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Symptom Intrusiveness, Chronic Conditions and Health-Related Quality of Life: Development of Conceptual and Measurement Models

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Symptom Intrusiveness, Chronic Conditions and Health-Related Quality of Life:

Development of Conceptual and Measurement Models

By

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Abstract

Background: The number of patients in the United States living with chronic conditions is increasing as patients are surviving conditions that were previously fatal. This increase in survival has resulted in a shift in the disease burden in the United States from infectious to chronic diseases. Many patients with chronic conditions experience associated symptoms that impact their health-related quality of life more significantly than those without associated symptoms. To enable patients to achieve what they determine to be an acceptable state of well-being, health care providers must first be aware of the factors and the relationships among the factors that impact the perceptions patients have of their health-related quality of life. To comprehensively assess their patients, health care providers must incorporate their objective perspectives with the subjective perspectives of their patients. A comprehensive assessment will enhance the ability of health care providers to develop treatment plans that enable patients to achieve the state of well-being they desire. Beyond traditional health-related quality of life instruments, an instrument is needed to assess patients' perceptions of the impact symptoms associated with a chronic condition have on their health-related quality of life. The impact of symptoms associated with chronic conditions is the focus of this dissertation.

Objective: The objective was first to conduct a review of the literature to define chronic wound pain, the focus of the study in this dissertation, as chronic wound pain is often under-assessed and under-treated as a result of inadequate knowledge related to this type of pain. The second objective was to develop a conceptual map illustrating the factors and the relationship among the factors that shape patients' perceptions of their health-related quality of life. The next objective was to develop a subjective health-related quality of life assessment instrument and to test the

reliability and validity of the newly developed instrument among patients experiencing pain associated with chronic wounds.

Results: The concept of chronic wound pain was explored and included defining this type of pain and identifying its prevalence, pathophysiology, and dimensions. The Chronic Illness/Disease States – Symptom Intrusiveness Model was developed to demonstrate the factors that contribute to patients' perceptions of their health-related quality of life and the Symptom Intrusiveness Rating Scale was developed as a method to subjectively assess patients' perceptions of their health-related quality of life. Validity and reliability testing of the new instrument was conducted among patients with chronic wound pain. Patients with chronic symptoms confirmed in cognitive pretesting that the items on the instrument were interpreted as intended. Experts in the field of health-related quality of life confirmed that the statements on the instrument were all relevant. Test retest confirmed reliability of the Symptom Intrusiveness Rating Scale when conducting retest 2 to 4 days after the initial survey. However, conducting a retest study 2 weeks after the initial survey was found not to be a feasible method of testing reliability in a patient population admitted to an acute care facility.

Conclusion: A subjective assessment can be quantified by utilizing the newly developed Symptom Intrusiveness Rating Scale, an instrument that focuses on the impact symptoms associated with chronic conditions have on patients' health-related quality of life. A comprehensive assessment will enhance a health care provider's ability to develop treatment plans that will improve the potential for patients to achieve their desired state of well being. Future research will focus on testing the validity and reliability of SyIRS in studies with larger sample sizes and participants with varied chronic symptoms.

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Introduction

The disease burden in the United States has shifted from infectious diseases to chronic conditions, with chronic conditions currently accounting for 75% of health expenditures and deaths annually (1). By the year 2020, an estimated 80 million Americans will experience multiple chronic conditions (2). Because of the significant impact chronic conditions have on the health care system and patients' health-related quality of life (HRQoL), it is vital for health care providers (HCP) to develop an in-depth understanding of this impact and the most effective ways to assess and treat these conditions. The assessment of chronic conditions must include a HCP's objective assessment as well as a subjective assessment from the perspective of the patients experiencing the chronic conditions and associated symptoms. As part of an assessment, HCPs must recognize that patients who are experiencing symptoms related to chronic conditions will assess the impact of the conditions on their HRQoL differently than patients who are not experiencing symptoms associated with the conditions. A review of the literature identified research related to the impact chronic conditions have on patients' HRQoL, yet a gap was noted in research that focused on the impact symptoms associated with a chronic condition have a HRQoL.

Responding to the need for such research, we first developed the Chronic Illness/Disease States – Symptom Intrusiveness Model (CIDS-SIM) to illustrate how symptoms associated with chronic conditions can impact patients' HRQoL. The development of CIDS-SIM is underpinned by the Complexity Theory that includes four assumptions which indicate: (a) the relationship between patients and their HCP is impacted by social determinants of health and HRQoL, (b) any one concept may or may not lead to a predictable change, (c) new behaviors will occur as a result of relationships patients have with others, and (d) factors that are blended can impact an

outcome (3). The first section of CIDS-SIM identifies factors that have an effect on the interaction patients have with their HCP. In the next section, CIDS-SIM illustrates that the outcome of this interaction impacts the perception patients have of *symptom intrusiveness*, the degree to which patients determine the symptoms associated with chronic conditions are intruding on their HRQoL. This section also identifies factors that contribute to patients' perceived degree of symptom intrusiveness. The third and final section of CIDS-SIM identifies the components that define HRQoL and also describes that the perceived degree of symptom intrusiveness will affect the perception patients have of their HRQoL.

It is often necessary to quantify the degree to which a symptom is impacting on patients' HRQoL to determine needed treatment and to evaluate the outcome of the treatment. Since the impact symptoms associated with chronic conditions have on patients' HRQoL can be assessed most accurately with input from the patients experiencing the symptoms, patients' subjective perspective should be included in the assessment. However, in the literature there is no evidence that revealed an instrument intended to subjectively assess and quantify the impact symptoms associated with chronic conditions have on patients' HRQoL. The Illness Intrusiveness Rating Scale (IIRS) developed by Dr. G. Devins (4) was identified, during the review of the literature, as an instrument that could be adapted to focus specifically on the impact of the symptoms of a chronic condition. The adapted instrument was titled the Symptom Intrusiveness Rating Scale (SyIRS). A study was conducted to test, first the feasibility of utilizing SyIRS to assess the perceptions patients have developed of the impact symptoms associated with a chronic condition have on their HRQoL. The validity and reliability of the instrument were also tested in this study which was conducted among a population experiencing pain associated with chronic wounds.

Pain

Pain, the most common reason for patients to seek medical care (5), has been defined in numerous ways by various individuals, groups, and organizations. In 1933 the Oxford English Dictionary defined *pain* as "a primary condition of sensation or consciousness, the opposite of pleasure; the sensation which one feels when hurt (in body or mind); suffering, distress" (p. 377) (6). The most widely accepted definition of pain was posited by the International Association for the Study of Pain (IASP) (1994), which defined *pain* as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (para 1). The IASP and many others who have extensively studied the pain phenomenon agree that pain is subjective (7-9). Patients' perceptions of their pain are affected by pervious experiences, emotional states, mental states, and cultural background (10-12).

Pain is a phenomenon experienced by most people at some point in life (1). It is also a sensation people fear and that can cause great distress and even disability. As such, pain, both acute and chronic, has been shown to be the factor with the greatest negative impact on patient's health-related quality of life (HRQoL) (13-15), affecting functional status and well-being (16). Acute pain is a beneficial type of pain as it signals patients that something is wrong and that action must be taken to prevent further injury (17). Chronic pain does not serve the same protective purpose as acute pain (5). It does not alert the body to injury, but instead can exist without any additional peripheral pain input (18).

Chronic Pain

Chronic pain is an experience as opposed to an expression of the immediacy of acute pain (19), a symptom that overwhelms all other symptoms and impacts a person's ability to work, eat, sleep, and be physically active (20). The time for which pain is considered to be chronic has been

defined in multiple ways. The IASP defines *chronic pain* as "pain that persists beyond normal tissue healing time, which is assumed to be 3 months" (p. 1250) (21). Pain is often deemed to be chronic if it lasts longer than 6 weeks (22); however, more recent research has noted that elements of chronic pain can be distinguished much earlier than 6 weeks post-injury (23). Pain has also been determined to be chronic if the pain has existed for 6 or more months in the previous year (24). In a survey conducted by the American Pain Society (2011), the more common type of chronic pain was one that flared frequently and was present on average almost 6 days per week. Almost 33% of those surveyed described their chronic pain as the worst pain they could possibly imagine and 66% of the respondents have been living with pain for more than 5 years (20).

Chronic pain is commonly a result of low back pain, headache, arthritis, nerve damage, cancer, and other conditions (20). A common cause of disability, chronic pain is not often curable yet it is manageable (25). HCPs who do not treat or who under-treat chronic pain do so, in part, because they lack adequate knowledge of chronic pain (25) and they often doubt the credibility of the patient claiming to experience chronic pain (19). Chronic pain is a self-reported condition, and HCPs often explain chronic pain as a psychological issue (26). As a result, patients are often afraid to report chronic pain for fear of the psychological label applied. If chronic pain is to be properly addressed, patients must be encouraged to discuss any chronic pain they are experiencing, its intensity, duration, location, onset, and triggers. They must also be encouraged to discuss feelings of anxiety, depression, or anger associated with their pain. In order to effectively treat those who express their chronic pain experience, HCPs need to be aware of signs of chronic pain and behaviors exhibited by those experiencing chronic pain (26).

Communication between HCPs and patients experiencing chronic pain is vital to overcoming these barriers and developing an effective management/treatment plan

Chronic Wound Pain

Chronic wound pain is a background symptom that can be intermittent or persistent and exists at rest, between wound-related procedures and/or when repositioning (27). It often does not have a specific trigger. Instead, chronic wound pain is often associated with the cause of the wound and local changes in the wound environment (27). Chronic wound pain is often a combination of acute and chronic pain (9).

Prevalence

Multiple attempts have been made to estimate the prevalence of chronic pain in the United States. Study results indicate 20% to 60% of Americans experience chronic pain (28). A survey conducted by the U.S. Department of Health and Human Services estimates that 26% or 76.5 million Americans report experiencing pain that lasted longer than 24 hours. Of the Americans who report having experienced pain, 42% or 32.13 million report pain that has lasted longer than one year (29).

In an Internet survey of 27,035 adults 18 and older, 30.7% noted pain that lasted longer than 6 months (30). This survey found that more females (64.8%) than males (35.2%) experienced chronic pain. When stratified by type of pain, the prevalence of chronic lower back pain was similar in females and males. The overall prevalence of chronic pain increased with age with the exception of females over 65 in whom the prevalence decreased. When the data from this study were adjusted for all other sociodemographic factors, the rate of chronic pain increased among those who were unemployed due to disability and among those in the lowest level of household income (< $25,000 per year) (30).

In a study conducted in the US, the National Center for Health Statistics reported that 42% of the respondents aged 20 and older and 57% of those aged 65 and older reported experiencing pain lasting 1 year or longer (5). A survey conducted by Research!America estimated that 100 million Americans experience chronic pain (31). A pharmaceutical corporation cited a survey indicating that 28% of the adult population or 56 million Americans experience chronic pain (32). Finally, it is estimated that 9% of the United States population experiences moderate to severe chronic pain and is more common in women than in men (29).

The prevalence of chronic wound pain, often associated with chronic wounds (33) is difficult to determine. Studies focused on the prevalence of chronic wound pain concluded that a majority of patients with chronic wounds experience wound pain to some extent (33, 34). A study by Phillips et al. noted that 87% of the participants in their study reported chronic wound pain as mild to severe (35).

Dallam (1995) reported that 59% of study participants experienced some degree of chronic wound pain, yet only 2% received analgesics in a timely manner (36). Szor and Bourguignon (35) focused on chronic pressure ulcer pain and noted that 87% of the participants reported pain during dressing change, 84% reported pain at rest, and 42% reported that they experienced pain all the time.

An estimated 80% of individuals with chronic wounds experience persistent pain with 50% of those people rating the pain as moderate or the worst pain they have experienced (27, 33, 34). Eighty percent of patients with chronic wounds experience pain that is persistent between dressing changes (27).

Dimensions of pain

The dimensions of pain, or the components that contribute to patients' perception of pain include biological, psychological, cultural (10), and previous experiences with pain (7). In 1965

when Melzack and Wall first formulated a description of the sensory transmission of a pain signal, they were aware that there was also an emotional and cognitive dimension related to the perception of pain (37). The three dimensions of the pain experience delineated by Melzack and Wall are: (a) sensory - the physical sensation, (b) affective - how pain affects a person's emotional state, and (c) cognitive – how a person makes sense of or explains his or her pain experience (37) A differentiation among patients experiencing chronic pain who have experienced previous trauma either physical or emotional and those who have not experienced trauma, is seen in the affective dimension of chronic pain (26). The cognitive dimension of chronic pain will be influenced by past experiences with pain, imagination, unconscious conflicts, and the significance of pain for the people experiencing it (26).

Assessment

An assessment that does not include an evaluation of all the dimensions of pain often results in the pain being under-estimated, under-assessed, under-treated and/or neglected by HCPs (38) Only an estimated 25% of those experiencing chronic pain receive appropriate treatment (32), and the lack of appropriate treatment is impacted by a lack of appropriate assessment due to the following:

- The perception a health care provider (HCP) develops of a patient's pain which is impacted by factors including; lack of a laboratory test that can assess pain intensity (38), a HCP's lack of adequate knowledge related to the mechanisms of pain (39, 40), and ineffective communication between patients experiencing the pain and their HCP (17).

- HCP's failure to believe a patient who states he or she is experiencing chronic pain (19). HCPs who do not treat patients' complaints of chronic pain as credible will most often not treat or under-treat the pain (19).
- Financial barriers, treatment non-adherence, and lack of a relationship with a HCP (32)

Acute pain, chronic pain, and chronic wound pain, which is often a combination of acute and chronic pain, must be managed appropriately as untreated pain or pain that is not under control has significant adverse effects on patients' perceptions of their HRQoL (29). Unrelieved pain can affect patients' ability to concentrate, maintain employment, exercise, socialize, sleep, participate in leisure activities, maintain their home, and/or have intimate relations. Untreated or undertreated pain also impacts patients' psychological well-being, increasing the incidence of depression, irritability, listlessness creating feelings of inability to cope and uselessness (29). Therefore, since acute, chronic, and chronic wound pain affect multiple aspects of a patient's life; the most effective treatment includes not only treatment of the physical symptoms of pain but also treatment that addresses the impact on patients' HRQoL (20, 41). The goal of a pain management plan is to return patients to their desired level of functioning. The most appropriate approach to effective management is multifaceted. Evidence based practice for the treatment of chronic pain includes (a) medication management, (b) non-medication management, and (c) complementary and alternative medicine (28, 42, 43).

An effective management/treatment plan for those experiencing chronic pain and chronic wound pain can impact patients in multiple ways enabling them to maintain their well-being and HRQoL (2). Effectively managing chronic pain and chronic wound pain will enable many

patients to maintain social relationships (44), vitality, and mental health (4, 45, 46) all which contribute to maintaining or improving ones sense of well-being and HRQoL (13).

Symptoms associated with chronic conditions often have a negative impact on patients' HRQoL, thus an assessment of these symptoms must be addressed from the perspective of the HCPs as well as from the perspective of the patients experiencing the symptoms. The work presented here explores the need for such an assessment by first presenting CIDS-SIM, an illustration of the factors and the relationship among the factors, which contribute to the perception patients have of the impact symptoms associated with a chronic condition have on their HRQoL. Next, SyIRS, a novel HRQoL assessment instrument that focuses on symptoms associated with chronic conditions, is presented as a way to subjectively assess the impact of symptoms associated with chronic conditions. To address the focus of the study conducted, the phenomenon of pain is explored including acute pain, chronic pain, and pain associated with chronic wounds. Finally, the results of a feasibility pilot study conducted among patients experiencing pain related to chronic wounds are presented. The goal of this work is to enhance the assessment HCPs conduct of patients who are experiencing symptoms associated with chronic conditions, thus improving the potential for patients experiencing this pain to achieve a HRQoL which they determine to be acceptable.

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Chronic Wound Pain: An Exploratory Review of the Literature

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Abstract

Purpose: Patients experiencing chronic wound pain state that relief of pain is most often their highest priority in treatment; yet chronic wound pain is often inadequately assessed, which can lead to the development of a treatment plan that does not sufficiently address pain relief. An inadequate assessment of chronic wound pain can result in patients experiencing unnecessary pain which can significantly impact their health-related quality of life. Factors that, in part, contribute to an ineffective assessment of chronic wound pain include lack of consensus among health care providers regarding the definition of chronic wound pain, lack of knowledge regarding the mechanisms of pain, lack of awareness of the complexity of chronic wound pain,, and lack of differentiation between acute pain and chronic pain as each relates to chronic wound pain. The purpose of this review is to serve as a starting point for an exploration of the concept of chronic wound pain including its pathophysiology, dimensions, and current definitions. The prevalence of acute, chronic, and chronic wound pain is also reviewed to support the need for further research in this field based on the number of patients experiencing chronic wound pain and the burden on the health care system.

