & IC Study**

4. **Study Eligibility**

*3. You have indicated that you have not been diagnosed with interstitial cystitis (IC) by a health care provider. If this is not correct, and you have been diagnosed with IC, please click the "Prev" button to change your answer to the previous question. If it is the case that you are not an IC patient, please take a second to indicate your role in the IC community. Please select all that apply.*

- [] Health Care Provider
- [] Researcher
- [] Other

Other (please specify):_________
### Quality of Life & IC Study

#### 5. Quality of Life

The following questions will ask you about your overall health, as well as your physical and mental health.

4. **Would you say that, in general, your current health is:**
   - Excellent
   - Very Good
   - Good
   - Fair
   - Poor

5. **Compared to one year ago, how would you rate your health in general now?**
   - Much better than one year ago
   - Somewhat better than one year ago
   - About the same
   - Somewhat worse than one year ago
   - Much worse than one year ago

6. **If there has been a change in your health in the past year, how much of that change is related to your IC?**
   - I have not had a change in my health in the past year
   - None of the change is related to IC
   - A small amount of the change is related to IC
   - A moderate amount of the change is related to IC
   - A significant amount of the change is related to IC
   - All of the change is related to IC

7. **Do you have a chronic illness(es) other than IC?**
   - Yes
   - No
### Quality of Life & IC Study

#### 8. If there has been a change in your health in the past year, how much of that change is related to another chronic illness(es) that you have?

- [ ] I have not had a change in my health in the past year
- [ ] None of the change is related to my other chronic illness(es)
- [ ] A small amount of the change is related to my other chronic illness(es)
- [ ] A moderate amount of the change is related to my other chronic illness(es)
- [ ] A significant amount of the change is related to my other chronic illness(es)
- [ ] All of the change is related to my other chronic illness(es)

#### 9. The following items are about activities you might do during a typical day. Does your IC now limit you in these activities? If so, please indicate how much.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Yes, limited a lot</th>
<th>Yes, limited a little</th>
<th>No, not limited at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Lifting or carrying groceries</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Climbing several flights of stairs</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Climbing one flight of stairs</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Bending, kneeling, or stooping</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Walking more than one mile</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Walking several blocks</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Walking one block</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
### Quality of Life & IC Study

#### 7. Quality of Life (cont')

The following questions will ask you about your overall health, as well as your physical and mental health.

**10. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your IC?**

<table>
<thead>
<tr>
<th>Problem</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut down the amount of time you spent on work or other activities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accomplished less than you would like</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were limited in the kind of work or other activities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Had difficulty performing the work or other activities (for example, it took extra effort)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**11. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious) that were brought on by your IC?**

<table>
<thead>
<tr>
<th>Problem</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut down the amount of time you spent on work or other activities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accomplished less than you would like</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Didn't do work or other activities as carefully as usual</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**12. During the past 4 weeks, to what extent has your IC interfered with your normal social activities with family, friends, neighbors, or groups?**

- [ ] Not at all
- [ ] Slightly
- [ ] Moderately
- [ ] Quite a bit
- [ ] Extremely
<table>
<thead>
<tr>
<th>Quality of Life &amp; IC Study</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>13. How much IC-related pain have you had during the past 4 weeks?</strong></td>
</tr>
<tr>
<td>- None</td>
</tr>
<tr>
<td>- Very mild</td>
</tr>
<tr>
<td>- Mild</td>
</tr>
<tr>
<td>- Moderate</td>
</tr>
<tr>
<td>- Severe</td>
</tr>
<tr>
<td>- Very severe</td>
</tr>
</tbody>
</table>

| **14. During the past 4 weeks, how much did your IC pain interfere with your normal work (including both work outside the home and housework)?** |
| - Not at all |
| - A little bit |
| - Moderately |
| - Quite a bit |
| - Extremely |
Quality of Life & IC Study

8. Quality of Life (cont')

The following questions will ask you about your overall health, as well as your physical and mental health.

15. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes the closest to the way you have been feeling.

How much of the time during the past 4 weeks...

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did you feel full of pep?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you been a very nervous person?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you felt so down in the dumps that nothing could cheer you up?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you felt calm and peaceful?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you have a lot of energy?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you felt downhearted and blue?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you feel worn out?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you been a happy person?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you feel tired?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has your physical problems or emotional problems interfered with your social activities like visiting with friends, relatives, etc.?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

16. How TRUE or FALSE is each of the following statements for you?

<table>
<thead>
<tr>
<th>Statement</th>
<th>Definitely true</th>
<th>Mostly true</th>
<th>Don't know</th>
<th>Mostly false</th>
<th>Definitely false</th>
</tr>
</thead>
<tbody>
<tr>
<td>I seem to get sick a little easier than other people</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I am as healthy as anybody I know</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I expect my health to get worse</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My health is excellent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Quality of Life & IC Study

17. Is there anything else that you would like to share about IC and your quality of life?
### Quality of Life & IC Study

#### 9. Social Support

The next set of questions will ask you about how often social support is available to you, if you need it.

18. People sometimes look to others for companionship, assistance, or other types of support. How often is each of the following kinds of support available to you, if you need it? Select one answer on each line.

<table>
<thead>
<tr>
<th>Kind of Support</th>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Someone you can count on to listen to you when you need to talk</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to give you information to help you understand a situation</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to give you good advice about a crisis</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to confide in or talk to about yourself or your problems</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone whose advice you really want</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to share your most private worries and fears with</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to turn to for suggestions about how to deal with a personal problem</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone who understands your problems</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to help you if you were confined to bed</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to take you to the doctor if you needed it</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to prepare your meals if you were unable to do it yourself</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Someone to help you with daily chores if you were asked</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
**Quality of Life & IC Study**

**10. Social Support (cont')**

The next set of questions will ask you about how often social support is available to you, if you need it.

19. People sometimes look to others for companionship, assistance, or other types of support. How often is each of the following kinds of support available to you, if you need it? Select one answer on each line.

<table>
<thead>
<tr>
<th>Type of Support</th>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Someone who shows you love and affection</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Someone to love and make you feel wanted</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Someone who hugs you</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Someone to have a good time with</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Someone to get together with for relaxation</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Someone to do something enjoyable with</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Someone to do things with to help you get your mind off things</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

20. Is there anything else that you would like share about your IC and social support?


## 11. Stress

The following questions will ask you about stress in your life.