Design: The design for this evaluation of the literature is an exploratory review.

Method: A literature search was conducted in the Ovid Medline, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, and PsycARTICLES electronic databases. Medical subject headings (MeSH) and keywords used for this review were *wound and injuries, chronic wound, pain, chronic pain,* and *prevalence.* The search was limited to articles in English and related to humans.

Results: Twenty-three articles were identified as relevant to this review. In addition to articles that represent current knowledge, seminal research was also identified for inclusion in this review.

Conclusions: Chronic wound pain is prevalent in the United States and significantly impacts those experiencing it. Chronic wound pain also poses a significant financial impact on the health care system. Although chronic wound pain significantly impacts patients and the health care system, this complex type of pain is often inadequately assessed resulting in treatment that does not sufficiently address pain. To improve patient outcomes and to decrease the financial burden on the health care system, health care providers need to assess chronic wound pain more effectively which will enhance their ability to develop treatment plans that more effectively address pain. Health care providers need to come to consensus on the definition of chronic wound pain, realize the complexity of chronic wound pain which has a physiological and emotional component, and develop their understanding of the pathophysiology of chronic wound pain.

Chronic Wound Pain: An Exploratory Review of the Literature

Pain is a symptom related to numerous medical conditions and the most common reason people seek medical care (1). It is a phenomenon experienced by most people at some point in their lives that causes great distress and disability (2). Pain also has a significant financial impact with health care costs and lost productivity related to pain estimated to be $61.2 billion annually in the United States (3). In studies related to a more specific type of pain, chronic wound pain, nearly 80% of people with chronic wounds experience pain either intermittently, continuously, or during procedures (4).

Although pain has a significant effect on people and the health care system, it is often under-estimated and under-treated (4). This pattern is found among multiple health care providers (HCPs) including physicians, nurses, and other health care professionals and across multiple settings including inpatient, outpatient, emergency departments, and long term care (5). One factor in the under-estimation and under-treatment of pain is inadequate knowledge among HCPs of pain (5). Pain, both acute and chronic, differs in function and benefit. Acute pain is a beneficial type of pain, providing a signal that something is physically wrong and that action must be taken to prevent further injury (6). In contrast, chronic pain serves no useful purpose and does not protect a person from further tissue damage (7). Pain associated with chronic wounds can be acute and/or chronic and can significantly impact patients' health-related quality of life (HRQoL) (4). Therefore, to effectively assess and treat chronic wound pain HCPs need to have a thorough understanding of the pathophysiology of acute and chronic pain and the dimensions of each type of pain.

The research questions that guided this review are:

1. What is the prevalence of acute pain, chronic pain, and chronic wound pain?

2. What is the pathophysiology of acute, chronic, and chronic wound pain?
3. What are the dimensions of pain?

Literature Review

A comprehensive, computer-assisted search of the literature was conducted in the Ovid Medline, Cumulative Index of Nursing and Allied Health Literature (CINAHL), PsycINFO, and PsycARTICLES electronic databases to identify the pathophysiology, pathways, and dimensions of chronic wound pain. The review was limited to English and humans, and to manuscripts included in the electronic databases from inception of the databases through January 2012. In Ovid Medline, the MeSH term *pain* (69718) was combined with the keyword *chronic wound* (571) resulting in 15 abstracts. In CINAHL, PsycINFO, and PsycARTICLES, the MeSH term *wound and injuries* (9043) was combined with the MeSH term *pain* (86072), and the keyword *chronic* (113798) which resulted in 29 abstracts. These abstracts were reviewed for relevancy to this review. Twenty manuscripts were identified. Seminal research related to the pathophysiology and dimensions of pain was also identified.

The electronic databases were also searched for prevalence data related to pain. The MeSH term *chronic pain* (8440) was combined with the MeSH term *prevalence* (582) resulting in 89 abstracts. After review, three manuscripts were identified as relevant to this review.

Prevalence

Limited studies have been conducted regarding the prevalence of pain, yet these studies indicate that acute, chronic, and chronic wound pain are significant in the United States. Table 2 notes the results of studies regarding the prevalence of pain.

Table 2 Pain prevalence

TYPE OF PAIN	SOURCE	DESIGN/SUBJECTS	N	PREVALENCE
Acute	National Center for Health Statistics *Trends in the Health of Americans* (8)	Population based survey of people over the age of 20	9,900	26%
Chronic	Hardt review of the National Health and Nutrition Examination Survey (NHANES) (9)	Random web-based survey	10,271	14.6%
	Clark (10)	Retrospective medical record review	300	50%
	National Center for Health Statistics *Trends in the Health of Americans* (8)	Population based survey of people over the age of 20	9,900	56%
Chronic wound	Phillips (11)	Retrospective study of people with lower extremity wounds	73	59%
	Dallam (12)	Cross-sectional study of people with chronic pressure ulcers	132	87% during dressing change 84% at rest 42% all the time

Pathophysiology

Pathways

The first attempt to understand pain pathways was made by Rene Descartes in 1664 and published in the *Treatise of Man* (13). The theory proposed that the transmission of pain was through a single channel from the skin to the brain. Descartes believed that when a person came in contact with a noxious stimulus, the skin in the area involuntarily moved, causing a thread to be pulled that opened a small valve in the brain through which animal spirits would travel to the muscles causing the withdrawal of the body part from the stimulus (13).

A more definitive theory of the pain pathways did not occur until the 20th century. In 1965, Melzack and Wall proposed a theory of pain pathways termed the Gate Control Theory (14). This theory posits that when an injury occurs there is a release of inflammatory mediators that cause the excitation of pain receptors in the area of the injury. Pain messages that originate

in the nerves associated with the damaged tissue travel along the peripheral nerves to the dorsal horn of the spinal cord and then to the brain. Melzack and Wall proposed that before the impulses can reach the brain, they encounter nerve gates in the dorsal horn substantia gelatinosa in the spinal cord. Small nerve fibers or pain receptors open the gate and allow the transmission of the signal. Large nerve fibers, normal receptors, promote the closing of the gate; therefore, the signal is not transmitted and pain is not perceived. Emotional factors including previous experiences with pain, culture, stress, and environment can affect the opening or closing of the gates through the release of neurotransmitters. When the gates are open, the impulses pass through and travel to the brain, and pain is perceived (14). When the gates are closed secondary to a sufficient alternate impulse such as massage, acupuncture, or even downward messages from the brain, the impulses are kept from reaching the brain, thus preventing a perception of pain (15). The Gate Control Theory suggests that mechanisms in the central nervous system control the perception of a noxious stimulus that integrates the impulse moving toward the central nervous system with the downward modulating or tempering process from the brain (14). This explains why similar stimuli can evoke different responses in different people.

Acute pain

Acute pain is incited by tissue damage and persists for varying lengths of time until healing takes place (16). It is perceived quickly as a result of a specific injury and is relatively short-lived. Acute pain is associated with hyperactivity of the sympathetic nervous system producing tachycardia, increased respiratory rate and blood pressure, diaphoresis, and dilated pupils (17). It follows nociceptive stimulation secondary to physical, thermal, or chemical tissue injury (16). The processes involved in nociception are transduction, transmission, perception, and modulation. Transduction begins when nociceptors or C fibers and A-delta fibers respond to

stimuli. The stimulation causes a release of chemical mediators from the damaged cells. These mediators activate and/or sensitize the nociceptors to the stimuli. An exchange of sodium and potassium ions occurs at the level of the cell membrane. This exchange results in the initiation of a pain impulse. The pain impulse is transmitted to the neurons in the dorsal horn of the spinal cord where excitatory neurotransmitters are released. The impulse is then transmitted to the brain stem and thalamus where the pain is perceived. The pain impulse can be modulated by the release of neurotransmitters that block or partially block the transmission of the pain impulse (16). Acute pain is frequently well localized, constant, and time limiting indicating that this type of pain resolves as the injury improves and heals (17). Acute pain is beneficial since it provides a signal to a person that a change must be made to prevent further injury (6).

Chronic Pain

Chronic pain is defined by the International Association for the Study of Pain (IASP) as pain that persists beyond normal tissue healing time (18). The time frame for which pain is considered to be chronic has been defined in multiple ways. Pain is most often classified as chronic if it lasts longer than 6 weeks (19). However, more recent research has noted that elements of chronic pain can be distinguished much earlier than 6 weeks post-injury (20), and pain has also been determined to be chronic if the pain exists for 6 or more months in the previous year (21). Chronic pain is commonly associated with various medical conditions including diabetes, arthritis, migraine headaches, fibromyalgia, cancer, shingles, sciatica, and previous trauma or injury (22). The physiology of chronic pain remains unclear, yet it is thought to be a result of nerve damage due to degeneration, pressure, inflammation, or infection (16). When a nerve becomes damaged in one of these manners, it becomes electrically unstable, firing

signals at inappropriate and random times, often in a disordered fashion. The associated pain is typically described as burning, shooting, stinging, or as a sensation of pins and needles (16). A person experiencing chronic pain experiences an altered transmission of the normal pain pathways resulting in central and peripheral sensitization in which the pain sensation is sustained after nociceptive stimuli have ceased (23). Three of the common altered pain transmission pathways noted with chronic pain are wind-up, allodynia, and primary hyperalgesia (24). Wind-up is a result of repeated stimulus of the same intensity which over time can lead to an increased neural response. Patients experience an increased pain response to the same stimuli as a result of this altered pain pathway. Allodynia presents as an area of enhanced sensitivity around or near the original site of injury in which an extreme pain response is elicited as a result of harmless stimuli. Finally, primary hyperalgesia results from injury due to inflammation, infection, or ischemia which produce chemical mediators that activate or sensitize nociceptors. When the injury persists the threshold for activation of nociceptors is decreased and the response to the stimuli is enhanced which leads to increased sensitivity to the area of damage (24).

Chronic wound pain

Chronic wound pain, the pain associated with chronic wounds, is noted at rest, during wound-related procedures, and/or when repositioning (4, 25). Chronic wound pain is frequently associated with the cause of the wound and local changes in the wound environment (25). After the initial injury, pain related to wounds that do not heal within the normal or expected time frame can be classified as chronic pain when it is triggered by persistent inflammation or by stimulation of the release of mediators that activate local pain receptors. Wound pain can also be triggered by procedures such as debridement or dressing changes and be classified in these instances as acute pain (25). Krasner classified wound pain in relation to the cause, referring to

pain that occurs during single, non-repetitive procedures such as wound debridement as *noncyclic acute pain* (26). If the pain occurs during repeated activities such as dressing changes or position changes, the pain is referred to as *cyclic acute pain.* Pain that occurs without manipulation is referred to as *persistent or chronic pain* (26). Therefore, pain associated with chronic wounds is often a combination of acute and chronic pain.

Pain dimensions

Pain dimensions are defined as the components that contribute to patients' perceptions of pain and include sensory, affective, and evaluative elements (14). The *sensory* dimension refers to a patient's description of one's pain including the location, quality, intensity, and duration. These descriptors relate to the increased sensitivity of neurons following an injury (27). Pain noted by this dimension can be caused by ischemia, inflammation, and/or neuropathic mechanisms. Treatments such as wound debridement can also elicit this type of pain. The *affective* dimension is the emotional response patients have to the pain experience. It is the dimension that indicates how pain makes patients feel (27). The *evaluative* dimension refers to patients' sense of how the pain affects their HRQoL. This dimension illustrates that patients' perceptions of pain are impacted by reminders in the environment, such as previous pain experiences and culture. When the environmental reminders are reinforced, pain behavior is reinforced and pain is more likely to persist. The affective and evaluative dimensions dominate the chronic pain experience (14).

Conclusions

Chronic wound pain, which can be acute and/or chronic, is a symptom that patients experiencing it express to be their highest priority in regards to management and treatment of their condition; yet it is often under-assessed and under-treated (25). It is also a symptom that is

critically understudied and which poses significant challenges for the HCPs. The prevalence of chronic wound pain, the impact it has on the health care system, and the lack of a clear understanding of this symptom confirm the need for further research related to the pathophysiology of this complex type of pain and effective ways to assess, manage, and treat patients experiencing it. Effective management and treatment will decrease the burden on patients with chronic wound pain and promote an improved state of well-being. The negative impact chronic wound pain has on patients' HRQoL is significant and therefore, should always be considered when assessing patients who express experiencing chronic wound pain. Further research is also needed regarding how this type of pain can be more effectively managed to improve patients' HRQoL.

One factor that impacts the effectiveness of the assessment and treatment of patients with chronic wound pain is an HCP's knowledge that this type of pain can be acute and/or chronic as well as their knowledge of the pathophysiology and dimensions of acute and chronic pain. By understanding the differences between acute and chronic pain, the way patients describe and perceive their pain, and patients' emotional responses to pain, HCPs will be able to effectively assess chronic wound pain.

Many symptoms related to chronic conditions such as chronic wound pain have a physiological and psychological component that significantly impact multiple aspects of patients' lives including their HRQoL; therefore, future studies are needed that will lead to the development of a theory that focuses on symptoms associated with chronic conditions. The development of a theory needs to begin with a conceptual model that indicates the concepts related to symptoms of a chronic condition and the relationship among the concepts.

Further research is also needed regarding effective assessment of chronic symptoms including chronic wound pain. Quantifying the impact chronic symptoms have on patients' HRQoL which encompasses both physiologic and psychologic components related to chronic symptoms, will enhance HCPs ability to develop an effective treatment plan and to assess the efficacy of the plan. With an understanding of the complexity of chronic wound pain including the mechanisms and dimensions of pain as well as incorporating the patients' perspectives of the pain experience in their assessment, HCPs will improve their ability to more positively impact on patient outcomes.

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The Chronic Illness/Disease States-Symptom Intrusiveness Model

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Abstract

Background: Patients indicate that symptoms they experience related to chronic conditions can significantly impact their health-related quality of life. Although this impact is considerable, there is limited related research and no theories were identified that addressed the intrusiveness of symptoms associated with chronic conditions on health-related quality of life. Therefore, the purpose was to identify components that contribute to patients' perceptions of how chronic symptoms impact their health-related quality of life and to develop a conceptual model that demonstrates the interaction among those components.

Method: The method used for the development of this conceptual model was Fawcett's Conceptual-Theoretical-Empirical technique.

Result: The Chronic Illness/Disease State – Symptom Intrusiveness Model was developed to illustrate the relationship among patients' interactions with their health care provider, symptom intrusiveness, and health-related quality of life. In contrast to other theories that address effects of patients' conditions, this unique conceptual model specifically addresses symptoms of chronic conditions and the impact on health-related quality of life from the perspective of the patients experiencing them.

Keywords: symptom, intrusiveness, chronic illness, chronic disease, health-related quality of life, patient-provider interaction, conceptual model

The Chronic Illness/Disease States - Symptom Intrusiveness Model

In the past century, the disease burden in the United States has shifted from infectious to chronic diseases, with chronic diseases accounting for 75% of health expenditures annually (1). Confirming this shift, it is estimated that by the year 2020, 80 million Americans will experience chronic conditions (2).

Many patients with chronic conditions experience associated symptoms that can significantly impact their health-related quality of life (HRQoL). When addressing chronic conditions, health care providers (HCPs) often objectively assess the etiology of patients' conditions (3) by analyzing, in part, a physical exam, blood tests, and radiologic studies. An evaluation based on an objective assessment alone will not take into account patients' perspectives of how symptoms they are experiencing impact their HRQoL

Through a comprehensive review of the literature, the Symptom Management Model was the only theory identified that addressed symptoms related to chronic conditions (4) and no theories were identified that addressed the intrusiveness of symptoms related to chronic conditions. Therefore, to address this gap, the Chronic Illness/Disease State – Symptom Intrusiveness Model (CIDS-SIM) was developed (Appendix A) to incorporate patient-HCP interactions, patients' perspectives of symptom intrusiveness, and the impact of chronic symptoms on patients' HRQoL. This model has been adapted with permission from Leventhal's Common Sense Model (5) and Spirig's Symptom Management Model (4). CIDS-SIM is underpinned by four theories that support the inclusion of the components identified in the model and the influence these components have on the perception patients have of the impact their chronic symptoms have on their HRQoL.

This manuscript outlines the method used to develop the Chronic Illness/Disease States – Symptom Intrusiveness Model (CIDS-SIM). The assumptions made during the development of the model, the theories used to underpin CIDS-SIM, and the concepts and relationships among the concepts are discussed.

Method

Research should begin with a conceptual model to identify key concepts and loosely identify the relationship among the concepts (6, 7). CIDS-SIM, a model that identifies concepts related to symptom intrusiveness and HRQoL, is the foundation for research related to this phenomenon. We used Fawcett's Conceptual-Theoretical-Empirical (C-T-E) technique to develop CIDS-SIM. The C-T-E approach in the development of a conceptual model includes the following steps: (a) name the conceptual model and identify its concepts, (b) classify concepts based upon characteristics of observation and measurement, (c) identify the definitional and relational propositions, (d) identify the hierarchy of deductive reasoning, and (e) diagram the conceptual model's concepts and propositions (6).

Assumptions

Several assumptions were made in the development of CIDS-SIM. Symptoms of a chronic condition impact patients differently than a chronic condition without associated symptoms. It was also assumed that the symptoms of a chronic condition impact patients differently than acute symptoms. In addition, the outcome of an interaction among patients and their HCPs can and will be influenced by factors that affect this communication. The outcome of this interaction affects patients' perceived intrusiveness of their chronic symptoms and this perception, in turn, affects patients' HRQoL. Finally, we assume that patients' perceptions of their HRQoL will impact further interactions with their HCPs.

Theoretical and Conceptual Underpinnings

Four theories provide the theoretical support for inclusion of the concepts identified in CIDS-SIM. These theories underpin the concepts of patients' subjective perspectives, patients' symptom experiences, the impact of chronic symptoms on patients' well-being, and the affect of patient-HCP interactions on patients' outcomes and HRQoL (4, 8-10). These theoretical foundations support the concepts of CIDS-SIM (Table 1).

The first theory is Leventhal's Common Sense Model (CSM), also known as the Illness Perception Model, the Illness Representations Model, the Self-Regulatory Model, and the Parallel Process Model (5). Leventhal began his research exploring fear messages in acute situations, noting that different types of information are needed to affect both attitudes and behaviors that patients have towards the perceived threat to health and well-being. Expanding on this theory, Leventhal and his colleagues included adaptations and coping skills needed by those experiencing chronic conditions. Leventhal has described five concepts of illness representation including: (a) identity – the name given to a condition and symptoms that relate to it, (b) cause – patients' beliefs about the etiology of their condition which may or may not be accurate, (c) time-line – belief regarding how long the condition will last, (d) consequences – patients' beliefs about consequences of their condition and how these consequences will impact on their social and physical activities, and (e) curability/controllability – beliefs patients have regarding the curability of a condition and the role they have in the curability (5). As noted in CSM, one major concept is patients' beliefs about their illness. These beliefs aid patients in making sense of their symptoms. CSM supports CIDS-SIM in addressing patients' subjective perspectives of their chronic illnesses and the perceived threats to their well-being.

Spirig adapted the CSM by introducing the concepts of symptom experience consisting of symptom occurrence and symptom distress to create the Symptom Management Model (SMM) (4). Symptom occurrence refers to the dimensions of symptom frequency, severity, and duration. Symptom distress reflects the emotional concepts including mental anguish and suffering. Spirig posits that patients' symptom experiences guide their actions. The symptom experiences patients have when combined with symptom management and treatment adherence determines their HRQoL. In contrast to Leventhal's CSM, Spirig places more importance on the social concepts of the SMM model indicating that social support is essential to symptom management and adherence (4). SMM supports CIDS-SIM in addressing patients' symptom experiences and its identified impact on their HRQoL.

Devins described illness intrusiveness as resulting from "disease and treatment induced disruptions to lifestyles, activities, and interests" (8, p. 591). Devins indicates that illness intrusiveness is a basic determinant of the psychosocial impact of chronic diseases (8) that results from illness-induced obstacles that prevent patients from participating in desired activities and interests. Illness intrusiveness is comprised of psychological well-being and is associated with emotional distress in the reduction of (a) positive outcomes derived from valued activities and (b) patients' control by limiting the ability to achieve positive outcomes. Devins' model depicts how disease and treatment factors affect illness intrusiveness, which influences patients' control and well-being (8). Because it addresses the impact of intrusiveness on patients' HRQoL, defined by Devins in terms of one's ability to participate in chosen activities and achieve positive outcomes, Devin's Illness Intrusiveness supports CIDS-SIM.

Complexity Theory is the final theoretical underpinning of CIDS-SIM and includes four assumptions (9). The theory first posits that relationships among patients and their HCPs are

influenced by the interactions themselves, patients' social determinants of health (SDoH), and their HRQoL. The second assumption of the Complexity Theory indicates that impacting one concept may or may not lead to a predictable change. Related to CIDS-SIM, this assumption indicates the need to address not one, but multiple concepts to affect HRQoL. The third assumption is that new behaviors will occur as a result of relationships patients have with others. CIDS-SIM relates to this assumption in depicting that interactions among patients and their HCPs can lead to changes in patients' behaviors related to perceived symptom intrusiveness and their HRQoL. The final assumption of Complexity Theory addresses the blending of patients' symptom intrusiveness and their SDoH which can result in varying perceptions of HRQoL (9). Complexity Theory supports CIDS-SIM in addressing outcomes of interactions among patients and their HCPs. This theory also supports the ultimate impact of this interaction on patients' HRQoL.

In summary, the identified theories influenced and support the development of CIDS-SIM and the identification of its components first by identifying that patients' subjective perceptions of factors related to their chronic conditions will impact their sense of well-being. SMM supports CIDS-SIM in its focus on the symptoms of chronic conditions and the effect symptom frequency, severity, and duration have on ones' HRQoL. Devins' research supports CIDS-SIM in identifying that the perception patients have of the intrusiveness of their chronic condition will affect their HRQoL. Finally, Complexity Theory influenced the development of CIDS-SIM by identifying that the outcome of the patient-HCP interaction impacts patients' HRQoL, all factors that impact HRQoL need to be addressed, and that SDoH and perceived symptom intrusiveness can have varying degrees of impact on patients' HRQoL.

Literature Review

To identify concepts related to chronic symptoms and the impact on HRQoL, a comprehensive, computer-assisted search of the literature was conducted in the National Library of Medicine PubMed service (PubMed), Cumulative Index of Nursing and Allied Health Literature (CINAHL), PsychINFO, and PsychARTICLES electronic databases to identify relevant research studies limited to English and humans. In PubMed, the term *chronic disease* [MeSH] (119,862) was combined with the term *symptom* [All Fields] (74,563) resulting in 2,071 abstracts. A combined search in CINAHL, PsychINFO, and PsychARTICLES using the keywords *symptom* (159,624) and *chronic* (178,706) resulted in 13,946 articles. This search was then combined with *intrusiveness* (714), which resulted in 20 articles. The final sample for review included 2091 abstracts from 1967 to 2011. No inclusion or exclusion criteria beyond research studies, human, and English were applied to the search so that all key terms relating to symptoms and/or intrusiveness in chronic conditions could be identified in the review of abstracts. To limit the number of terms to be included in our conceptual model similar terms were then combined into a common term.

Chronic Illness/Disease States – Symptom Intrusiveness Model

The first step of the C-T-E structure includes naming of the conceptual model and identifying its concepts (6). The intent was for the name of the model to include the key concepts that impact patients' perception of their HRQoL; therefore, chronic illness, chronic disease, and symptom intrusiveness comprise the name. Through a review of the literature the key concepts of the model were identified and defined (Table 2).

Major Concepts

A *chronic illness/disease state* is one that is constantly present and long lasting (11). *Chronic illness* is defined as a patient's subjective perspective, a perspective known only to the patient. In contrast, *chronic disease* represents a health care provider's (HCP) objective perspective, which reflects the provider's focus on the etiology of the condition (3). An important factor related to chronic conditions is symptoms associated with the condition. A *symptom* is defined as a subjective indication of a change from normal well-being or appearance (12). *Intrusiveness* is the process of interfering with biopsychosocial well-being (4). Therefore, to understand the intrusiveness of symptoms associated with chronic conditions, this manuscript discusses: (a) the interaction among patients and their HCPs, (b) the intrusiveness of patients' symptoms, and (c) the impact of symptom intrusiveness on patients' health-related quality of life (HRQoL). Despite the impact of symptom intrusiveness, the literature includes limited research regarding how interactions among patients and their HCPs influence patients' perceived symptom intrusiveness, and how symptom intrusiveness affects patients' HRQoL.

Several of the concepts of CIDS-SIM have widely accepted definitions and are referenced in this model. Multiple definitions, each with minor variations, were noted for other concepts. Therefore, we have defined these concepts, taking into consideration the previously defined terms noted in the literature.

Observability of Concepts

The second step in the formalization of a C-T-E structure is to classify concepts on the basis of their observability (6). We used Kaplan's concept classification schema as it refers to phenomena that can be directly or indirectly observed and phenomena that are theoretical which can be interpreted on questionnaires (6). Concepts identified in CIDS-SIM can be directly

observed through auditory and visual senses and indirectly observed through patients' signs and symptoms. Concepts can also be observed in patients' responses to questionnaires (7).

Relationship of Concepts

The third step in the formalization of a C-T-E structure is to define concepts and relationships among concepts (6). CIDS-SIM first notes the difference between illness and disease. Chronic illnesses entail patients' subjective perspectives, which are unknown to anyone other than themselves (3). Chronic diseases entail HCPs' objective perspectives, which focus on the etiology of patients' conditions. Perceptions patients have of their chronic illness states are derived from the following: (a) their sense of self-efficacy, (b) concurrent symptoms of co-morbid conditions, (c) their mental health, (d) stigma felt by patients due to their chronic symptoms, and (e) any social determinants of health impacting on patients. Patients' perceptions of their well-being are the basis for interactions with their HCPs. HCPs formulate appraisals of patients' chronic disease states based upon their knowledge of the physiology of patients' symptoms; and the age, gender, and race/ethnicity of HCPs' and their patients (13). When communication, both verbal and nonverbal, is ineffective, participants in the interaction may form differing perceptions of patients' health and well being. If ineffective communication occurs, patients will often feel a lack of respect from their HCPs and develop perceptions that their HCPs did not attempt to understand their perspectives (13).

The outcomes of interactions between patients and their HCPs, and perceptions each has of the patients' health and well being will impact on the symptom intrusiveness perceived by patients as depicted by the relationships noted in CIDS-SIM. Symptom intrusiveness includes: (a) patients' control and ability to cope with chronic symptoms, (b) symptoms patients are currently experiencing related to any co-morbid conditions, (c) intensity of chronic symptoms,

and (d) the extent to which patients adhere to a mutually agreed upon treatment plan. The greater the disparity noted in appraisals of chronic conditions among patients and their HCPs, the greater the intrusiveness of symptoms experienced by patients.

HRQoL is comprised of functional status, mental health, and social relations (14). The symptom intrusiveness experienced by patients will impact on these components of HRQoL. More perceived symptom intrusiveness will result in a greater negative impact on patients' HRQoL. This perceived impact on HRQoL will in turn negatively impact on patients' perceptions of their chronic illness states. This impact on HRQoL and the resulting impact on chronic illness states will promote a negative cyclical process involving patients' perceptions of their health and well being, the degree of symptom intrusiveness, and the impact on HRQoL.

Propositions

The fourth step in the formalization of a C-T-E structure is to identify propositions that are widely accepted and therefore do not require testing (6). Assumptions related to the development of CIDS-SIM are discussed earlier in this manuscript. Briefly, assumptions of CIDS-SIM relate to the different perceptions of chronic illness and disease states, the impact of patients' interactions with their HCPs, and affects of their perceived symptom intrusiveness on their HRQoL.

Diagram of Conceptual Model

The fifth and final step in the formalization of a C-T-E structure is the construction of a diagram of the conceptual model's concepts and propositions (6). The relationships among concepts of CIDS-SIM are depicted in Figure 1. The solid lines and arrows indicate the directional relationships among concepts. As this diagram illustrates, CIDS-SIM provides a

comprehensive view of the phenomenon of intrusiveness of symptoms related to chronic illness disease states and the impact on HRQoL.

Discussion

As noted previously, there has been a shift in disease burden from infectious disease to chronic conditions. By the year 2020, chronic conditions are expected to affect 80 million Americans. To treat this population effectively, HCPs must understand the effects that patient-HCP interactions have on patients' perceptions of their symptom intrusiveness. HCPs must also understand and assess the impact of patients' perceived symptom intrusiveness related to their chronic conditions and how this affects their HRQoL.

Theories related to chronic conditions often explore conditions as opposed to focusing on symptoms of the chronic conditions. CIDS-SIM provides a unique way to address chronic conditions by focusing on the associated symptoms, perceptions of symptom intrusiveness, the impact symptom intrusiveness has on HRQoL, and the effect symptom intrusiveness has on future patient-HCP interactions. CIDS-SIM also includes factors that contribute to the primary components of the model including: perceptions of self-efficacy, any current symptoms of co-morbid conditions, mental health, perceptions of stigma, and social determinants of health.

Communication is vital to understanding patients' perceptions of their symptom intrusiveness. HCPs' appraisals of patients' perceptions of their chronic conditions is included in this model as HCPs' appraisals impact on the outcome of interactions among patients and their HCPs. This vital communication is also impacted by patients' appraisals of their health status. Results of patient – HCP interactions affect patients' perceptions of symptom intrusiveness, which in turn impacts upon their HRQoL.

Conclusion

CIDS-SIM identifies multiple concepts and interactions among those concepts that will enable HCPs to understand how patients develop perceptions of their HRQoL. CIDS-SIM will assist HCPs in understanding that patient-HCP interactions impact patients' perceived symptom intrusiveness; perceived symptom intrusiveness impacts patients' perceptions of their HRQoL, and HRQoL in turn impacts on further patient-HCP interactions. Our goal in developing CIDS-SIM was to provide an illustration of factors that HCPs' must recognize and components that should be included in an assessment to enhance the potential for more positive patient outcomes.

The development of CIDS-SIM is the first step in the process of developing the CIDS-SIM theory. To further the development of this theory, multiple areas of CIDS-SIM will require research. Research is needed related to the interactions between patients' and their HCPs and the way the outcome of this interaction impacts patients' perceived symptom intrusiveness. There is also a need to identify if a HRQoL assessment instrument that focuses on the impact of chronic symptoms is available to enhance HCPs' objective assessment. If an instrument is not identified, the next step in this process will be to develop an instrument to assess the degree to which patients' chronic symptoms impact HRQoL. The development of this instrument will further elucidate the relationships among the concepts depicted in CIDS-SIM.