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>21. In the past month, how often have you felt overwhelmed by the demands placed on you in your life?</td>
<td>Never, Rarely, Sometimes, Often, Always</td>
</tr>
<tr>
<td>22. In the past month, how often have you felt frustrated trying to live up to your own expectations and standards?</td>
<td>Never, Rarely, Sometimes, Often, Always</td>
</tr>
<tr>
<td>23. In the past month, how often have you felt that your needs as a person were being left unmet?</td>
<td>Never, Rarely, Sometimes, Often, Always</td>
</tr>
<tr>
<td>24. In the past month, how often have you felt uncertain or apprehensive about your future?</td>
<td>Never, Rarely, Sometimes, Often, Always</td>
</tr>
<tr>
<td>25. In the past month, how often have you felt that there were problems in your life that could just not be solved?</td>
<td>Never, Rarely, Sometimes, Often, Always</td>
</tr>
<tr>
<td>26. In the past month, how often have you felt that there were so many every day hassles and crises that you lost track of the things that were really important to you?</td>
<td>Never, Rarely, Sometimes, Often, Always</td>
</tr>
</tbody>
</table>

27. Is there anything else that you would like to share about your IC and stress?
Quality of Life & IC Study

12. Self-Efficacy

The following questions will ask you about how the symptoms of interstitial cystitis (IC) affect you.

For each of the questions, please indicate the number which corresponds to your certainty that you can now perform the following tasks (with 1 = Very Uncertain and 10 = Very Certain).

28. As of now, how certain are you that you can (with 1 = Very Uncertain and 10 = Very Certain):

<table>
<thead>
<tr>
<th>Task</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decrease your IC symptoms quite a bit?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continue most of your daily activities?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keep IC symptoms from interfering with your sleep?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Make a small to moderate reduction in your IC symptoms by using methods other than taking extra medication?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Make a large reduction in your IC symptoms by using methods other than taking extra medication?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 13. Self-Efficacy (continued)

The following questions will ask you how you feel about your ability to control your IC.

For each of the following questions, please indicate the number that corresponds to the certainty that you can now perform the following activities or tasks (with 1 = Very Uncertain and 10 = Very Certain).

#### 29. As of now, how certain are you that you can (with 1 = Very Uncertain and 10 = Very Certain):

<table>
<thead>
<tr>
<th>Question</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control your fatigue?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjust your activities to remain active without aggravating your IC?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do something to help yourself feel better if you are feeling blue?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manage your IC symptoms during daily activities?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manage your IC symptoms so that you can do the things you enjoy doing?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deal with the frustration of IC?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Quality of Life & IC Study**

**14. Self-Efficacy (continued)**

The next questions ask you about how confident you are about performing certain activities.

For each of the following questions, please indicate the number that corresponds to your certainty that you can perform the task as of now (with 1 = Very Uncertain and 10 = Very Certain). Please consider what you routinely do, not what would require a single extraordinary effort.

**30. As of now, how certain are you that you can (with 1 = Very Uncertain and 10 = Very Certain):**

<table>
<thead>
<tr>
<th>Activity</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work as much as you would like?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintain your social life?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Travel away from home for a weekend?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enjoy sexual intercourse?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have uninterrupted sleep for longer than three hours?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise as you did in the past?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eat the foods that you like to eat?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Take care of family responsibilities?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Go longer than 2 hours before emptying your bladder during the day?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Go longer than 2 hours before emptying your bladder during the night?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**31. Is there anything else that you would like to share about your IC and self-efficacy?**

---

Page 16
Quality of Life & IC Study

15. IC Symptoms

The following questions will ask you about your IC symptoms.

32. Please answer the questions below related to your IC symptoms.

During the past month:

<table>
<thead>
<tr>
<th>Question</th>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>A good bit of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>How often have you felt the need to urinate with little or no warning?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Have you had to urinate less than 3 hours after you finished urinating?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Have you experienced pain, burning, or discomfort due to your IC?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

33. During the past month, how often did you most typically get up at night to urinate?

☐ None
☐ One time
☐ Two times
☐ Three times
☐ Four times
☐ Five or more times
Quality of Life & IC Study

16. IC Problems

The following questions will ask you about problems you may or may not have with your IC.

34. Please answer the following questions related to the problems associated with your IC symptoms.

During the past month:

<table>
<thead>
<tr>
<th>Question</th>
<th>No problem</th>
<th>Very small problem</th>
<th>Small problem</th>
<th>Medium problem</th>
<th>Big problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>How much of a problem has frequent urination during the day been for you?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>How much of a problem has getting up at night to urinate been for you?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>How much of a problem has the need to urinate with little warning been for you?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>How much of a problem has pain, burning, or discomfort due to your IC been for you?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

35. Is there anything else that you would like to share about your IC and your symptoms?

[Blank space for response]
### Quality of Life & IC Study

**17. Demographics**

The following questions will ask you to tell us a little bit more about yourself.

**36. Do you live in a state or territory of the United States?**

- [ ] Yes
- [ ] No
### Quality of Life & IC Study

#### 18.

**37. In what U.S. state or territory do you live?**

[ ]
### Quality of Life & IC Study

#### 38. In what country do you live?

#### 39. Please describe to the best of your ability the type of community in which you live by choosing one of the following options - urban, suburban or rural.

People who live in urban areas often live in cities, where buildings are closer together and built higher. There is generally a form of public transportation available.

People who live in suburban areas often live in the outskirts of cities and commute to work. Buildings are further apart and lower than in cities. The population is lower than that of cities.

People who live in rural areas live in areas where there is more land, and the population is lower. Buildings are usually further apart than in suburban areas.

- [ ] Urban
- [ ] Suburban
- [ ] Rural

#### 40. How old are you (in years)?

#### 41. What is your gender?

- [ ] Male
- [ ] Female
- [ ] Other

#### 42. Are you Hispanic or Latino?

- [ ] Yes
- [ ] No
Quality of Life & IC Study

43. What do you consider to be your race?
   - American Indian
   - Asian
   - Native Hawaiian/Other Pacific Islander
   - Black/African American
   - White/Caucasian
   - Other

44. If Other, please specify:
# Quality of Life & IC Study

## 20. Demographics (con’t)

The following questions will ask you to tell us a little bit more about yourself.

### 45. What is your marital status?
- [ ] Married
- [ ] Divorced
- [ ] Married but separated
- [ ] Widowed
- [ ] In a Relationship
- [ ] Single

### 46. What is the highest level of education that you've completed?
- [ ] Eighth grade or less
- [ ] Some high school
- [ ] High school graduate or GED
- [ ] Some college
- [ ] College graduate
- [ ] Graduate degree

### 47. Are you currently employed (either full-time or part-time)?
- [ ] Yes
- [ ] No

### 48. Have you been diagnosed with interstitial cystitis (IC) or painful bladder syndrome (PBS) by a health care provider?
- [ ] Yes
- [ ] No

### 49. How long, in years, have you had symptoms of interstitial cystitis (IC) or painful bladder syndrome (PBS)? Please round to the nearest whole number.

### 50. How long, in years, has it been since you were diagnosed with interstitial cystitis (IC) or painful bladder syndrome (PBS)? Please round to the nearest whole number.

---

Page 23
<table>
<thead>
<tr>
<th>Quality of Life &amp; IC Study</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>51. Is there anything else that you would like to share about yourself and your experience living with IC?</strong></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
Quality of Life & IC Study

21. Thank You!

Thank you so much for taking the time to complete this survey. If you have any further comments that you would like to share, please do so below. When you are done with the survey, click "Done" below.

52. Further Comments:


Appendix E

Dear Member of the ICA Community,

The purpose of this e-mail is to remind you about your invitation to participate in the “Quality of Life & IC Study.” If you have already participated in the study by filling out the survey, please disregard this message. Please do not fill out the survey more than once. You are eligible to complete the survey if you have been diagnosed with IC at some point in your life, and you are 18 years of age or older.

The purpose of this study, which consists of a one-time, online anonymous survey, is to gain a better understanding of the types of things that impact quality of life in people living with IC. The survey asks questions about your perceptions of quality of life, social support, stress, your ability to do things that you need/want to do in life, disease symptoms and severity, and basic demographics. The survey is short and takes no more than 30 minutes to complete. The survey is anonymous, as it does not ask for any identifying information.

This study is being conducted by Laura Santurri, MPH, CPH, a doctoral candidate in Health Education and Promotion at Kent State University (KSU) and with the support of theInterstitial Cystitis Association (ICA). In addition to being an IC patient for the past 14 years, Ms. Santurri has also been involved in IC support group leadership and patient advocacy for the past decade, as well as IC research (through her academics) for the past eight years. Her research efforts are guided by her dissertation committee, which consists of faculty from both KSU and The Ohio State University.

There are no risks in participating in this study that are greater than those encountered in everyday life, and you would be subject to no penalties or consequences if you decide not to participate. You may also stop answering questions and withdraw from the study at any time without penalty.

If you are ready to take the survey, please click the following link:
https://www.surveymonkey.com/s/8826RTD

If you would like to obtain additional information about the study, please contact:

Laura Santurri, MPH, CPH  
17576 Auburn Road  
Chagrin Falls, Ohio, 44022  
lsanturri@kent.edu (e-mail)  
330-608-1830 (phone)

OR

Kele Ding, MD, PhD  
142 Nixon Hall  
Kent State University  
Kent, Ohio 44242  
kding@kent.edu (e-mail)  
330-860-0938 (phone)
Appendix E

Information about KSU's rules for research can be obtained by contacting the IRB at 330-672-2704.

Thank you for your time and consideration. Your participation in this study may lead us to have a better understanding of what it is like to live with IC.
Dissertation Committee
Health Education and Promotion
Kent State University
Kent, Ohio

January 6, 2011

Dear Committee Members,

On behalf of the Interstitial Cystitis Association (ICA), I am pleased to offer this letter of support for the dissertation research of Laura Santurri, MPH, CPH, on the effect of social support and self-efficacy on the impact of stress on health-related quality of life in people living with interstitial cystitis (IC).

As the only nonprofit association dedicated solely to improving the quality of healthcare and lives of people living with IC, the ICA is excited about the opportunity to work with Laura on her dissertation by sending out study invitation emails to the IC community with which the ICA is connected. This approach allows Laura to benefit from the reach of our targeted patient network while permitting the ICA to abide by our policy of not selling or disseminating patient data.

We are grateful for the opportunity to work with Laura on this research and look forward to her sharing useful trending information about our membership, as well as suggestions about the type of health education and support that could be provided by the ICA to the more than four million people affected by this chronic, life-altering bladder condition.

Please let me know if I can be of additional assistance.

Sincerely,

[Signature]

Barbara Gordon, RD
Executive Director, Interstitial Cystitis Association
bgordon@ichelp.org
<table>
<thead>
<tr>
<th>Title</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title 1</td>
<td>80</td>
</tr>
<tr>
<td>Title 2</td>
<td>75</td>
</tr>
<tr>
<td>Title 3</td>
<td>90</td>
</tr>
<tr>
<td>Title 4</td>
<td>85</td>
</tr>
<tr>
<td>Title 5</td>
<td>70</td>
</tr>
</tbody>
</table>

**Score Breakdown:**
- Title 1: 80%
- Title 2: 75%
- Title 3: 90%
- Title 4: 85%
- Title 5: 70%
APPENDIX E

STUDY INVITATION
Appendix E

Study Invitation

Laura Santum

From: Interstitial Cystitis Association 

Sent: Tuesday, March 06, 2012 2:47 PM

To: Laura Santum

Subject: A Letter from Laura

ICA eNews

A Service of the Interstitial Cystitis Association

Dear Member of the ICA Community,

The purpose of this email is to invite those who are living with interstitial cystitis (IC) to participate in the "Quality of Life & IC Study." To be eligible to complete the survey, you must have been diagnosed with IC at some point in your life, and you must be 18 years of age or older.

Read More

Get the IC News You Can Use!

Help us continue the fight to advocate for IC patients, secure dedicated NIH funding, serve as a central hub for IC patients and healthcare providers, and fund promising scientific research.

Conquering IC. Changing Lives.

The Interstitial Cystitis Association (ICA) is the only non-profit health association solely dedicated to improving the quality of healthcare and lives of people living with interstitial cystitis (IC). The ICA provides advocacy, research funding, and education to ensure early diagnosis and optimal care with dignity for people affected by IC.
Appendix F
IRB Incident Report

Laura Santurri

From: Laura Santurri <lsanturri@kent.edu>
Sent: Monday, March 12, 2012 7:27 PM
To: 'Washko, Paulette'; SYMONS, CYNTHIA; DING, KELE; Tony.Buffington@cvm.osu.edu; Tony.Buffington@cvm.osu.edu; bgordon@ichelp.org
Cc: "BARNBAUM, DEBORAH"
Subject: RE: Protocol #12-053
Attachments: Study Invitation Reminder 3.12.12.docx

Paulette,

Thank you so much for the quick reply – I think we can reasonably insert this language into an announcement that would go out to the same folks who were invited in the first place.

Barbara - I know that you were going to include a second invitation to participate in the study in a newsletter that was going to be sent out via email to the same listserve that received the first invite. Would it be possible to use the language in the attached document for that announcement?

Thank you to everyone for the quick support in this matter!