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Table 1 Theoretical Foundation for Concepts of CIDS-SIM

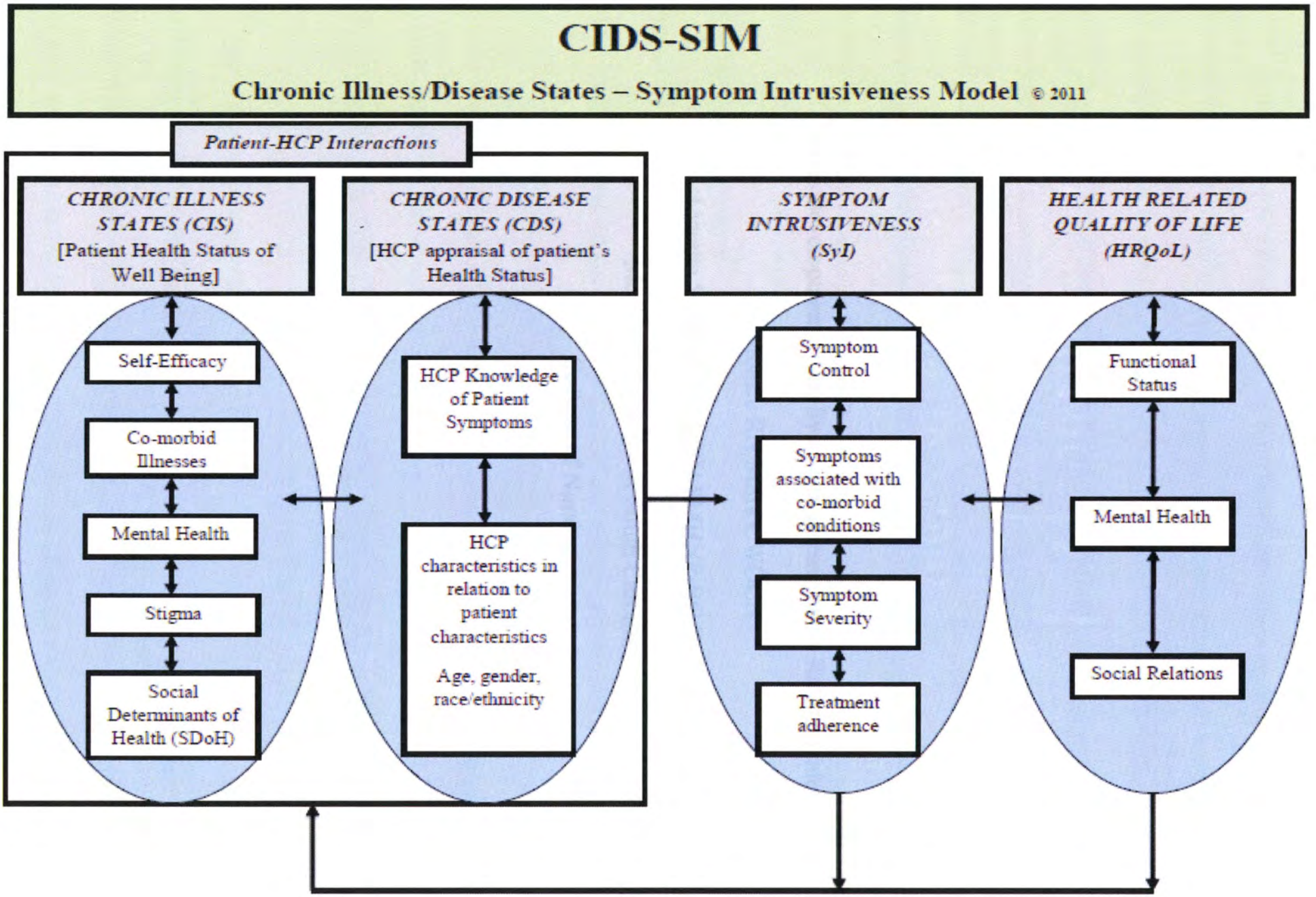
Theories that underpin CIDS-SIM	Theory concepts used to develop CIDS-SIM
Common Sense Model (CSM)	Patients' subjective perspective
Symptom Management Model (SMM)	Symptom experience, impact on HRQoL
Illness Intrusiveness	Illness intrusiveness as a basic determinant of the psychosocial impact of chronic diseases
Complexity Theory	Patient – HCP interaction, impact on HRQoL

Table 2 Definition of Concepts

Concept	Definition
Chronic Illness States	The subjective perspective of the patient that is unknown to anyone other than the patient.
Self-Efficacy	A patient's belief in his or her ability to yield an identified degree of functioning that can influence cognitive, motivational, affective and selection processes (15)
Symptoms of Co-morbid Illnesses	Two or more biopsychosocial disease processes that co-exist with an initial disease process, which may impact a patient's health outcomes.
Mental Health	The functioning of the mind related to thinking, behavior, and a state of well being (4)
Stigma	The verbal or non-verbal communication that occurs among persons where one person impresses upon another person the label of social unacceptability.
Social Determinants of Health	Biopsychosocial facets related to age, gender, race/ethnicity, inborn characteristics, environment, education, disability, socioeconomic status, social support, material resources, access to health services, and social networks.
Chronic Disease States	The objective perspective of the HCP that looks at the etiology of the condition.
HCP Knowledge of Patient Symptoms	A HCP's objective appraisal is impacted by his or her knowledge of the symptom (13).
HCP Characteristics in relation to Patient characteristics: Age, Gender, Race/ Ethnicity	A HCP's characteristics affect his or her perception of the patient's health (16).

Patient – HCP Interactions	Any verbal and non-verbal communication or exchange that occurs between a patient and his or her HCP (17).
Symptom Intrusiveness	A subjective or objective change from normal, which interferes with patients' biopsychosocial well being.
Symptom Control	A patient's coping strategy to balance his or her perceived risk(s) against the emotional reaction(s) to the health threat (18).
Symptom Occurring Simultaneously with Symptoms of Co-morbid Illnesses	Co-existing symptoms or co-morbid symptoms are defined as the presence of concurrent chronic symptoms (19).
Symptom Severity	The level of intensity that a patient experiences related to symptoms of his or her chronic illness.
Treatment Adherence	The extent to which a patient follows a previously mutually agreed upon treatment plan (4).
Health-Related Quality of Life	A patient's sense of well being determined by his or her subjective evaluation of current functional ability as compared to his or her expectations (20).
Functional Status	The ability that a patient has to perform self-care and participate in physical activities (21).
Mental Health	The functioning of the mind related to thinking, behavioral and a state of well being (4).
Social Relations	An interaction or relationship between two or more individuals or groups.

APPENDIX A


CIDS-SIM
Chronic Illness/Disease States – Symptom Intrusiveness Model © 2011
Patient-HCP Interactions
CHRONIC ILLNESS STATES (CIS)
[Patient Health Status of Well Being]
CHRONIC DISEASE STATES (CDS)
[HCP appraisal of patient's Health Status]
SYMPTOM INTRUSIVENESS (SyI)
HEALTH RELATED QUALITY OF LIFE (HRQoL)
Self-Efficacy
Co-morbid Illnesses
Mental Health
Stigma
Social Determinants of Health (SDoH)
HCP Knowledge of Patient Symptoms
HCP characteristics in relation to patient characteristics
Age, gender, race/ethnicity
Symptom Control
Symptoms associated with co-morbid conditions
Symptom Severity
Treatment adherence
Functional Status
Mental Health
Social Relations

Initial Development of the Symptom Intrusiveness Rating Scale

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Abstract

Background: The number of patients surviving with multiple chronic conditions is increasing. Therefore, health care providers' (HCPs') ability to comprehensively assess and effectively treat patients with chronic conditions is vital, especially since many with chronic conditions exhibit associated symptoms or treatment side effects that significantly impact their health-related quality of life (HRQoL). To enhance the development of effective treatment plans, HCPs must take into account both their objective perspectives regarding their patients' conditions and patients' subjective perspective about symptom intrusiveness – the degree to which symptoms or treatment side effects intrude on their HRQoL. At present, the literature contains no description of a subjective HRQoL assessment instrument that focuses on symptoms and treatment side effects; thus, the development of such tool is necessary and will add to the body of knowledge related to HRQoL assessment.

Objective: Our objective was to develop an HRQoL assessment instrument that focuses on the subjective symptoms and treatment side effects of chronic conditions and their impact on HRQoL. This novel instrument is designed to provide results related to patients' subjective assessments that can augment HCPs' objective assessments by identifying areas related to HRQoL that should be addressed in treatment plans. The inclusion of subjective assessments will aid in developing more effective treatment plans thus improving the potential for positive patient outcomes.

Result: The Symptom Intrusiveness Rating Scale (SyIRS) was developed. An assessment instrument that focuses on the impact of subjective symptoms and treatment side effects, this scale allows respondents to indicate on a one-to-five Likert scale the degree to which they perceive their symptoms or treatment side effects are intruding on their HRQoL. HRQoL is

defined in terms of the domains functional status, social relations, and mental health with five subcomponents in each domain.

Keywords: Symptom Intrusiveness Rating Scale, health-related quality of life, assessment, instrument, subjective symptoms, subjective side effects, symptom intrusiveness, treatment side effects intrusiveness, chronic conditions

Initial Development of the Symptom Intrusiveness Rating Scale (SyIRS)

Improvements in health care and changes in health care policy have resulted in an increasing number of patients surviving chronic conditions that were previously fatal (1). As a result of this increasing survival rate, a growing percentage of patients present to their health care providers (HCPs) with multiple co-morbid conditions, thus shifting the disease burden in the United States from infectious to chronic diseases (2). Studies have confirmed this shift, in showing that patients with chronic conditions account for 75% of health care expenditures annually (2, 3). By the year 2020, it is estimated that 80 million Americans will have multiple chronic conditions (4).

The perspectives HCPs develop of their patients' well-being are objective and based primarily on the results of laboratory tests, radiologic studies, and physical exams. HCPs' often focus on identifying the etiology of symptoms or treatment side effects and developing treatment plans aimed at a cure (5). However, a cure is often not possible with chronic conditions; therefore, the focus of treatment in this population needs to include effective management of symptoms. HCPs are challenged to assess chronic conditions by integrating their objective perspectives with the subjective perspectives of patients experiencing symptoms or treatment side effects associated with chronic conditions. A review of the literature identified the lack of a subjective HRQoL assessment instrument that focuses on the impact of chronic symptoms and treatment side effects from the patients' perspectives; therefore, the focus or our research was to identify a process by which HRQoL could be subjectively assessed in this population.

In research, as investigators attempt to quantify a phenomenon, a method of measurement is a vital component. However, an instrument is not always available that assesses the focus of researchers' work. In such a case researchers find it necessary to develop a new instrument or

revise an existing instrument that will adequately assess the focus of a study. The process of instrument development or revision involves clearly identifying what is to be measured, generating a pool of items, formatting the instrument, seeking expert review of the relevancy of instrument items, and evaluating the validity and reliability of the newly developed instrument (6). Our goal was to assess symptom intrusiveness, the degree to which patients determine that symptoms or treatment side effects of chronic conditions impact on their health related quality of life (HRQoL); therefore, to obtain relevant data, following this process of instrument development was crucial.

The results of a comprehensive literature search indicated the lack of a subjective HRQoL assessment instrument that focused on the intrusiveness of symptoms or treatment side effects associated with chronic conditions. We thus identified the need for an instrument that could be adapted to focus on symptoms and treatment side effects. Permission was received to modify the Illness Intrusiveness Rating Scale (7) with the resulting instrument identified as the Symptom Intrusiveness Rating Scale (SyIRS) (Appendix A).

This paper describes the initial phases toward the development of the SyIRS instrument, designed to subjectively assess the intrusiveness of symptoms or treatment side effects associated with chronic conditions that impact patients' HRQoL. This instrument will assist HCPs in identifying areas of need with the goal of improving HRQoL. SyIRS will also enable researchers to assess the impact of the symptoms and treatment side effects of chronic conditions on HRQoL as well as the outcomes of interventions. Validity and reliability studies, the final phase of instrument development, are currently being developed and conducted in populations with specific chronic symptoms and treatment side effects.

Conceptual Framework

We conducted a literature review of theoretical studies related to symptoms, finding only one theory that addressed symptom experiences related to chronic conditions (8). Of the theories reviewed, no theory addressed the intrusiveness of symptoms related to chronic conditions. To address this noted gap in literature, we developed the Chronic Illness/Disease State – Symptom Intrusiveness Model (CIDS-SIM) (Appendix B) (9). This model has been adapted with permission from Leventhal's Common Sense Model (10) and Spirig's Symptom Management Model (11). The purpose of CIDS-SIM is to illustrate the relationships among patients' appraisals of their chronic conditions, HCPs' assessments of patients' well-being, patients' perceived symptom or treatment side effect intrusiveness, and the impact of that perception on their HRQoL.

CIDS-SIM first identifies the difference between disease and illness (9). Disease is an HCP's objective perspective, which focuses on the etiology of a condition. Illness is a patient's subjective perspective and is unknown to anyone other than the patient (12). The perspective a patient develops of one's own chronic condition is derived from the following: (a) one's sense of self-efficacy, (b) concurrent symptoms or treatment side effects of co-morbid conditions, (c) one's mental health, (d) stigma felt by a patient due to one's symptoms or treatment side effects, and (e) the social determinants of health impacting on a patient. The patient's perspective of one's own well being is the basis for any interaction with one's HCP (13). The appraisal a HCP formulates of a patient's chronic condition is based on his or her knowledge of the pathophysiology of a patient's symptom or treatment side effect, as well as the differences and/or similarities in age, gender, and/or race/ethnicity between an HCP and the patient. When communication, both verbal and nonverbal, is ineffective, an HCP and patient can develop

different perceptions of a patient's health and well being, and a patient will often feel a lack of respect from the HCP, developing a perception that the HCP did not attempt to understand the patient's perspective (13).

The symptom or treatment side effect intrusiveness experienced by a patient will impact on one's HRQoL, which is comprised of a patient's functional status, social relations, and mental health (14). The greater the symptom or treatment side effect intrusiveness perceived by a patient, the greater the negatively perceived impact on HRQoL. This perceived impact on HRQoL will in turn negatively impact on a patient's perception of one's chronic condition. This impact on HRQoL and the resulting impact on a chronic condition will promote a negative cyclical process involving a patient's perception of one's health and well being, the degree of symptom or treatment side effect intrusiveness, and the impact on HRQoL (14).

Definitions of Terms

The terms *symptom* and *side effect* were defined to determine the appropriateness of including both in the same assessment instrument related to the impact of these consequences of chronic conditions on a patient's HRQoL. The term *symptom* is defined as a mental and/or physical condition change that develops from and accompanies an illness and is perceptible to the patient who experiences it (15). A *side effect* is defined as a consequence of a treatment that results in an unintended secondary effect that is perceptible to the patient who experiences a change in one's biopsychosocial status (15). A side effect can be perceived as a *symptomatic* change in one's status as it accompanies the primary condition. Since a side effect can be perceived as a symptomatic change in a patient's biopsychosocial status, a side effect can be considered a symptom and thus be included in a subjective assessment of symptoms.

Literature Review

A comprehensive, computer-assisted search of the literature was conducted in the Ovid Medline, Cumulative Index of Nursing and Allied Health Literature (CINAHL), PsycINFO, and PsycARTICLES electronic databases to identify relevant assessment instruments that evaluate the impact of symptoms and treatment side effects on patients' HRQoL. The review was limited to English, humans, and research studies included in the electronic databases from inception of the databases through January 2012. In Ovid Medline, the MeSH term *health-related quality of life* (14371) was combined with *questionnaires* (216834) resulting in 5818 abstracts. The resulting abstracts were combined with the MeSH term *symptom (affective and behavioral)* (9440), keyword *side effect* (94895), and keyword *intrusiveness* (339) which resulted in no abstracts for review.

In a combined search in CINAHL, PsycINFO, and PsycARTICLES, the MeSH term *health-related quality of life* (9033) was combined with *questionnaires* (198418), resulting in 2905 abstracts. The resulting abstracts were combined with the MeSH term *symptom* (17294) and the keyword *side effects* (30203), which resulted in 556 abstracts for symptoms and 34 abstracts for side effects. When the combined search of *health-related quality of life* and *questionnaires* (2905) was combined with *symptoms* (556), *side effects* (34), and the keyword *intrusiveness* (831) a total of 15 abstracts were identified. These abstracts were reviewed for questionnaires that assessed the intrusiveness of symptoms and treatment side effects on HRQoL. No questionnaires were identified that met this criterion; therefore, a gap was noted in the literature.

Instrument Development

The development of an instrument is a multi-phase process (16). The first phase of development is to determine the need for an instrument to measure an identified construct. Once

a need is identified, it is prudent to determine if an existing instrument can be used or amended to address the current need as the development of a new instrument requires significant time, effort, and expertise. If an instrument is identified, permission to use or adapt the instrument should be obtained from the researcher. The process then involves developing the item pool, determining the format, and finally testing the reliability and validity of the new instrument (16). The initial phases of the development of SyIRS are discussed here.

Phase 1: Determine need

The symptoms and the treatment side effects of chronic conditions are often assessed only from the objective perspectives of the HCPs. An assessment that is limited by the perspective from which the evaluation is conducted can lead to an ineffective treatment/management plan. Research has indicated that an objective assessment alone does not accurately reflect the complexity of the impact of symptoms or treatment side effects on patients' HRQoL (17). A comprehensive assessment of chronic conditions including associated symptoms and treatment side effects must include both the objective perspectives of the HCPs as well as the subjective perspectives of patients afflicted with chronic conditions. Therefore, the goal was to develop an instrument that would subjectively assess the degree to which symptoms or treatment side effects impact on patients' HRQoL. This assessment is intended to enhance the objective assessments completed by HCPs thus enhancing the ability of HCPs to develop more effective management/treatment plans.

A review of the literature identified several instruments that assess the impact chronic conditions have on patients' HRQoL. Our work is based on the assertion that patients with symptoms or treatment side effects associated with their chronic conditions will assess the impact the condition has on their HRQoL differently than patients not experiencing related

symptoms or treatment side effects. The impact patients note related to their functional status, social relations, and/or mental health is more often associated with the symptoms or treatment side effects of the chronic conditions. Therefore, a need was identified for an instrument that specifically assesses the impact of symptoms or treatment side effects on patients' HRQoL.

Phase 2: Explore available instruments

A literature review, as noted previously, indicated there were no instruments in which the intrusiveness of symptoms or treatment side effects was the basis for the assessment of HRQoL. Condition-specific assessment questionnaires as well as generic questionnaires that assessed HRQoL were found; however, condition-specific instruments were not adaptable for use with all chronic conditions and associated symptoms or treatment side effects. Therefore, they were not appropriate for use with multiple chronic conditions. The generic HRQoL questionnaires identified, the SF-36 (18) and the SF-36v2 (19), did not address the intrusiveness of symptoms or treatment side effects. Therefore, a HRQoL instrument to assess the impact of symptoms and treatment side effects on patients' HRQoL was needed.

Phase 3: Adapt Illness Intrusiveness Rating Scale

The Illness Intrusiveness Rating Scale (IIRS) (20) was found during a literature review of the term intrusiveness. This psychometrically tested instrument was suitably structured; however, the IIRS, which explores the intrusiveness of an illness, does not address the intrusiveness of symptoms or treatment side effects of chronic conditions. Permission was obtained from Dr. Gerald Devins to adapt IIRS to focus on the intrusiveness of symptoms and treatment side effects; therefore, the new assessment instrument was titled the Symptom Intrusiveness Rating Scale (SyIRS).

Domain Identification

A second literature review was conducted to identify the domains of HRQoL. The dimensions of HRQoL most often noted in the literature relate to physical, social, cognitive, sexual, and psychological functioning as well as productivity, sleep disturbances, and bodily symptoms (21). Researchers have merged the noted dimensions, indicating that HRQoL is comprised of a person's physical, psychological, social, and spiritual well being (22). After review of the literature, HRQoL is defined in the development of SyIRS as: (a) functional status – ability to perform activities of daily living, (b) social relations – the relationships between patients and their social world, and (c) mental health – level of cognitive or emotional well being.

Item Development

Once the three domains of HRQoL were identified and defined, further review of the literature was conducted to identify aspects that define each domain. Items that were developed to comprise the functional status domain included activities that most patients are involved in on a daily basis in caring for themselves. The social relations domain was determined to be related to interactions patients generally have with family and/or friends. The mental health domain includes items related to the ability to cope with normal stresses, contributions to the community, and patients' perceptions of their own abilities. As items were developed and revised, we continuously confirmed that SyIRS did not veer from the intent of the assessment instrument by confirming in the current literature that all items developed related to one of the defined domains of HRQoL.

In the development of scale items, consideration was also given to the number of items and the length of time it would take to complete the assessment (6). Items were all written as positive declarative statements for consistency.

Response Scale

In 1984, O. D. Duncan expanded upon the definition of *measurement*, numbers applied to objects or events according to distinct rules, by adding the component that the numbers are to be assigned in such as way as to be compatible with varying degrees of quality (6). The Likert Scale, a commonly used measurement, is used for the response format of SyIRS to identify the degree to which patients believe their symptoms and treatment side effects associated with chronic conditions impact their HRQoL. The statements included in SyIRS are followed by response options that reflect equal distance between responses (6) and which indicate the frequency patients assess that their symptoms or treatment side effects are impacting on their HRQoL. The response options on SyIRS are based on a 5-point Likert scale indicating never, occasionally, about half the time, frequently, and all the time which is similar to the 7-point Likert scale used on IIRS.

Phase 4: Plan for testing SyIRS

In developing a generic instrument, we are aware of the need to conduct psychometric testing of SyIRS. To confirm that SyIRS assesses patients' HRQoL, the following psychometric tests are currently being conducted; (a) content validity, requesting input from experts on the relevancy of the items on SyIRS, (b) cognitive pretesting, interviewing a limited number of patients to confirm that subjects will interpret the items on SyIRS as intended, (c) face validity, asking the respondents if SyIRS appears to be assessing their HRQoL, (d) criterion validity, correlating the results of SyIRS with an instrument that has had validity previously confirmed, (e) internal consistency, assessing if all the items on SyIRS assess HRQoL, and (f) test retest, administering SyIRS to the same patients more than once to confirm the stability of SyIRS over time.

Conclusion

SyIRS has been developed to provide a subjective assessment instrument to quantify the intrusiveness of symptoms and treatment side effects on HRQoL from the perspectives of patients afflicted with chronic conditions. The development of SyIRS addresses the need for a subjective instrument that is intended to augment HCPs' objective evaluations, thus enabling the development of comprehensive assessments for patients with chronic conditions. This growing population is in need of comprehensive assessments to enhance the ability of HCPs to develop effective treatment plans, which will improve the potential for patients to achieve the HRQoL which they define as acceptable for themselves.

In future work, psychometric testing of SyIRS is necessary with a large sample size and among patient with diverse chronic conditions experiencing varied symptoms and treatment side effects. Once psychometrically tested, the subjective results obtained from SyIRS are intended to enhance HCPs' objective assessments of patients experiencing symptoms and treatment side effects associated with chronic conditions.

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Appendix A

SYMPTOM INTRUSIVENESS RATING SCALE (SyIRS)

CIRCLE THE NUMBER THAT DESCRIBES HOW MUCH YOUR SYMPTOM OF _____ AFFECTS THE ITEM LISTED.

(insert symptom)

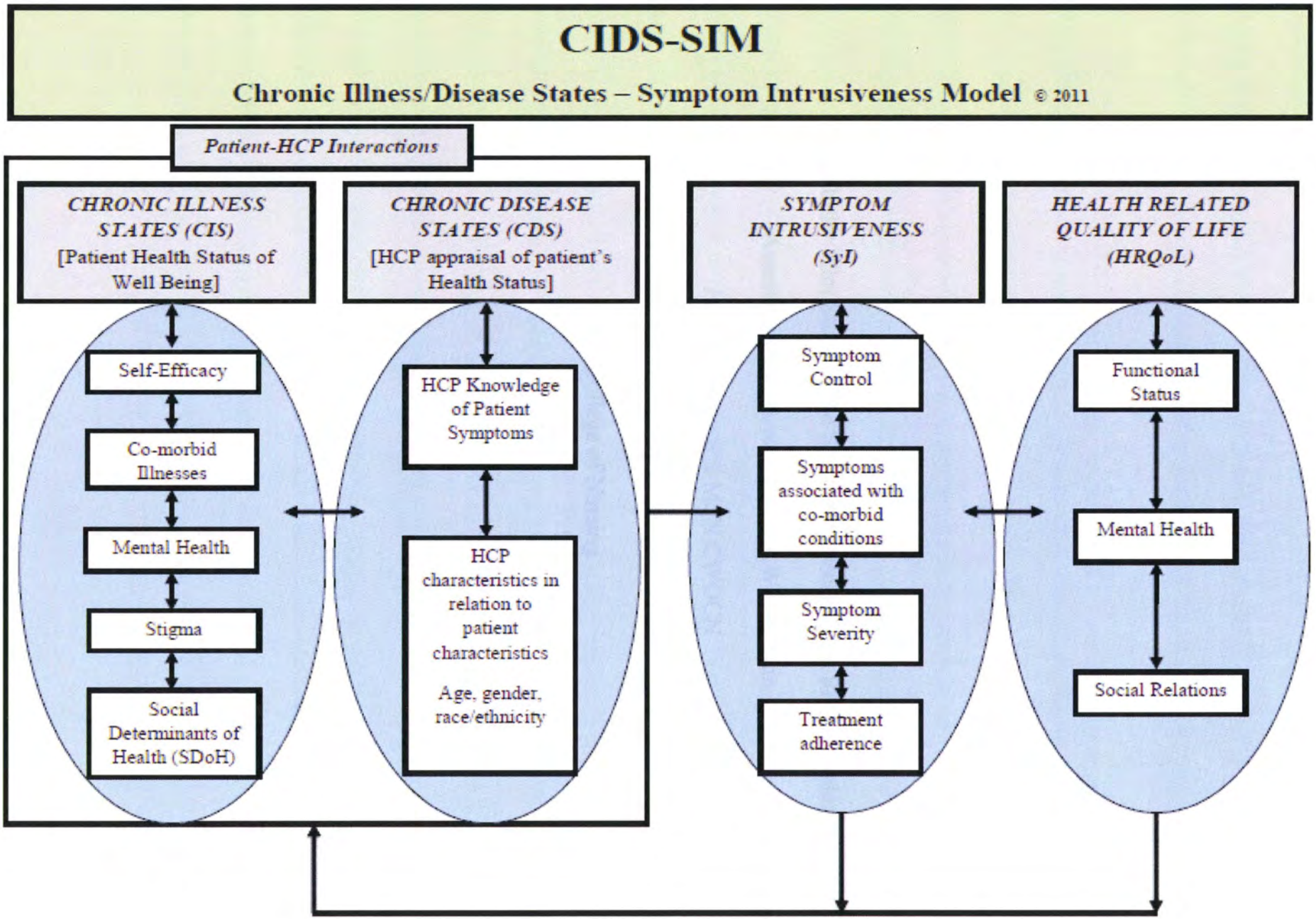
FUNCTIONAL STATUS*	**never**	**occasionally**	**about half the time**	**frequently**	**always**
• Ability to care for yourself (bathing, dressing, eating)	1	2	3	4	5
• Ability to maintain employment	1	2	3	4	5
• Ability to care for your home (light cleaning, laundry, cooking)	1	2	3	4	5
• Ability to complete errands (shopping, post office)	1	2	3	4	5
• Ability to drive a car or use public transportation	1	2	3	4	5

SOCIAL RELATIONS*	**never**	**occasionally**	**about half the time**	**frequently**	**always**
• Ability to visit with family or friends	1	2	3	4	5
• Ability to attend activities outside your home (church, social activities, etc.)	1	2	3	4	5
• Ability to participate in pleasurable activities (painting, sports, knitting etc.)	1	2	3	4	5
• Ability to be affectionate (hugs, intimate relations etc.) with those you would like to be affectionate with (spouse, children, significant other etc.)	1	2	3	4	5

• Ability to ask friend or family member for assistance	1	2	3	4	5
MENTAL HEALTH*	**never**	**occasionally**	**about half the time**	**frequently**	**always**
• Ability to enjoy pleasurable activities	1	2	3	4	5
• Ability to be happy	1	2	3	4	5
• Ability to manage your outward feelings (crying, anger outbursts, etc.)	1	2	3	4	5
• Ability to think, concentrate, or make decisions	1	2	3	4	5
• Ability to have feelings of self-worth	1	2	3	4	5

* Section heading will not be included in survey given to participants. Items will be randomly ordered.

Appendix B


CIDS-SIM
Chronic Illness/Disease States – Symptom Intrusiveness Model © 2011
Patient-HCP Interactions
CHRONIC ILLNESS STATES (CIS)
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CHRONIC DISEASE STATES (CDS)
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SYMPTOM INTRUSIVENESS (SyI)
HEALTH RELATED QUALITY OF LIFE (HRQoL)
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Co-morbid Illnesses
Mental Health
Stigma
Social Determinants of Health (SDoH)
HCP Knowledge of Patient Symptoms
HCP characteristics in relation to patient characteristics
Age, gender, race/ethnicity
Symptom Control
Symptoms associated with co-morbid conditions
Symptom Severity
Treatment adherence
Functional Status
Mental Health
Social Relations

A Feasibility Pilot Study of the Symptom Intrusiveness Rating Scale: Assessing Patients with Chronic Wound Pain

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Abstract

Purpose: The purpose of this study was to determine the feasibility of administering the Symptom Intrusiveness Rating Scale (SyIRS) to assess the health-related quality of life (HRQoL) of patients admitted to an acute care hospital who were experiencing chronic wound pain. In this study, tests were also conducted to determine if SyIRS is a valid and reliable instrument.

Design: The study was designed as a feasibility pilot study with respondents recruited as a convenience sample from individuals admitted to an urban 500-bed acute care hospital.

Method: The study included 4 phases. The first phase included completion and analysis of cognitive pretesting of SyIRS among 10 participants. In the second phase, content expert review regarding the relevance of SyIRS items was obtained and analyzed. The third phase consisted of the administration of SyIRS and the SF-36v2, and in the fourth and final phase validity and reliability testing were completed and the results analyzed.

Results: Cognitive pretesting indicated that respondents comprehend the items on SyIRS as intended. Content expert review confirmed the validity of SyIRS with an S-CVI/Ave of 0.90. Correlation analysis between the results of SyIRS and SF-36v2 indicated strong correlation with a coefficient of .917 and a p-value of .000. Retest of SyIRS conducted 2 to 4 days after the initial test confirm reliability with a correlation coefficient range of -.460 to -.560 and a p-value of .000 to .001. Results of this study indicated that conducting retest of SyIRS to confirm reliability 2 to 4 weeks after the initial survey completion is not a feasible in this population. Exploratory regression analysis did not identify any variables as having predictive value related to the SyIRS score.

Conclusions: SyIRS total and sub scores correlated highly with those of the SF-36v2, a psychometrically tested HRQoL instrument. These findings indicate that the SyIRS instrument can effectively assess the HRQoL of patients experiencing chronic wound pain.

A Feasibility Pilot Study of the Symptom Intrusiveness Rating Scale: Assessing Patients with Chronic Wound Pain

Pain has been shown to be the factor with the greatest negative impact on health-related quality of life (HRQoL) yet this impact is often not assessed by health care providers (HCP) when evaluating patients experiencing chronic wound pain (1-3). HCPs most often use the analog or visual pain measurement scales to assess patients' pain. These instruments are appropriate in determining the intensity of chronic wound pain; however, these scales do not address how chronic wound pain impacts patients' HRQoL, defined in this study as functional status, social relations, and mental health. Without an assessment of chronic wound pain that includes both the HCPs' objective assessments and patients' subjective assessments of the impact of chronic wound pain on their HRQoL, a cycle of unfavorable biopsychosocial outcomes may ensue. Therefore, a thorough patient-centered assessment of chronic wound pain, including the impact on patients' HRQoL, is vital to enhance the development of an effective chronic wound pain treatment plan.

This study explored the use of the Symptom Intrusiveness Rating Scale (SyIRS), a novel subjective instrument that focuses on the impact of chronic symptoms, as a method to assess the impact chronic wound pain has on HRQoL (Appendix A). SyIRS is intended to augment HCPs' objective assessments of chronic symptoms thus providing HCPs with a comprehensive assessment on which to base the development of their treatment plans.

To substantiate the use of SyIRS, it is necessary to determine if SyIRS reliably and accurately identifies the impact chronic symptoms have on HRQoL. Therefore, the research questions that guided this study are:

1. Is the Symptom Intrusiveness Rating Scale a valid and reliable instrument to assess the impact chronic wound pain has on patients' HRQoL?
2. Is the design utilized in this study an effective method to assess the validity and reliability of the SyIRS?

Background

Nearly half of all Americans seek medical care each year due to pain (4). In the United States, health care costs and lost productivity related to pain have been estimated to be $61.2 billion annually (5). In addition to being costly, pain is a sensation people fear and which can cause great distress and disability. Both acute and chronic pain have been shown to be factors with the greatest negative impact on health related quality of life (HRQoL) (1-3) affecting functional status and well-being (6). A more specific type of pain, chronic wound pain, significantly impacts patients experiencing it (7). Studies have shown that nearly 80% of people with chronic wounds experience pain either intermittently, continuously, or during procedures, such as debridement and/or dressing changes (7). Chronic wound pain significantly impacts peoples' HRQoL including functional status, social relations, and mental health (8). Although pain is a symptom that has significant impact on people, it is often misunderstood, under-assessed and under-treated (9).

Definition of terms

Pain

The most widely accepted definition of pain was posited by the International Association for the Study of Pain (IASP) in 1994. The IASP defined *pain* as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (10) p. 210. The IASP and others who have extensively studied the pain

phenomenon also agree that pain is subjective (7, 11, 12). The subjective perception people have of their pain is affected by previous experiences, emotional states, mental states, and cultural background (13-15).

Chronic wound pain

Pain that is associated with a chronic wound is either an intermittent or persistent symptom that is often in the background and exists at rest and between procedures (16). An estimated 80% of people with chronic wounds experience persistent pain with 50% of those people rating the pain as moderate or the worst pain they have experienced (16-18). This persistent pain often has no specific trigger (16). Franks and Moffat assessed the impact of clinical and social factors on a person's HRQoL and found that as the duration of a wound increases so does the reported incidence of wound pain. This phenomenon is explained by repeated injury and nerve damage (19).