Laura Santurri, MPH, CPH
Adjunct Instructor
Master of Public Health Program
Case Western Reserve University

Doctoral Candidate
Health Education and Promotion
College and Graduate School of Education, Health and Human Services
Kent State University

From: Washko, Paulette [mailto:pwashko@kent.edu]
Sent: Monday, March 12, 2012 2:09 PM
To: lsanturri@kent.edu; SYMONS, CYNTHIA; DING, KELE; Tony.Buffington@cvm.osu.edu; Tony.Buffington@cvm.osu.edu; bgordon@ichelp.org
Cc: BARNBAUM, DEBORAH
Subject: FW: Protocol #12-053
Importance: High

Hello, Laura,

I am writing in response to the confidentiality issue that you are having with your study #12-053. Thank you for being your investigative and follow-up efforts are commendable. The IRB chairperson, Dr. Deborah Barnbaum, made the following recommendation:

Can you request that ICA send a follow-up email using all of the email addresses used for the study invitation? This follow-up email should not have to mention a breach in confidentiality per se, but simply communicate a “thank you” for those that chose to participate. The email could be signed by you and should mention that while there was no “compensation” for the study...participant input was invaluable, that they would not be receiving additional information via email or phone regarding this study, and should they have
any questions/concerns to contact you. Also, given the information that I provided for you below, ICA and KSU should be mentioned in the subject line.

This follow-up email should not cause undue alarm, but rather provide subjects with information that they may need should further confidentiality breaches occur.

Please let us know your thoughts on this issue.

Also, please see additional information that was sent to us today regarding a different online study:

Less than 24 hours after our survey announcement went out, the local news stations had an expose on a survey scam that enabled potential participants to register for Starbucks cards, and warned the public not to open up the announcement or take the survey! Our survey allows participants to register for Starbucks cards. We did not have anything in the announcement visible via email that identified our affiliation with KSU, which would have been important if we had known in advance that the news stations would be covering this issue; however, there was no way of foreseeing this in advance! One person who received our randomized survey said he thought it was spam and did not open it up. He also heard the news coverage about a scam survey.

Thank you

Respectfully,

Paulette Washko
Kenton State University
Manager, Research Compliance | 224 Cartwright Hall | 330.672.2704 | pwashko@kent.edu

From: MCCREARY, KEVIN R
Sent: Monday, March 12, 2012 9:17 AM
To: Washko, Paulette
Subject: Fwd: Protocol #12-053

Please see forwarded message. Call me if you need anything.

-------- Original Message --------
Subject: Protocol #12-053
From: Laura Sihn <lsihn@kent.edu>
To: "MCCREARY, KEVIN R" <kmccrey1@kent.edu>
CC: "SYMONS, CYNTHIA" <csymons@kent.edu>, "DING, KELE" <kding@kent.edu>, "Tony.Buffington@cvm.osu.edu" <Tony.Buffington@cvm.osu.edu>, "bgordon@ichelp.org" <bgordon@ichelp.org>

Mr. McCreary,

I am writing to you in regard to Protocol #12-053, which was approved on February 3, 2012, as Level I – Exempt Research (Exemption 2).

This past Friday, I received an e-mail from a survey respondent indicating that she had been receiving phone calls from someone claiming to be from the Quality of Life & IC Study (the title of my study). She indicated that they had left
several voicemails, and when she finally spoke to them, they indicated that she had qualified for a gift card as compensation for completing the survey. When she asked the person to identify themselves, they hung up the phone.

This was very concerning to me, and I've been in communication with my dissertation committee, the Executive Director of the ICA (the organization who is supporting my research by sending out the study invitation e-mail to their community), and technical support with SurveyMonkey.com (the mechanism by which my survey is administered) all weekend. Here's what we know:

1. My study does not involve compensation for survey completion, nor does it involve contacting survey respondents in any way. The survey does not ask for any identifying information. It was designed to be purely anonymous, self-administered, and web-based.
2. The survey respondent's contact information is not in my survey data. While a respondent could choose to type in their contact information into one of the open-ended responses, I have searched all open-ended responses for her name and e-mail address (which I have because she contacted me about the situation), and came up with no results.
3. SurveyMonkey.com has confirmed that there is no evidence to suggest that my account has been accessed by a third party (i.e. hacked). I also have not shared my account information with anyone. Regardless, I changed my password yesterday.
4. The ICA has confirmed that their database also has not been hacked, and that their patient contact information is in no way tied to an individual's survey data. The ICA simply sent out the e-mail invitation for me and has provided a link to the survey from their website. Once a respondent clicks on that link, they have left the ICA's website. Regardless, the ICA has changed their password to their database.
5. I have had over 900 responses to the survey thus far, and I have no other reports of this happening to anyone else.
6. I have been in communication with the survey respondent who reported the phone calls to inform her that they are not legitimate and that she should not provide her contact information to anyone who calls her claiming to be involved with the study. I warned her also to check her computer for viruses, and, to pull down any posts about taking the survey on social media, if she had indeed done that.

I have attached documentation of my communication with my committee, the ICA, the survey respondent, and with SurveyMonkey.com. I wanted the IRB to be aware of this, and, to ask for your guidance on the situation. If there is anything else that I need to do to address the matter, please let me know.

Thank you for your time and assistance.

Laura Santucci, MPH, CPH
Doctoral Candidate
Health Education and Promotion
College and Graduate School of Education, Health and Human Services
Kent State University

Adjunct Instructor
Master of Public Health Program
Case Western Reserve University
Laura Santurri

From: Laura Santurri <lsanturri@kent.edu>
Sent: Sunday, March 11, 2012 5:37 PM
To: 'kmccrea1@kent.edu'
Cc: 'csymons@kent.edu'; kding@kent.edu; 'Tony.Buffington@cvm.osu.edu'; bpgordon@ichelp.org
Subject: Protocol #12-053
Attachments: ICA e mail 3.11.12.pdf; Survey Respondent E mail 3.11.12.pdf; SurveyMonkey.com e mail 3.11.12.pdf

Mr. McCreary,

I am writing to you in regard to Protocol #12-053, which was approved on February 3, 2012, as Level I – Exempt Research (Exemption 2).

This past Friday, I received an e-mail from a survey respondent indicating that she had been receiving phone calls from someone claiming to be from the Quality of Life & I.C. Study (the title of my study). She indicated that they had left several voicemails, and when she finally spoke to them, they indicated that she qualified for a gift card as compensation for completing the survey. When she asked the person to identify themselves, they hung up the phone.

This was very concerning to me, and I’ve been in communication with my dissertation committee, the Executive Director of the ICA (the organization who is supporting my research by sending out the study invitation e-mail to their community), and technical support with SurveyMonkey.com (the mechanism by which my survey is administered) all weekend. Here’s what we know:

1. My study does not involve compensation for survey completion, nor does it involve contacting survey respondents in any way. The survey does not ask for any identifying information. It was designed to be purely anonymous, self-administered, and web-based.
2. The survey respondent’s contact information is not in my survey data. While a respondent could choose to type their contact information into one of the open-ended responses, I have searched all open-ended responses for her name and e-mail address (which I have because she contacted me about the situation), and came up with no results.
3. SurveyMonkey.com has confirmed that there is no evidence to suggest that my account has been accessed by a third party (i.e. hacked). I also have not shared my account information with anyone. Regardless, I changed my password yesterday.
4. The ICA has confirmed that their database also has not been hacked, and, that their patient contact information is in no way tied to an individual’s survey data. The ICA simply sent out the e-mail invitation for me and has provided a link to the survey from their website. Once a respondent clicks on that link, they have left the ICA’s website. Regardless, the ICA has changed their password to their database.
5. I have had over 900 responses to the survey thus far, and I have no other reports of this happening to anyone else.
6. I have been in communication with the survey respondent who reported the phone calls to inform her that they are not legitimate and that she should not provide her contact information to anyone who calls her claiming to be involved with the study. I warned her also to check her computer for viruses, and, to pull down any posts about taking the survey on social media, if she had indeed done that.