Health-related quality of life

HRQoL has been defined in numerous ways, leading, in part; to the difficulty researchers and clinicians have had in assessing it (20). Within the framework of medicine, *HRQoL* has been defined as quality of life (QoL) (21). In this definition, two components comprise HRQoL. The first component, *health*, is defined as the state of absolute physical, mental, and social well-being. The second component, *QoL*, is defined as the sense of satisfaction people experience in various aspects of their life and the ability to participate in activities they choose within family, work, and social environments (21). *HRQoL* has also been defined as a subjective multidimensional experience that is a summation of the positive and negative qualities that illustrate peoples' life (20). Researchers have noted the lack of distinction in defining HRQoL between the determinants or predictors and the dimensions or attributes. This lack of division

has led to confusion related to the conceptual and operational definitions of HRQoL. As a result, researchers strive to identify those attributes that are most salient to people with a condition impacting their HRQoL (20).

HRQoL dimensions

The dimensions of HRQoL most often noted in the literature relate to physical, social, cognitive, sexual, and psychological functioning as well as productivity, sleep disturbances, and bodily symptoms (21). Other researchers have merged the noted dimensions indicating that HRQoL is comprised of peoples' physical, psychological, social, and spiritual well-being (20). After a comprehensive review of the literature, HRQoL is defined in this study as functional status, social relations, and mental health. The spiritual dimension of HRQoL noted in the literature is a complex, often abstract dimension and beyond the scope of this study.

Assessment

Chronic wound pain

A comprehensive and consistently completed assessment of chronic wound pain is the foundation of an effective chronic wound pain management/treatment plan (1). Research related to chronic wound pain assessment, although limited, has indicated that focusing solely on determining pain intensity, as many pain assessments do, does not accurately reflect the complexity of the impact of the pain (22). Therefore, a more comprehensive assessment is needed to fully understand the effects of chronic wound pain.

Health-related quality of life

An assessment of patients' HRQoL provides information regarding any subjective adverse effects a medical condition may have (21). An assessment of HRQoL is one approach that appraises the illness experience from the perspective of patients. Vetter (2007) has defined

three categories of HRQoL assessment instruments including: (a) generic (b) condition-specific measures, and (c) preference-based measures. Generic measures assess the continuum between well-being and death by providing a general review of HRQoL. These measures can be used in a variety of medical settings and the reported scores can be used to expand upon the objective signs and symptom of the condition noted by the HCP. Condition-specific measures are generally utilized to determine clinically significant responses to treatment or the progression of the condition. A measure that is condition specific will identify small incremental changes in the domains being measured. Preference-based measures expand on the descriptive nature of generic and condition-specific measures by incorporating a person's opinion concerning the desirability of a particular health state from the person's perspective (21).

Symptom Intrusiveness Rating Scale

Patients with chronic symptoms will often assess the impact of the condition on their HRQoL differently than patients without related symptoms. A comprehensive review of the literature identified the lack of a subjective assessment instrument that focused on the symptoms of a chronic condition and the impact the symptoms have on HRQoL. SyIRS, developed to address this gap, was adapted with permission from the Illness Intrusiveness Rating Scale (IIRS), a subjective assessment instrument developed by Dr. Gerald Devins (23) that focuses on the impact of a condition. SyIRS was developed to specifically assess the impact chronic symptoms have on HRQoL from the perspective of the people experiencing the symptoms. The results of SyIRS are intended to augment HCPs' objective assessments with the subjective perspectives of patients experiencing the symptoms.

Methodology

Institutional Review Board

Prior to beginning this study, approval was obtained from the Institutional Review Board (IRB) of the university where the principal investigator (PI) is a student. Approval was also obtained from the IRB at the acute care facility where this study was conducted.

Study Design

This study was designed as a feasibility pilot study to assess the validity and reliability of SyIRS among people experiencing chronic wound pain. The study involved the self-administration of two surveys, SyIRS and the SF-36v2 twice within 2 to 4 days.

Variables

The independent variables (IV) in this study include age, gender, race/ethnicity, employment status, educational level, marital status, and other people in household. The dependent variables (DV) are the scores obtained on the physical and mental subscales on SyIRS and SF-36v2.

Setting/Sample Size

Fifty respondents were recruited as a convenience sample from individuals admitted to an urban 500-bed acute care facility in a mid-south city. Respondents were enrolled over a period of 3 months. For the continuous outcome measures, SyIRS and SF-36v2, with 50 participants the 95% confidence interval estimate of the correlation between the scales had precision of $\pm$ 0.29.

Inclusion/Exclusion criteria

Inclusion criteria were: (a) 21 years of age and older, (b) a numeric wound pain intensity rating of 2 or greater, (c) wound reported for at least 4 weeks, and (d) ability to complete a self-administered survey. Exclusion criteria included: (a) end-of-life as identified by the HCP, (b)

cognitive impairment including inability to comprehend instructions or survey content, and (c) inability to read and/or understand the English language.

Data Collection

Cognitive Pretesting

The first phase of the study was to conduct cognitive pretesting of SyIRS to critically evaluate if a target population comprehends and processes each item on the survey as intended by the researcher (24). SyIRS is intended to assess people experiencing symptoms of a chronic condition; therefore, subjects who were experiencing varied chronic symptoms were recruited. Participants were interviewed one-on-one at the facility where the entire study was conducted. An interview manual, developed prior to testing, was used to promote consistency during the cognitive pretesting. The goal of cognitive pretesting was to elicit information relevant to the participants' interpretation of the SyIRS items (24). Since the participants in cognitive pretesting are not intended to be representative of the larger population, fewer participants were recruited (N=10) for this phase of the study then were recruited for the next phase (25, 26).

The PI conducted cognitive pretesting utilizing concurrent verbal probing. The process involved first asking the survey questions followed by probes. The PI also asked unscripted "emergent" probes and/or neutral probes as a follow up for unanticipated problems and further clarification. The PI was aware of potential bias and avoided asking any leading questions that could have inadvertently guided a respondent's answer.

Surveys and survey completion

The surveys utilized in this study were SyIRS and SF-36v2. SyIRS is comprised of 15 items, which are randomly ordered for administration and reflect activities and mental states related to the three components of HRQoL: functional status, social relations, and mental health.

In this study chronic wound pain was indicated in the instructions as the chronic symptom being assessed. The responses on the SyIRS survey are based on a Likert Scale indicating; 1- never, 2 – occasionally, 3 – about half the time, 4 – frequently, 5 – always. The SyIRS total score range is 15 to 75. The range of scores in the physical subscale is 8 to 40 and in the mental subscale the range of scores is 7 to 35.

The SF-36v2 is a psychometrically tested HRQoL assessment instrument (27). Previous studies have confirmed content, concurrent, criterion, construct, and predictive validity of SF-36v2. SF-36-v2 has been noted to correlate with the results of 225 other measures. Reliability coefficients, using both internal consistency and test-retest, have exceeded the recommended level of 0.70. Reliability estimates were consistent in 200 reported studies and 30 test-retest studies (27).

SF-36v2 is an 11-item questionnaire that measures the overall health status, functional status, and HRQoL of individuals or groups (28). The SF-36v2 questionnaire utilizes eight domains: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. Responses on the SF-36v2 are based on the Likert scale with varying responses and are scored utilizing norm-based scoring (28).

The preferred time between the completions of surveys when conducting test re-test reliability testing is 2 to 4 weeks (29). The average length of stay in the acute care facility where the study was completed is 5.1 days. There was concern in developing the study, that patients discharged prior to the retest at 2 weeks would not be compliant in completing and returning the surveys via the mail. Although the time frame between administrations is less than recommended, to ensure the availability of test-retest data, patients were asked to complete the survey the second time 2 to 4 days after the initial administration while still an in-patient;. To

determine if it would be feasible to complete the re-test portion of reliability testing in the recommended 2 to 4 week time frame, after patients are discharged, respondents who were admitted to the facility for less than 2 weeks were asked to first complete retest 2 to 4 days after initial administration and then were also given the surveys upon discharge with a self-addressed stamped envelope. The patients were asked to complete the survey during the week noted on the survey and to return the survey to the PI via the mail system. The return rate for completion of the survey 2 weeks after the initial administration was calculated.

Data analysis

Internal consistency was assessed using Cronbach's alpha. Reliability was assessed using Pearson's correlation coefficient for SyIRS total score at first and second administration. Further, the relationship between SyIRS and SF-36v2 was examined using Pearson's correlation coefficient.

In addition, exploratory regression was conducted to determine if the independent variables; age, gender, race/ethnicity, employment status, education level, marital status, or people in household were predictive of symptom intrusiveness. Individual regression modeling was used with SyIRS total score as the dependent variable and each of the demographic variables as independent variables. Subsequently, exploratory forward regression was conducted to determine which independent variables were predictors of the results of SyIRS accounting for other variables in the model. Next, models were developed using SyIRS as DV, the SF-36v2 physical and mental subscale scores as the first independent variable of interest and the individual demographic variables as adjustment variables. Finally, SF-36v2 physical and mental subscale scores were added to the model including all IVs to examine the relationship of the demographic variables accounting for quality of life.

Results

Demographics

Fifty patients were approached to participate in the study. All 50 signed an informed consent form agreeing to participate, met inclusion and exclusion criteria, and were enrolled in the study. Table 1 indicates the demographic characteristics of the respondents. One respondent died 36 hours after completion of the second survey administration. The death was reported to the university and facility IRBs. Each IRB determined the death to be unrelated to the study.

Cognitive pretesting

The cognitive pretesting respondents (N=10) ranged in age from 36 to 74; four were male and six were female. Each respondent was experiencing symptoms related to a chronic condition. The results of cognitive pretesting indicated that the items on SyIRS were interpreted by the respondents as was intended; therefore, no changes in the items were made.

Content validity

Two experts in the field of HRQoL were asked to review the statements included in SyIRS. The review by experts included rating each item as 1 - not relevant, 2 - somewhat relevant, 3 - quite relevant or 4 - highly relevant in relation to HRQoL. After the reviews were completed, the scale-level content validity index average (S-CVI/Ave) was calculated as 0.90 indicating excellent content validity (30). Therefore, all items that comprise SyIRS were retained

Reliability - Internal consistency and Correlation coefficients

A Cronbach's alpha of .904 indicated high internal consistency suggesting that the items included in SyIRS all measure HRQoL.

SyIRS total score at initial administration was strongly positively correlated with the SyIRS total score at second administration 2 to 4 days later ($r=.92$, $p < .005$). The physical and

mental subscale scores of SyIRS and SF-36v2 showed a moderate negative correlation on the initial completion ($r = -.56$, $p < .005$ and $r = -.46$, $p < .001$ respectively) versus the second completion 2 to 4 days later ($r = -.55$, $p < .005$ and $r = -.53$, $p < .005$ respectively) (Table 2). High scores of the SF-36v2 indicate high levels of HRQoL while high scores on SyIRS indicate high levels of symptom intrusiveness and therefore, low levels of HRQoL. Due to this difference in scoring on these two instruments a negative correlation between SyIRS and SF-36v2 suggests reliability.

Reliability - Regression

In table 3 results of the regression analyses are shown. Regression models with SyIRS as DV and demographic variables individually as the IV indicated that none of the IVs are significant as a predictor of symptom intrusiveness. In an overall model including all IVs none of the IVs predicted symptom intrusiveness, $R^2 = .05$, $p < .938$. This model including all IVs accounted for only 5 % of the variance in SyIRS scores.

The physical subscale of SF-36v2, when analyzed as a single IV, accounted for 18% of the variance in the results of SyIRS. The mental subscale of SF-36v2 as a single IV accounted for 25% of the variance. Variance in the SyIRS scores explained by SF-36v2 physical subscale increased to 22% and to 29% for the mental subscale when demographic variables were included in the model. Demographic variables remained non-significant.

Discussion

Cognitive Pretesting

The participants in cognitive pretesting are not intended to be representative of the population being surveyed, but they should have some degree of connection to the topic of the

survey (25). A large number of respondents is not essential in conducting cognitive pretesting as critical issues with a survey are often identified with a small sample of respondents. Due to the number of respondents in this phase of the study and as the respondents were not representative of the population of people with chronic symptoms, an analysis of the cognitive pretesting results was based on the response of the participants in regards to wording and understanding of the survey items, current evidence related to items that assess HRQoL, and the opinion of experts in the field of HRQoL (25).

Reliability testing

Reliability testing of SyIRS included first correlating the results of SyIRS on the initial survey administration with the results of SyIRS on the second administration 2 to 4 days later. These results indicated a strong positive correlation (.92/.000). Correlation coefficients were also calculated based on the results of the first and second administrations of SyIRS and SF-36v2. The method of scoring SyIRS and SF-36v2 is an aspect that must be considered in the correlation analysis. SF-36v2 scores are presented as the physical component summary (PCS) and the mental component summary (MCS). Therefore, the items on SyIRS were categorized as physical (SyIRS-p) and mental (SyIRS-m) allowing the PI to perform correlation analysis. Also related to scoring, higher scores obtained on SF-36v2 indicate a more positive perception of HRQoL. A more positive perception of HRQoL is reflected in lower scores on SyIRS. Therefore, a negative correlation between the results obtained on SyIRS and SF-36v2 confirms a certain degree of reliability.

The correlation analysis, using a two-tailed test, indicated a strong negative correlation between the results of the physical components of SyIRS and SF-36v2 on both test and retest, a strong negative correlation between the mental component on the first administration of the

surveys, and a moderate correlation between the mental components on the second retest (Table 2). The p-value noted in the correlation analysis indicates that the relationships noted in this study are not coincidental or obtained by chance. These results further confirm the reliability of SyIRS in assessing HRQoL.

Three respondents (6%) in this study were patients at the facility where the study was conducted for greater than 2 weeks and completed the retest after 2 weeks while still admitted to the facility. Four respondents (8%), who had been discharged prior to 2 weeks, returned the 2 week retest surveys, as instructed. One respondent (2%) died after the 2 day retest yet before the 2 week retest. Therefore, the completion rate for retest of the surveys 2 weeks after the initial survey completion was 14%. Because the rate was very low, a correlation coefficient was not calculated. This result indicates that retest, 2 to 4 weeks after initial administration, is not a feasible method to test reliability in a patient population in which a majority are discharged from an acute care facility prior to completing retest of an instrument at the recommended time.

In the regression model, quality of life, as reflected in the scores of SF-36v2 physical and mental subscales, explained most of the variance in the model. The independent variables contributed minimally to variance in the model. A statistically significant relationship was noted between the subscales of SF-36v2 and the results of SyIRS yet not between the results of SyIRS and the independent variables. The results of this analysis are limited by the small sample size and could potentially lead to a Type II error, failing to reject the null hypothesis or stating there is no relationship between the DV and the IV when there could actually be a relationship. Studies conducted with a larger sample size are needed to confirm the regression results obtained in this study which indicates that none of the IVs are predictors of symptom intrusiveness.

Limitations

A limitation noted in this study is the use of a convenience sample. A problem associated with convenience sampling, the weakest form of sampling, is that the subjects available to the PI may not be representative of all people experiencing chronic wound pain (29) thus not allowing for generalizability of the results. The small sample size in this study is also a limitation. The small sample size increased the probability of collecting data that was not reflective of the population studied. A larger sample size would provide the ability to correct atypical data that may be collected.

The timing for conducting test-retest of SyIRS and SF-36v2 was also a limitation. Retest was conducted 2 to 4 days after the initial test due to concern that patients would be discharged in less than 2 weeks and retest data would not be collected. Conducting retest 2 to 4 days after the first test may have led to performance on the first test influencing performance on the second test, deliberation on initial responses influencing a person's response on the retest, and variation in the administration of the surveys (30). Conducting retest in the recommended time, 2 to 4 weeks, was a limitation in this study as 86% of the respondents were discharged prior to this time and did not complete retest 2 weeks after the initial test as requested.

There were limitations noted in the cognitive pretesting phase of this study. The PI's limited experience and lack of formal education related to cognitive pretesting is a limitation. Inherent limitations in the process of cognitive pretesting are the small sample size recruited and the potential that the respondents are not representative of the population being studied.

Conclusion

The studies investigating chronic wound pain, although limited, have begun to raise awareness among HCPs of the complexity of chronic wound pain. HCPs' ability to develop

effective treatment/management plans is, in part, dependent upon the quality of assessment. An assessment of chronic wound pain can be enhanced by SyIRS, a subjective assessment instrument, as it identifies the aspects of a person's HRQoL that are impacted by chronic wound pain. A comprehensive assessment will enhance HCPs ability to develop an effective management/treatment plan for individuals experiencing chronic wound pain, which can impact people in multiple ways enabling them to maintain their desired HRQoL (2). Effectively managing chronic wound pain will enable many people to maintain social relationships (27), vitality, and mental health (24-26) all which contribute to maintaining or improving a sense of well-being and HRQoL (13).

This pilot study confirms the validity and reliability of SyIRS in a population experiencing chronic wound pain. Studies with a larger sample size from this population are needed to confirm the predictive power of the IVs on the results of SyIRS. Further studies conducted among patients with varying chronic symptoms are also needed to confirm the validity and reliability of SyIRS as a HRQoL assessment instrument. Studies are also needed to confirm the interpretation of the scores obtain on SyIRS.

Key Points

- Pain has been shown to be the factor with the greatest negative impact on health-related quality of life (HRQoL), yet this impact is often not assessed by health care providers (HCP) when evaluating patients experiencing chronic wound pain
- A comprehensive assessment of chronic wound pain includes both an HCP's objective assessment and the patient's subjective assessment

- A comprehensive assessment of chronic wound pain will enhance HCPs' ability to develop an effective treatment plan and improve the potential for more positive patient outcomes.

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Appendix A Symptom Intrusiveness Rating Scale (SyIRS)

SYMPTOM INTRUSIVENESS RATING SCALE (SyIRS)

CIRCLE THE NUMBER THAT DESCRIBES HOW MUCH YOUR SYMPTOM OF _____ AFFECTS THE ITEM LISTED.

(insert symptom)

FUNCTIONAL STATUS*	**never**	**occasionally**	**about half the time**	**frequently**	**always**
• Ability to care for yourself (bathing, dressing, eating)	1	2	3	4	5
• Ability to maintain employment	1	2	3	4	5
• Ability to care for your home (light cleaning, laundry, cooking)	1	2	3	4	5
• Ability to complete errands (shopping, post office)	1	2	3	4	5
• Ability to drive a car or use public transportation	1	2	3	4	5

SOCIAL RELATIONS*	**never**	**occasionally**	**about half the time**	**frequently**	**always**
• Ability to visit with family or friends	1	2	3	4	5
• Ability to attend activities outside your home (church, social activities, etc.)	1	2	3	4	5
• Ability to participate in pleasurable activities (painting, sports, knitting etc.)	1	2	3	4	5
• Ability to be affectionate (hugs, intimate relations etc.) with those you would like to be affectionate with (spouse, children, significant other etc.)	1	2	3	4	5
• Ability to ask friend or family member for assistance	1	2	3	4	5

MENTAL HEALTH*	**never**	**occasionally**	**about half the time**	**frequently**	**always**
• Ability to enjoy pleasurable activities	1	2	3	4	5
• Ability to be happy	1	2	3	4	5
• Ability to manage your outward feelings (crying, anger outbursts, etc.)	1	2	3	4	5
• Ability to think, concentrate, or make decisions	1	2	3	4	5
• Ability to have feelings of self-worth	1	2	3	4	5

* Section heading will not be included in survey given to participants. Items will be randomly ordered.

Table 1 Respondent Demographics

AGE N=50 M=58.12 SD – 17.28		GENDER N=50		MARITAL STATUS N=50		RACE/ETHNICITY N=50		EMPLOYMENT STATUS N=50		EDUCATION LEVEL N=50		Pain Rating NRS N=50	
21-40	22% (11)	Male	44% (22)	Married/ partner	54% (27)	White	48% (24)	Employed	28% (14)	< 8th grade	2% (1)	0-3	2%(1)
41-59	28% (14)	Female	56% (28)	Single	6% (3)	Black	46% (23)	Unemployed	30% (15)	9-12 grade	38% (19)	4-6	60%(30)
60-79	36% (18)			Separated	8% (4)	White Non-Hispanic	6% (3)	Retired	42% (21)	Some college	42% (21)	7-10	38%(19)
>80	14% (7)			Divorced	20% (10)					4 yr college	12% (6)		
				Widowed	12% (6)					Adv college	6% (3)		

Table 2 Correlation Table

SyIRS test-retest		SyIRS/SF-36v2 test-retest	SyIRS-p to PCS	SyIRS-m to MCS
Correlation/p-value		**Administration**	**Correlation/p-value**	**Correlation/p-value**
.917/.000		Test	-.560/.000	-.460/.001
		Retest (2-4 days after test)	-.554/.000	-.532/.000

Strong correlation -1.0 to -0.5 or 0.5 to 1.0
Moderate correlation -0.5 to -0.3

Table 3 Regression

Model*	Independent variables(s)	R^2	Beta	P-value
1	Age	.026	-.160	.266
2	Gender	.001	-.026	.857
3	Race/Ethnicity	.000	.021	.883
4	Employment status	.034	-.185	.198
5	Education level	.021	.143	.321
6	Marital status	.005	.069	.636
7	Other people in household	.001	-.025	.864
8	SF-36v2 physical component	.177	-.421	.002
9	SF-36v2 mental component	.247	-.497	.000
10	SF-36v2 physical component + Age	.064	.253	.076
11	SF-36v2 physical component + Gender	.029	.171	.236
12	SF-36v2 physical component + Race/Ethnicity	.001	-.025	.861
13	SF-36v2 physical component + Employment status	.056	.238	.097
14	SF-36v2 physical component + Educational level	.000	-.022	.878
15	SF-36v2 physical component + Marital status	.003	.057	.695
16	SF-36v2 physical component + Other people in household	.011	-.103	.478
17	SF-36v2 mental component + Age	.053	.231	.107
18	SF-36v2 mental component + Gender	.004	-.065	.652
19	SF-36v2 mental component + Race/Ethnicity	.036	-.189	.188
20	SF-36v2 mental component + Employment status	.016	.126	.384
21	SF-36v2 mental component + Educational level	.016	-.125	.388
22	SF-36v2 mental component + Marital status	.003	.052	.721
23	SF-36v2 mental component + Other people in household	.037	.191	.184
24	Age + gender	.026	-.020	.891
25	Model 24 + race/ethnicity	.027	.025	.869
26	Model 25 + employment status	.037	-.146	.497
27	Model 26 + educational level	.042	.077	.638

28	Model 27 + marital status	.048	.085	.582
29	Model 28 + other people in household	.051	.057	.719
30	Model 29 + SF-36v2 physical component	.217	-.432	.005
31	Model 29 + SF-36v2 mental component	.287	-.529	.001

*SyIRS total score used as dependent variable

Conclusion/Summary

This dissertation addresses several key concepts related to patients with chronic conditions; symptom intrusiveness and health-related quality of life (HRQoL). There is a gap in the assessment of the impact symptoms of chronic conditions have on health-related quality of life. This dissertation focused on developing a conceptual model and a measurement approach to the intrusiveness of symptoms on patients with chronic wound pain. This dissertation document includes four manuscripts. The first manuscript discusses chronic wound pain, a type of pain that is often misunderstood and under-assessed resulting in the lack of effective treatment. This is, in part, related to the lack of agreement on how to define chronic wound pain; pain that can be acute, for example during dressing changes, and/or chronic throughout the healing process. This manuscript identifies the need for further research on the factors related to chronic wound pain that impact patients' perceptions of their HRQoL and an effective method for assessing this impact.

Three manuscripts address chronic symptoms and the impact these symptoms have on patients' HRQoL. To illustrate this impact, the Chronic Illness Disease States – Symptom Intrusiveness Model (CIDS-SIM) was developed. CIDS-SIM is a conceptual model that demonstrates that the outcomes of an interaction among nurses, health care providers (HCPs), and patients with symptoms associated with chronic conditions will affect patients' perceived symptoms intrusiveness, the degree to which patients believe chronic symptoms are impacting their HRQoL. Patients' perceptions of symptom intrusiveness will influence the impact they determine their symptoms are having on their HRQoL. The perception patients have of their HRQoL will then have an impact on further interactions with their HCP. This impact may have negative outcomes on effectively managing the symptoms.

With a focus on the segment of CIDS-SIM that relates to the perception patients have of the impact chronic symptoms have on HRQoL, the Symptom Intrusiveness Rating Scale was developed to address the need for an instrument to assess this impact as noted in the third manuscript. SyIRS was developed as a method to subjectively quantify the impact on functional status, social relations, and mental health, and the results of the scale are intended to augment nurses and HCPs objective assessments of chronic symptoms, enhancing the ability to develop a comprehensive assessment and ultimately a more effective treatment plan.

The results of the study presented in the fourth manuscript in this dissertation indicate SyIRS is a HRQoL assessment instrument that has the ability to assess the impact chronic symptoms have on patients' HRQoL in a population experiencing chronic wound pain. First, results indicate, through cognitive pretesting, that the instructions and statements comprising SyIRS are interpreted by those completing the survey as was intended. Next, content validity results indicated that the statements included in SyIRS are relevant to an assessment of HRQoL. Reliability test results noted a moderate to strong correlation between the results of SyIRS and the psychometrically tested SF-36v2 in initial survey completion and a retest 2 to 4 days later. Conducting retest 2 weeks after the initial administration was shown to not be a feasible method of testing reliability in this population who were inpatients at an acute care facility at the time of the initial survey completion yet 94% had been discharged prior to the retest at 2 weeks. Only 6% of the discharged patients returned the survey as requested.

Limitations

Several limitations affect the substantiation of the work in this dissertation. First, only one segment of CIDS-SIM was studied. Multiple areas of this model will require further research to confirm the identified factors and the relationship among the factors. The study

presented in this dissertation, related to CIDS-SIM, focused on a limited population, those experiencing pain associated with chronic wounds. Further research is needed to study SyIRS among people with varied symptoms related to various chronic conditions. The study also utilized a convenience sample. Therefore, the respondents in the study may not represent all people experiencing pain associated with chronic wounds. Utilizing test retest as a method to assess reliability of SyIRS was also a limitation in this work. The results of the retest 2 to 4 days after initial administration may have been influenced by memory of the answers provided on the first completion. In addition, the recommended retest interval of 2 to 4 weeks after initial administration cannot be utilized in this study design as contact with too many participants is lost after patients are discharged.

Implications for Practice

The development of CIDS-SIM will assist nurses and other health care providers in understanding the factors that influence the perception patients have of the impact of chronic symptoms on their HRQoL. The availability of SyIRS, a HRQoL assessment instrument that quantifies this impact, will enable nurses and HCPs to comprehensively assess these patients by combining the patients' subjective assessment with an objective assessment to enhance the development of an effective treatment plan. SyIRS can also be utilized to assess the effectiveness of treatment by allowing nurses and HCPs to observe changes in the results of SyIRS prior to the onset of treatment and after treatment has begun, noting if the intended improvement in patients' perception of their HRQoL has actually occurred.

To improve the HRQoL of the increasing number of people with chronic conditions seeking their care, nurses who are mainly charged with bedside assessments, are challenged to comprehensively assess their patients and contribute to the development of a treatment plan that

includes management of the symptoms which their patients indicate are significantly impacting their HRQoL. In addressing the patients' perceptions, nurses and HCPs can assist patients in achieving a state of well-being that patients have defined as acceptable and that allows them to function at the level they desire, retain social relationships with those they choose to, and maintain a level of mental health they determine is acceptable.

Appendix 1 Institutional Review Board Approval MUSC

Institutional Review Board for Human Research (IRB)
Office of Research Integrity (ORI)
Medical University of South Carolina

Harborview Office Tower
19 Hagood Ave., Suite 601, MSC857
Charleston, SC 29425-8570
Federal Wide Assurance #1888

APPROVAL: **HR# 20583**

This is to certify that the research proposal entitled:

Intrusiveness of pain associated with chronic infected wounds

and submitted by: **Jill Marie Monfre, RN MSN**
Department: **Nursing**
Sponsor: **other**
Supporting Sponsor: **Molnlycke Health Care**

for consideration has been reviewed by the IRB and approved with respect to the study of human subjects as adequately protecting the rights and welfare of the individuals involved, employing adequate methods of securing informed consent from these individuals and not involving undue risk in the light of potential benefits to be derived therefrom. No IRB member who has a conflicting interest was involved in the review or approval of this study, except to provide information as requested by the IRB.

Continuing Review Approval Date: **11/14/2011**
Approval Expiration: **11/13/2012**

Type: Expedited

Chair IRB 1 _____
Susan D. Newman, PhD, RN, CRRN

Statement of Principal Investigator:

As previously signed and certified, I understand that approval of this research involving human subjects is contingent upon my agreement:

1. To report to the Institutional Review Board for Human Research (IRB) any adverse events or research related injuries which might occur in relation to the human research. I have read and will comply with IRB reporting requirements for adverse events.
2. To submit in writing for prior IRB approval any alterations to the plan of human research.
3. To submit timely continuing review reports of this research as requested by the IRB.
4. To maintain copies of all pertinent information related to the research activities in this project, including copies of informed consent agreements obtained from all participants.
5. To notify the IRB immediately upon the termination of this project, and/or the departure of the principal investigator from this institution and the project.

Appendix 2 Institutional Review Board Approval SFH

Saint Francis
Hospital - Memphis

5959 Park Avenue
Memphis, TN 38119-5199
Tel 901.765.1000
www.saintfrancishosp.com

October 20, 2011

Jill Monfre, RN, MSN, PhD Candidate
Saint Francis Hospital-Memphis
5959 Park Avenue
Memphis, TN 38119

Re: Intrusiveness of pain associated with chronic infected wounds
Principal Investigator: Jill Monfre, RN, MSN
Sponsor: Molnlycke Healthcare, Wound Ostomy Continence Nurses Society

Dear Ms. Monfre,

The Saint Francis Hospital Institutional Review Board reviewed the Annual Report and request for continuation of the above referenced protocol. The board has determined that the Protocol and Informed Consent document meet Criteria **45 CFR Sec. 46.111** for IRB approval of research. The board has requested the Informed consent document be revised to add language reflecting that the subject's medical record be reviewed.

Approval for this Protocol and Informed Consent document is granted for one year, and **valid through October 19, 2012.**

An Annual Report should be submitted to the SFH IRB for continuing review by October 01, 2012.

This report is to include:

1. The total number of subjects enrolled
    a. Subjects screened
    b. Subjects enrolled at Saint Francis Hospital
    c. Subjects terminated/withdrawn with details of termination
2. Study results to date (sponsor or collaborating group Annual Report):
    a. If report not available, a brief description of your results.
    b. Subject response (favorable, unfavorable, or no response)
3. Unexpected events (Safety Reports) not previously submitted to SFH IRB along with documentation indicating how the event relates to the study.
4. The status of the protocol, whether open or closed to accrual.

We appreciate your endeavors in all investigational studies. Please feel free to call if we can provide further assistance.

Sincerely,

F. Michael Lachine, MD, CMO
Chair, Institutional Review Board

Attachment 3 Consent Form

Saint Francis Hospital - Memphis
It's Your Life. Live It Well!

Informed Consent Form and Authorization

Subject Name:	**Date:**
Research Study Title: *Intrusiveness of pain associated with chronic infected wounds (Chronic Wound Pain)*	
Study Sponsor: Wound Ostomy Continence Nurses Society	
Protocol #:	**Principal Investigator:** Jill Monfre

INVITATION

You are invited to join a research study called Chronic Wound Pain. Jill Monfre RN along with Saint Francis Hospital is in charge of this research study.

Participation in this study is Voluntary. If you join the study, you can change your mind and stop at anytime. If you do not want to participate, your present or futures medical care will not change or be any different. It will not change the help that is available from your doctor or Saint Francis Hospital now or in the future.

A signed copy of this consent form will be a permanent part of your medical record while you are in this study. You will be given a copy of this form after it is signed for your records.

You will be required to sign additional Saint Francis Hospital consent forms regarding the procedures you will have performed by your Doctor while at Saint Francis Hospital.

PURPOSE AND BACKGROUND

The Wound Ostomy Continence Nurses Society and Molnlycke Health Care sponsors of this research study. You are being invited to take part in this study because you have a chronic wound and pain. Chronic means long lasting or persistent.

The purpose of this study is to measure your responses using a survey focusing on your feeling or symptoms of:

(a) weaknesses, exposure, or feelings of helplessness

(b) shame and loneliness

(c) symptom control and results

(d) quality of life as it relates to long lasting or slow healing wounds

(e) social support

PROCEDURES AND REQUIREMENTS

This study includes:

- A questionnaire which you can complete yourself or which can be read to you by the researcher who will make the answers you choose. This questionnaire will take no more than 20 minutes to complete
- A review of your chart will be done to note the number you rated your pain at and any wound cultures already collected

Because this study is voluntary you may withdraw or stop at any time and it will not change the care available from your doctor, or Saint Francis Hospital now or in the future.

POTENTIAL RISKS

There is a rare possibility of discomfort during the culture collection.