I have attached documentation of my communication with my committee, the ICA, the survey respondent, and with SurveyMonkey.com. I wanted the IRB to be aware of this, and, to ask for your guidance on the situation. If there is anything else that I need to do to address the matter, please let me know.
Thank you for your time and assistance.

Laura Santurri, MPH, CPH
Doctoral Candidate
Health Education and Promotion
College and Graduate School of Education, Health and Human Services
Kent State University

Adjunct Instructor
Master of Public Health Program
Case Western Reserve University
Laura Santurri

From: SYMONS, CYNTHIA <cymons@kent.edu>
Sent: Sunday, March 11, 2012 12:31 PM
To: Laura Santurri; Barbara Gordon
Cc: DING, KELE; Tony.Buffington@cvm.osu.edu; Nicole Mehall
Subject: RE: FW: Quality of Life and IC survey question

I appreciate all your quick attention and thoughts about this matter. Laura - my best suggestion is that you send a message to the IRB followed by the chronology of messages (in original text) from all of us involved in the problem solving process. In that way the IRB will have information about the whole matter as it unfolded.

Each of you has contributed possible contributing variables about which I had not thought. As a result of your contributions to this process, it is my belief that Laura will be able to proceed in a way that best protects the members of the ICA while maintaining fidelity to her data collection process and so the integrity of her study as proposed.

Again, thanks to all. Best, C. Symons

Cynthia W. Symons, D.Ed., CHES
Professor, Health Education and Promotion
Kent State University
Kent, OH 44242
(330) 672-0681

From: Laura Santurri [lsanturri@kent.edu]
Sent: Sunday, March 11, 2012 12:15 PM
To: ‘Barbara Gordon’
Cc: SYMONS, CYNTHIA; DING, KELE; Tony.Buffington@cvm.osu.edu; ‘Nicole Mehall’
Subject: RE: FW: Quality of Life and IC survey question

Thanks for the reply. I will communicate with Rebecca regarding the issue. I also may suggest to her that she check her computer for viruses (in this day and age, it's not impossible).

I also will send the Kent State Institutional Review Board a message about what has happened, just to keep them in the loop (and I will cc all of you on that message).

I will let everyone know if anyone else reports this. Thanks to everyone for your support in the matter!

Laura Santurri, MPH, CPH
Adjunct Instructor
Master of Public Health Program
Case Western Reserve University

Doctoral Candidate
Health Education and Promotion
College and Graduate School of Education, Health and Human Services
Kent State University

From: Barbara Gordon [mailto:bgordon@kchelp.org]
Sent: Sunday, March 11, 2012 9:04 AM
To: Laura Santurri
Hi, Laura,

This is upsetting.

On the ICA end, once folks click on the link from the ICA site and go to the Survey Monkey page set up for the survey, the link to the ICA ends. The ICA does not have any data on who completes the surveys, who clicked on the link and simply viewed the survey's landing page. If someone were to hack into the ICA database, information about this survey is not contained in the database; however, we will, just as you did, change database access passwords.

Another thought is that she may emailed a note or posted on her social media networks that she took the survey and someone who she thought was a friend is not really a friend. As we all know too well, there have been some online friends who befriended us with an ulterior motive. Just a thought that you may also suggest if she has posted online, she delete those message. Sadly, we all need to be cautious about what we share on Facebook and other message boards.

Please let me know if you hear from additional people.

Best, Barbara

Barbara Gordon, RD
Executive Director, Interstitial Cystitis Association
301-772-4654

Help us make the dream to "Imagine no IC" come true. Contribute online at www.interstitialcystitis.org.

--- Original Message ---
Subject: FW: Quality of Life and IC survey question
From: 'Laura Santurri' <lsanturri@kent.edu>
Date: Sat, March 10, 2012 5:14 pm
To: <ksemenova@kent.edu>, <jlding@kent.edu>, <Tony.Buffington@owm.ou.edu>

Barbara,

See the message that I received below. This is very concerning to me, and I've been communicating with my committee today about what to do.

What I do know:

1. My instrument does not contain any identifying information, and I've confirmed with Rebecca that she did not type in her contact information anywhere on the survey. To confirm this, I searched all open-ended responses for her name and email address, with no results.
2. SurveyMonkey.com has confirmed that my account has NOT been accessed by a third party. I also have not shared my account information with anyone. Regardless, I just changed my password. Even if someone did hack into my SurveyMonkey.com account, however, they wouldn't have been able to get her contact information, because it's not in the survey results.
I've communicated with Rebecca, letting her know that these phone calls are NOT legitimate and that she should not provide any contact information to anyone who calls claiming to be involved with this study.

Rebecca indicated in a follow-up e-mail that she was told that she would receive a gift card to Walmart ($100) as compensation for participating in the study. When she asked the person on the phone to whom she was speaking, the person hung up.

This is the only message that I received about this happening to someone (and I've had a total of 900 responses thus far).

I'm confused as to how this could have happened — is there any way that someone could get access to the ICA Database? I feel badly that this has happened, and I am willing to do whatever needs to be done to ensure that this doesn’t happen to anyone else.

-Laura

From: beccamk43@aol.com Sent: Friday, March 09, 2012 12:27 AM
To: bjurten@kent.edu, kdingle@kent.edu
Subject: Quality of Life and IC survey question

Hello,
I had taken the survey online for Quality of Life & IC. I completed they survey and gave my information. Tuesday, 3/6/2012. Yesterday, Wednesday, 3/7/2012. I was contacted by an unavailable number stating that I qualified for compensation for completing the survey. The lady who called did not identify herself, just stated that I had taken the Qualitity of Life & IC survey online and that thanks to my contributions, I qualified for compensation. My response was ok, but I need you to identify yourself, to which the call was terminated. I was just curious if this was a legitimate phone call, and if so why I was hung up on, and if it is not a legitimate phone call, are you aware this is taking place?
Thank you,
Rebecca
Hi Rebecca,

I've been in communication with all members of my dissertation committee, as well as the Executive Director of the ICA. What we know about the situation:

1. Your contact information is not in my survey data.
2. There is no evidence that my SurveyMonkey.com account has not been accessed by a third party (i.e. hacked).
3. Your survey data is in no way attached to the ICA's contact information for you, and there is no evidence that their database has been hacked.
4. No one else has reported that this has happened to them.

The above are all good things, but I'm still concerned that this happened to you. Did you happen to post anything about taking the survey on Facebook or another social media outlet? I'm wondering if someone might have seen that and decided to "prank" you. I might also suggest checking your computer for viruses – I know that viruses can allow people to see your e-mail, as well as your web browsing history.

We're monitoring the situation closely, and we will certainly take more aggressive action should anyone else report this happening to them. Please also let me know if you receive more phone calls. Once again, I am sorry that this happened to you, and if there is anything else that I can do, please let me know.

Laura Santurri, MPH, CPH
Adjunct Instructor
Master of Public Health Program
Case Western Reserve University

Doctoral Candidate
Health Education and Promotion
College and Graduate School of Education, Health and Human Services
Kent State University

---

Thank you for the response and for attempting to trace the call. I am communicating with my dissertation committee and the President of the ICA regarding the matter. I will follow-up with you to let you know what actions are being taken to prevent this from happening to anyone else.

-Laura

---

From: beccam643@aol.com [mailto:beccam643@aol.com]
Sent: Saturday, March 10, 2012 1:43 PM
To: ksanturr@kent.edu
Subject: Re: Quality of Life and IC survey question

No, I did not give out any contact information. I meant gave my information, as in the answers. I never filled in anything with my name, address, or phone number. That was what was strange to me.
I received another call later yesterday about this survey and my compensation. They do in fact use the Quality of Life & IC title when stating the survey, the call from and unavailable number, I asked them to identify themselves and they hang up.
They tell me I qualify for a 100 gift card and a Walmart gift card.
I tried to gain more information from them, but they hung up as soon as I start to questions. I called my phone company to see if they could trace the call back to a number, and no they say it is an unavailable number.

I am relieved to know you are looking into this. I was suspicious of this call, but I would hate for someone else to get taken advantage of.

-----Original Message-----
From: Laura Santurr <lsanturr@kent.edu>
To: beccam643 <beccam643@aol.com>; kdino <kdino@kent.edu>
Sent: Sat, Mar 10, 2012 12:12 pm
Subject: RE: Quality of Life and IC survey question

I forgot to ask – when you say, “gave my information,” did you provide contact information somewhere in the survey? The Quality of Life & IC Study survey does not ask for any identifying information somewhere in it, so I’m just trying to understand how someone got your phone number. I do not want this to happen to anyone else.

From: beccam643@aol.com (mailto:beccam643@aol.com)
Sent: Friday, March 09, 2012 12:27 AM
To: ksanturr@kent.edu, kdkino@kent.edu
Subject: Quality of Life and IC survey question

Hello,
I had taken the survey online for Quality of Life & IC. I completed they survey and gave my information, Tuesday 3/6/2012. Yesterday, Wednesday, 3/7/2012, I was contacted by an unavailable number stating that I qualified for compensation for competing the survey. The lady who called did not identify herself, just stated that I had taken the Quality of Life & IC survey online and that thanks to my contributions, I qualified for compensation. My response was ok, but I need you to identify yourself, to which the call was terminated. I was just curious if this was a legitimate phone call, and if so why I was hung up on, and if it is not a legitimate phone call, are you aware this is taking place?
Thank you,
Rebecca
Laura Santurri

From: SurveyMonkey Customer Support <surveymonkey1@mailwc.custhelp.com>
Sent: Saturday, March 10, 2012 2:48 PM
To: laura.santurri@case.edu
Subject: survey concern [Incident: 120310-000199]

Recently you requested personal assistance from our on-line support center. Below is a summary of your request and our response.

If this issue is not resolved to your satisfaction, you may reopen it within the next 7 days.

Thank you for allowing us to be of service to you.

If you submitted your question via our Help Center as a logged in customer, you can access your question from the "My Questions" section of the Help Center.

Subject
survey concern

Discussion Thread

Response Via Email (Ruth Buchannon) 03/10/2012 11:48 AM
Hi there Laura,

I'm really sorry your respondent had such a strange experience! I have not heard of such a thing taking place—we don't place phone calls to respondents; or even have a panelist program that offers this kind of incentive so I'm quite stumped what this call may have been regarding. If you hear about this happening with any of your other respondents, I'd be quite surprised, but if so please let us know ASAP.

I looked at your account history and I don't see any evidence that the account is being accessed by a 3rd party—but if you see or hear of anything troubling and don't share your account; please drop us a line with as much information as possible (telephone number, name; etc) so we can look into this.

Take care!
Ruth
Customer Operations Representative

Need respondents to take your survey?
Check out https://smaudience.wufoo.com/forms/surveymonkey-audience-customer-request-form/def/field437-ruth

Customer By Web Form 03/10/2012 10:35 AM
I am currently collecting data for my dissertation using SurveyMonkey.com, and I received an e-mail today from a survey respondent indicating that they had received a phone call (a few times) this past week from someone claiming that they qualified for compensation for completing the survey (see attached pdf). This is terribly concerning to me - my survey does not ask for any identifying information, although someone could
enter it into one of my open-ended questions if they chose to do so.

Is it possible for you to tell me if someone has hacked into my SurveyMonkey.com account?

Any help that you can possibly provide would be much appreciated.

**Question Reference #: 120310-000199**

Category Level 1: Privacy and Security  
Category Level 2: Data Storage  
Date Created: 03/10/2012 10:35 AM  
Last Updated: 03/10/2012 11:48 AM  
Status: Replied

[---001:00195703612---]
APPENDIX G

STUDY INVITATION REMINDER
Appendix G

Study Invitation Reminder

Laura Santurri

From: Interstitial Cystitis Association <ICAnews@ichelp.org>
Sent: Thursday, March 15, 2012 5:13 PM
To: Laura Santurri
Subject: Prelief Linked to Wound Healing

ICA eNews
A Service of the Interstitial Cystitis Association

Visit the [ICA website](http://www.ica.org) to view this week’s stories

---

Get the IC News You Can Use!
Help us continue the fight to advocate for IC patients, secure dedicated NIH funding, serve as a central hub for IC patients and healthcare providers, and fund promising scientific research.

---

Conquering IC. Changing Lives.
The Interstitial Cystitis Association (ICA) is the only non-profit health association solely dedicated to improving the quality of healthcare and lives of people living with interstitial cystitis (IC). The ICA provides advocacy, research funding, and education to ensure early diagnosis and optimal care with dignity for people affected by IC.

---

Interstitial Cystitis Association 1760 Old Meadow Road, Suite 500, McLean, VA 22102
Phone: 703-443-2070 | Fax: 703-696-3280 | ATTN: ICA | Email: info@icnetwork.org

Copyright 2012 © Interstitial Cystitis Association. All Rights Reserved.
Donate
Join
Magazine
About Us
Login
My Home
Store

Search:
Search

Home
About IC
  What is Interstitial Cystitis?
  4 to 12 Million May Have IC
  Anyone Can Get IC
  Different Names for IC
  Frequently Asked Questions
  Causes of IC
  Symptoms of IC
    General IC Symptoms
    Pain & IC
    Humor's Ulcers
    IC Flares
  Women & IC
    Pregnancy
    Intimacy
    Pelvic Exam Tips
  Men & IC
    Intimacy
    Support For Men
  Children & IC
  La Cistitis Intersticial
  IC in Other Languages
  Associated Conditions
    Allergies and Sensitivities
    Celiac Disease
    Chronic Fatigue Syndrome
    Chronic Prostatitis
    Endometriosis
    Fibromyalgia
    Irritable Bowel Syndrome
    Lupus
- Pelvic Floor Dysfunction
- Pudendal Neuralgia
- Siapren's Syndrome
- Vulvodynia

- IC Awareness Toolkit

- Diagnosis & Treatment
- Diagnosis of IC
  - Initial Evaluation for IC
  - Diagnosing Complicated IC Cases
  - Promising IC Diagnostic Tests
  - Wrong Diagnosis
- IC Treatment Guidelines
- IC Treatments
  - IC Diet & Self Management
  - Physical Therapy
  - Antidepressants
  - Antihistamines
  - Pentosan Polysulfate Sodium
  - Bladder Instillations
  - Immunosuppressants
  - Surgical Procedures
  - Neuromodulation
  - Botox
  - Other Medicines
  - Over-the-counter Medicines
- Management of IC Pain
- Complementary Therapies
  - Complementary vs. Alternative
  - Herbs & Dietary Supplements
  - Mind-body Medicine
  - Body-based Practices
  - Energy Medicine
- Bringing Treatments to Market
- IC Healthcare Provider Toolkit
  - Join the Provider Registry
  - Order Educational Materials
  - Get Professional Perspectives
  - CME/CEU
  - IC Reading List
- IC Pilot Research Program

- Living with IC
  - Interstitial Cystitis (IC) Diet
    - What We Know about IC & Diet
      - AUA & ACOG Clinical Guidelines
      - Long Island IC Diet Study
      - USF IC & Diet Study
    - What to Eat—and What Not to Eat
      - IC Elimination-Challenge Diet
      - Food Diaries

- A Balanced Diet Is the Best IC Diet
- Differing Approaches on IC & Diet
  - Allergy, Food & Chemical Sensitivity Testing
  - Gluten-Free Diet
  - IC Food List
  - Antiveast Therapy & IC
  - Alkaline Diet & IC
  - Nutritional Supplements
  - Cooking Tips & Substitution Lists
- Fitness & IC
  - Exercise & IC
  - Managing Stress
  - IC & Sleep
  - Quitting Smoking
- Public Restrooms & Travel Tips
- IC on a Budget
- Disability & IC
  - Talking with Your Employer
  - ICA Podcast on Disability
  - Social Security Disability Insurance
  - Disability Insurance
  - Handicapped Parking Permits
  - Disability Resources & Workbook
- IC Resources
  - ICA Update
  - ICA e-Newswire
  - ICA Store
  - Interstitial Cystitis Reading Lists
  - Helpful Products
- IC & Healthcare Toolkit
  - Health Insurance
  - Finding the Right Doctor
  - Pain Diaries
  - Learn About Your Medications
  - Create a Pill Card
  - Patient Assistance Programs
  - Support Groups
  - ICA Membership
  - Helpful Links & Organizations
- Support
  - Find a Healthcare Provider
  - Ask an IC Question
    - FAQs
    - Glossary of Terminology
  - Support Groups
    - US Support Groups
    - International Support Groups
    - Online Support
    - Starting a Support Group

http://www.ichelp.org/page.aspx?pid=1129&srctid=1&erid=4108527&trid=0a2b982b-d7a... 3/25/2012
ICA eNews March 15, 2012

ICA eNews

Interstitial Cystitis (IC) & Chronic Pelvic Pain News

March 15, 2012

Thanks to everyone for their very generous donations to the ICA. We are so very grateful and privileged to work on behalf of such a tremendous community. Please keep them coming and we will continue marching on...

IC Top IC Stories

• Quality of Life and IC Survey

http://www.ichelp.org/page.aspx?pid=1129&srcid=1&erid=4108527&trid=0a2b982b-d7a... 3/25/2012
• Relief Linked to Wound Healing
• Advocacy Wing: Dedicated Research Funding
• An IC Birthday Wish
• Voices of Hope Blog: Never Give Up
• National Vulvodynia Association—Call for Proposals

IC & Chronic Pain Events

• Gathering of IC Patients in Oklahoma
• Melanie Barton – April 12, Lyme and IC
• IC Support Group Updates
  • IC Support Group of Metro Atlanta, Mar 15, Cartersville, GA
  • New IC Support Group, Phoenix, AZ
  • New IC Support Group, Chicago, IL

http://www.ichelp.org/page.aspx?pid=1129&archid=1&serid=41085278&trid=0a2b982b-d7a... 3/25/2012
News & Events
• Connect
  ◦ ICA Facebook Community
  ◦ ICA on Twitter
  ◦ ICHelp YouTube Channel

Interstitial Cystitis Association

1760 Old Meadow Road, Suite 500, McLean, VA 22102
itimail@ichelp.org

Copyright 2012 Interstitial Cystitis Association

http://www.ichelp.org/page.aspx?pid=1129&srcid=1&crid=4108527&trid=0a2b982b-d7a...  3/25/2012
Diagnosis & Treatment

- Diagnosis of IC
  - Initial Evaluation for IC
  - Diagnosing Complicated IC Cases
  - Promising IC Diagnostic Tests
  - Wrong Diagnosis
- IC Treatment Guidelines
- IC Treatments
  - IC Diet & Self Management
  - Physical Therapy
  - Antidepressants
  - Antihistamines
  - Pentosan Polysulfate Sodium
  - Bladder Instillations
  - Immunosuppressants
  - Surgical Procedures
  - Neuromodulation
  - Botox
  - Other Medicines
  - Over-the-counter Medicines
- Management of IC Pain
- Complementary Therapies
  - Complementary vs. Alternative
  - Herbs & Dietary Supplements
  - Mind-body Medicine
  - Body-based Practices
  - Energy Medicine
- Bringing Treatments to Market
- IC Healthcare Provider Toolkit
  - Join the Provider Registry
  - Order Educational Materials
  - Get Professional Perspectives
  - CME/CEU
  - IC Reading List
  - ICA Pilot Research Program

Living with IC

- Interstitial Cystitis (IC) Diet
  - What We Know about IC & Diet
    - AUA & ACOG Clinical Guidelines
    - Long Island IC Diet Study
    - USF IC & Diet Study
  - What to Eat—and What Not to Eat
    - IC Elimination-Challenge Diet
    - Food Diaries


3/25/2012
Quality of Life & IC Study

- A Balanced Diet Is the Best IC Diet
- Differing Approaches on IC & Diet
  - Allergy, Food & Chemical Sensitivity Testing
  - Gluten-Free Diet
  - IC Food List
  - Antidepressant Therapy & IC
  - Alkaline Diet & IC
  - Nutritional Supplements
  - Cooking Tips & Substitution Lists

- Fitness & IC
  - Exercise & IC
  - Managing Stress
  - IC & Sleep
  - Quitting Smoking

- Public Restrooms & Travel Tips

- IC on a Budget

- Disability & IC
  - Talking with Your Employer
  - ICA Podcast on Disability
  - Social Security Disability Insurance
  - Disability Insurance
  - Handicapped Parking Permits
  - Disability Resources & Workbook

- IC Resources
  - ICA Update
  - ICA e-Newswire
  - ICA Store
  - Interstitial Cystitis Reading Lists
  - Helpful Products

- IC & Healthcare Toolkit
  - Health Insurance
  - Finding the Right Doctor
  - Pain Diaries
  - Learn About Your Medicines
  - Create a Pill Card
  - Patient Assistance Programs
  - Support Groups
  - ICA Membership
  - Helpful Links & Organizations

- Support
  - Find a Healthcare Provider
  - Ask an IC Question
    - FAQs
    - Glossary of Terminology
  - Support Groups
    - US Support Groups
    - International Support Groups
    - Online Support
    - Starting a Support Group


3/25/2012
A Letter from Laura

Dear Member of the ICA Community,

The purpose of this e-mail is to remind you about your invitation to participate in the “Quality of Life & IC Study.” For those of you who have already participated, thank you very much for your participation. While your input was invaluable, please note that there is no compensation for participation. Also, you will not receive any additional information, or requests for further information, via e-mail or phone. If you have questions about the study, please contact Laura Santurri (lsanturri@kent.edu) directly.

If you have not yet filled out the survey, you can still do so. You are eligible to complete the survey if you have been diagnosed with IC at some point in your life, and you are 18 years of age or older.


3/25/2012
The purpose of this study, which consists of a one-time, online anonymous survey, is to gain a better understanding of the types of things that impact quality of life in people living with IC. The survey asks questions about your perceptions of quality of life, social support, stress, your ability to do the things that you need/want to do in life, disease symptoms and severity, and basic demographics. The survey is short and takes no more than 30 minutes to complete. The survey is anonymous, as it does not ask for any identifying information.

This study is being conducted by Laura Santurri, MPH, CPH, a doctoral candidate in Health Education and Promotion at Kent State University (KSU) and with the support of the Interstitial Cystitis Association (ICA). In addition to being an IC patient for the past 14 years, Ms. Santurri has also been involved in IC support group leadership and patient advocacy for the past decade, as well as IC research (through her academics) for the past eight years. Her research efforts are guided by her dissertation committee, which consists of faculty from both KSU and The Ohio State University.

There are no risks in participating in this study that are greater than those encountered in everyday life, and you would be subject to no penalties or consequences if you decide not to participate. You may also stop answering questions and withdraw from the study at any time without penalty.

If you are ready to take the survey, please click the following link:
https://www.surveymonkey.com/s/B526RTD

If you would like to obtain additional information about the study, please contact:

Laura Santurri, MPH, CPH
17576 Auburn Road
Chagrin Falls, Ohio, 44023
lsanturri@kent.edu (e-mail)
330-608-1830 (phone)

OR

Kele Ding, MD, PhD
142 Nixson Hall
Kent State University
Kent, Ohio 44242
kding@kent.edu (e-mail)
330-672-0688 (phone)

Information about KSU’s rules for research can be obtained by contacting the IRB at 330-672-2704.

Thank you for your time and consideration. Your participation in this study may lead us to have a better understanding of what it is like to live with IC.

Revised March 15, 2012

Research

3/25/2012
• Research Results
• Clinical Trials
  - Need Help Recruiting?
  - Studies Seeking Patients
• Conference Reports
  - AAPM
  - AURS
  - ASTA
  - ICOTIUGA
  - SHUH
• Literature Reviews
  - Embryology
  - Epidemiology/Genetics
  - Diagnosis/Assessment
  - Treatments/Drug Discovery
  - Social Issues
  - Medical Education
  - Basic Research
• Landmark IC Studies
  - MAPP
  - RICE
  - BACH
• ICA Basic Research Program
  - What We've Learned Thus Far
  - Current Projects
  - Request for Proposals
  - Donate to IC Research
• ICA Patient Surveys
  - CAM Survey (2009)
  - Music Therapy (2009)
  - Trends in IC Study (2007)
  - Diet Survey (2004)
  - Other ICA Surveys & Polls
• Research Toolkit
  - Funding Opportunities
  - Help with Recruitment
Appendix H

Study Invitation Final Reminder

Laura Santurri

From: Interstitial Cystitis Association <ICAnews@ichelp.org>
Sent: Monday, March 26, 2012 4:15 PM
To: Laura Santurri
Subject: Last Chance to Respond

ICA eNews
A Service of the Interstitial Cystitis Association

Dear Member of the ICA Community,

The purpose of this email is to invite those who are living with interstitial cystitis (IC) to participate in the "Quality of Life & IC Study." To be eligible to complete the survey, you must have been diagnosed with IC at some point in your life, and you must be 18 years of age or older.

Read More

Get the IC News You Can Use!
Help us continue the fight to advocate for IC patients, secure dedicated NIH funding, serve as a central hub for IC patients and healthcare providers, and fund promising scientific research.

Conquering IC: Changing Lives.
The Interstitial Cystitis Association (ICA) is the only non-profit health association solely dedicated to improving the quality of life for those living with interstitial cystitis (IC). The ICA provides advocacy, research funding, and education to ensure early diagnosis and optimal care with dignity for people affected by IC.

Interstitial Cystitis Association 1780 Old Meadow Road, Suite 500, McLean, VA 22102
Phone: 703-442-2070 | Fax: 703-506-3266 ATTN: ICA | Email: icanews@ichelp.org

Copyright 2012 © Interstitial Cystitis Association. All Rights Reserved
REFERENCES
REFERENCES

Altuntas, C. Z., Daneshgari, F., Sakalar, C., Goksoy, E., Gulen, M. F., Kavran, M., . . .


Marks, J. S. (2003). We're living longer, but what about your quality of life? *Chronic Disease Notes & Reports, 16*(1), 2.