BENEFITS

[Subjects will not enjoy any personal benefit from participating in this Research Study. In the future, knowledge gained from the Research Study may help other people.]

ALTERNATIVES

You may withdraw or stop at any time and it will not change the care available from your doctor, or Saint Francis Hospital now or in the future.

COMPENSATION

There will be no compensation to for being in this study.

IN CASE OF INJURY

NA, minimal risk to patients

By signing this form you will not give up any legal rights.

The research study will cover the cost of a wound culture that is not ordered by your physician as part of your medical care

TERMINATION WITHOUT CONSENT

Your being in this study could be stopped, with or without your agreement because:

- The Doctor believes it is in your best interest to stop the study or,
- It is stopped by the study sponsor(s),
- By the FDA,
- By Saint Francis Hospital IRB
-

In any case, the study doctor/staff will explain to you the reason for your removal from the study.

COSTS

There will be no added costs to you for taking part in this study. Saint Francis Hospital will bill you and your insurance carrier for standard treatment. You will be billed for any deductibles or co payments.

NEW FINDINGS

NA

NUMBER OF SUBJECTS

The number of subjects who will participate in the Research Study is estimated to be 120.

CONFIDENTIALITY AND AUTHORIZATION TO USE AND DISCLOSURE OF HEALTH INFORMATION

This Informed Consent and Authorization form explains use and disclosure of health information.

"Informed Consent" tells the purpose of the study. It is designed to give you what you need to decide if you want to participate in a research study. It tells how information is collected and how the sponsor will use the study data, including your health information received during the study.

"Authorization" refers to the use and disclosure of your health information. This means your doctor, the hospital or clinic, their staff, the Sponsor, its agents, and contractors may see your health information.

In order to maintain privacy, the study staff (individuals working on the study) will use an assigned study number and/or initials, as identifier on your study records. Your name will not be on study records.

Please be aware that representatives of the groups below may see your records to check research data:

- Food and Drug Administration (FDA)
- *Committee for the Protection of Human Subjects*
- Saint Francis Hospital IRB
- Wound Ostomy Continence Nurses Society
- Molnlycke Health Care

The FDA and IRB representative can see personal identifiers in your records and will use steps to protect your privacy.

- The FDA regulates Sponsor (s) work in developing and assuring safety, quality and performance of its Drug or Device.
- The IRB, is require to watch over the study to make sure it is safe and effective in regards to medical products, treatments, and how research is done at Saint Francis Hospital.

If reports or publications result from this study, you will not be identified.

Once your information is given to the study sponsors, the IRB/IEC, government agencies, or it is a possible that your medical information will be re-disclosed and may no longer be protected by United States Federal privacy regulations. The laws of your state may provide further protection. Confidentiality will be maintained within the limits of the law.
If you participate in the study, you allow the use and disclosure of study findings. If you do not to authorize these uses and disclosures of your health information, you will not be able to participate in the study.

By signing this consent, you are authorizing such access.

AUTHORIZATION EXPIRATION DATE

In signing this form, you allow the use and disclosure of your information for purposes of this study at any time in the future.

WITHDRAWAL

Because this study is voluntary you may withdraw or stop at any time and it will not change the care available from your doctor, or Saint Francis Hospital now or in the future.

Any information obtained before withdrawal may be used and disclosed as per this form by the Sponsor and Researchers.

CONTACTS

If you have questions:

- About the study or feel you have a research study related injury contact:

Jill Monfre at 765-2019

- Your rights as a study participant contact:

Saint Francis Hospital Institutional Review Board between 8:30am to 5:00pm at 901 765 1801.

In writing: Saint Francis Hospital IRB
% Donna Rye, RN Research Site Manager
5959 Park Avenue
Memphis, TN 38119

- your privacy and health information contact:

Saint Francis Hospital Customer Service from 8:30am to 5:00pm 901.765.1932 or The Corporate Privacy Office 1-877-893 8363 Ext. 6709

Statement of Consent and Authorization for the Chronic Wound Pain Research Study

My Signature below indicates that I voluntarily agree to join this study and agree to the following information:

- I have been told the reasons, for this research study and agree to participate.

- The study procedures, risks and benefits have been explained to me.
- I have been able to ask questions and they have been answered.
- I have read or had read to me this consent form; initialed each page and I will receive a signed copy.
- A copy of this signed consent form is required to be on my medical chart while I am in Saint Francis Hospital, and on future charts, if I am readmitted to the hospital while participating in this study, and will be a permanent part of my medical record.
- I can refuse to take part or stop being in this study at any time without affecting present or future medical care.
- I voluntarily agree to participate in this study; I authorize the use and disclosure of my medical information as it is explained in this consent form.

_____ Date_____
Signature of Patient or Patient's Legally Authorized Representative

_____
Printed Name of Patient or Patient's Legally Authorized Representative

_____
Legally Authorized Representative's Relationship to Patient (If applicable)

Witness to the Consent and Authorization

_____ Date _____
Name & Title of Person Obtaining Informed Consent and Authorization
(Must be Investigator or Designee)

_____
Printed Name & Title of Person Obtaining Informed Consent and Authorization

Appendix 4 Protection of Human Subjects

Risks to Human Subjects

a. ***Human Subjects Involvement, Characteristics, and Design***

Describe the involvement of human subjects in the work outlined in the Research Strategy section.

In the proposed study human subjects will complete two (2) surveys, SyIRS and SF-36v2 and a single face validity question.

Describe and justify the characteristics of the subject population, including their anticipated number, age range, and health status if relevant.

The anticipated number of subjects for this pilot study is 25-50.

The characteristics of the human subjects in the proposed study include:

Age 21 years or older due to different methods of assessing the affect of chronic symptoms in children and adults and the cognitive ability to complete the surveys.
Ability to communicate effectively using the English language as the PI is only able to communicate in English
Presence of a chronic wound and experiencing chronic wound pain as the focus of the study is related to the specific chronic symptom chronic wound pain.

Describe and justify the sampling plan, as well as the recruitment and retention strategies and the criteria for inclusion or exclusion of any subpopulation.

As this is a pilot study which is testing the validity and reliability of a survey and there is not intent to administer the surveys for this purpose to thousands of individuals, the recommended number of subjects is 25-50 (35). The goal of respondent recruitment will be to recruit 25-50 subjects representative of diverse gender, ethnic groups and age range. The PI will approach potential subjects during the recruitment phase of the study, explain the purpose of the study and what will be required of the participant. If the individual agrees to participate informed written consent will be obtained.

Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that 'prisoners' includes all subjects involuntary incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.

Special vulnerable populations will not be included in the proposed study.

If relevant to the research, describe procedures for assignment to a study group. As related to human subjects' protection, describe and justify the selection of an intervention's dose, frequency, and administration.

Participants in the proposed study will not be assigned to a study group.

List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the research. Explain how data from the site(s) will be obtained, managed, and protected.

Data will only be collected from one acute care facility in Memphis, Tennessee; no other sites will be used for this study.

b. ***Sources of Materials***

Describe the research material obtained from living individuals in the form of specimens, records, or data.

Information to be obtained from the participants' medical record includes:
Demographics: age, gender, and race/ethnicity
History: wound and wound pain
Wound parameters: size, exudate, periwound condition and wound bed condition
Pain: intensity and triggers

Describe any data that will be collected from human subjects for the project(s) described in the application.

Data obtained will include the responses to the SyIRS, SFG-36v2 surveys, and demographic information.

Indicate who will have access to individually identifiable private information about human subjects.

The Pi will have access to identifiable information related to the study participants for the purpose of communication with the individuals during the study. No identifiable information will be recorded in the study materials.

Provide information about how the specimens, records, and/or data are collected, managed, and protected as well as whether material or data that include individually identifiable private information will be collected specifically for the research project.

The surveys utilized in this study can be completed:

1. By the participant utilizing the paper survey and pencil OR
2. If requested by the participant, the PI will read the instructions, questions, and possible answers to the participant and record the participant's response on the survey form

A master list of the names of participants will be compiled for identification for re-administration of the SyIRS. The master list will only be available to the researcher. Participants will be assigned a random number for data entry purposes. Study materials will be stored in a locked cabinet in the office of the PI.

c. ***Potential Risks***

Describe the potential risks to subjects (physical, psychological, financial, legal, or other), and assess their likelihood and seriousness to the human subjects.

There are not identified risks to study participants.

Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the research.

There are no alternative treatments or procedures related to the proposed study.

Appendix 5 Cognitive Pretesting Manual

DIRECTIONS	VERBAL COMMENTS
When initially approaching a potential participant the following script will be used	"Hello (potential participant's name) _____. My name is _____. In addition to my role at the hospital, I am a nurse researcher and a doctoral student at the Medical University of South Carolina. I am conducting a study that will include patients admitted to the hospital. As part of this study I need to determine if what I intend by the items that are included in a survey the patients will be completing is how people interpret the items. If you agree to participate there will be no compensation and I can assure you that I will not record any personnel information that will identify you. Your participation will take less than one hour. Participating in this part of the study will help us in developing a survey that accurately reflects how chronic symptoms affect a person's health related quality of life. Would you be willing to participate in this phase of the study by reading the items on the survey and answering questions regarding what you think the meaning of the item is?"
If the individual does not want to participate.	"(Individual's name) _____ thank you for your time"
If the individual agrees to participate If the patient will complete the surveys in his or her hospital room	"(Individual's name) _____ thank you for agreeing to participate in this study. The room where the testing will be completed is available to us _____ (note when room is available) and I am available _____ (PI will note when she is available). When would be a convenient time for you to complete this phase of the study?" I am available _____ (PI will note when she is available). When would be a convenient time for you to complete this phase of the study?"
At the predetermined time, take the participant to the identified location or meet with patient in his or her hospital room if that is where the patient will complete the surveys, for completion of cognitive pretesting. Have available a copy of the survey and a pencil. Ask the participant The interviewer will be aware, from the medical record review, if the patient is able to drink liquids and will ask this question only if the patient is allowed to drink	"Is there anything I can do to make you more comfortable?" "Would you like something to drink?"
When the respondent is comfortable show the respondent the survey and give the instructions -	"Please read the directions for completing the study at the top of the first page"

INSTRUCTIONS FOR COMPLETING THE SURVEY	INTERVIEWER COMMENTS/QUESTIONS	RESPONDENT COMMENTS
Circle the number that describes how your symptom of _____ affects the item listed.	When the survey is conducted the symptom being experience by the person completing the survey will be inserted in the blank space. 1. Please tell me in your own words what these instructions mean to you?	
The answer category for all items which the respondent will see on the survey is: 1 – never 2 – occasionally 3 – about half the time 4 – frequently 5 – most of the time	I will now ask you about each item on the survey; I will indicate which item I am referring to by the number of the item on the survey. After you read the item and select your response I will ask you 2-3 questions regarding the item. Do you have any questions	

SURVEY ITEM & PROBE (Pr)

1-ability to care for yourself

Pr 1 – what does "care for yourself" mean to you

2-ability to maintain employment

Pr 1 – what does "maintain employment" mean to you

Pr 2 – does this item apply to you

3-ability to care for your home

Pr 1 – what does "care for your home" mean to you

Pr 2 – how easy or hard was it for you to select a response to this item

4-ability to complete errands

Pr 1 – what does complete errands mean to you

5-ability to drive a car or use public transportation

Pr 1 – what does "ability to drive" mean to you

Pr 2 – what does "ability to use public transportation" mean to you

Pr3 – was it easy or hard for you to select a response while considering both of these activities

6-ability to visit with family or friends

Pr 1 – what does "ability to visit" mean to you

Pr 2 – what were you thinking as you selected a response to this item

7-ability to attend activities outside your home

Pr 1 – what does "activities outside your home" mean to you

Pr 2 – what were you considering as you selected a response to this question

8-ability to participate in pleasurable activities

Pr 1 – please repeat this question in your own words

Pr 2 – how did you select your response

9-ability to be affectionate with those you would like to be affectionate with

Pr 1 – what does "affectionate" mean to you

Pr 2 – is it ok to have this item in this survey

10-ability to ask friends or family members for assistance

Pr 1 – tell me in your own words what this item is stating

11- ability to enjoy pleasurable activities

Pr 1 – what does "enjoy pleasurable activities" mean to you

Pr 2 – what were you thinking as you selected your answer to this item

12-ability to be happy

Pr 1 – what does "happy" mean to you

Pr 2 – how easy or hard was it to select a response to this item

13-ability to manage your outward feelings

Pr 1 – what does "outward feelings" mean to you

Pr 2 – what does "manage" mean to you in this item

14-ability to think, concentrate, and make decisions

Pr 1 – what does "think" mean to you

Pr 2 – what does "concentrate" mean to you

Pr 3 – what does "make decisions" mean to you

Pr 4 – how easy or hard was it for you to select a response with think, concentrate, and make decisions in the same item

15-ability to have feelings of self-worth

Pr 1 – what does "self-worth" mean to you

Pr 2 – was it easy or hard for you to select a response to this item

GENERAL FEEDBACK QUESTIONS (asked at the conclusion of the interview)
Are there items that you think are important that are not included in this survey
Were there items on the survey that you did not like
Were there items on the survey that you did not want to answer
Overall, what did you think of this survey

Neutral probes that can be asked by the interviewer when it is appropriate include	• Tell me more • What do you mean • Is there more you would like to add

At conclusion of cognitive pretesting

"(Participant name) _____thank you for participating in this interview. What you have said to me here will be combined with what other people has said. This survey will be revised according to those responses. I appreciate you assistance

Appendix 6 – Cognitive Pretesting Results

SyIRS instructions	Probe	Participant responses (multiple responses duplicated by respondents)
Interpretation of survey instructions	Repeat these instructions to me in your own words	"Mark how my symptom affects what is in each statement and mark it from 1 to 5. What each number means is on the pages"
SyIRS statement/*probe*	**Probe**	**Participant responses (multiple responses duplicated by respondents)**
Ability to maintain employment	What does maintain employment mean to you	"I can come to work every day" "I am at work when I am suppose to be" "I can keep a job" "My pain doesn't keep me from working"
Ability to visit with family or friends	What does ability to visit mean to you	"Carry on a conversation" "Ability to socialize" "Go to someone's house" "Go for a face-to-face visit"
Ability to be happy	What does happy mean to you	"Enjoy life" "Content, satisfied" "Not sad"
Ability to attend activities outside your home	What does activities outside your home mean to you	"Go to things away from my house" "Parties, holiday parties" "Church, movies"
Ability to participate in pleasurable activities	Repeat this question in your own words	"Being able to run, I like to run" "Being able to enjoy life" "Being able to do fun things"
Ability to be affectionate with those you would like to be affectionate with	What does affectionate mean to you	"Kissing, touching" "Signs of love and friendship" "Tolerating someone in your space" "Hugging someone and letting them hug you"
Ability to have feelings of self worth	What does self worth mean to you	"Am I still an OK person" "To like yourself" "Being a good person and knowing it" "Like yourself"
Ability to drive a car our use public transportation	What does ability to drive, ability to use public transportation mean to you	"Go to the bus stop" "Ride a bus" "Drive my car when I want to" "Able to get to the bus stop"
Ability to ask friends or family member for assistance	Tell in your own words what this statement is saying	"Asking for help with something you normally do yourself" "Asking for help when my knee pain keeps me from doing it myself"
Ability to complete errands	What does complete errands mean to you	"Getting things done that need to be done" "Go to the grocery store" "Go to the post office"
Ability to enjoy pleasurable activities	What does enjoy pleasurable activities mean to you	"Watching, observing" "Fun things"

Ability to care for your home	What does care for your home mean to you	"Clean my house" "Maintain my house" "Cleaning, laundry"
Ability to manage your outward feelings	What does outward feelings mean to you	"Not being irritable" "Not showing emotion" "Not balling"
Ability to think, concentrate, and make decisions	What does think, concentrate, make decisions mean to you	"Able to focus" "Using your head"
Ability to care for yourself	What does care for yourself mean to you	"Take a shower" "Put on my clothes" "Do my hair"

Appendix 7 Interview Manual for Survey Administration

Script for interviewers on how to introduce study (researcher's directions are italicized, scripts are in bold)

When initially approaching a potential participant for consent to participate in this study, the following script will be used

"Hello Mr./Mrs./Ms./Miss _____. My name is _____. I am a nurse researcher and a doctoral student at the Medical University of South Carolina. I am conducting a study about how your symptom of_____ (insert symptom) can affect your HRQoL. This study involves completing 2 surveys at three separate times; once within the next 24 hours then in 2-4 days and the last time will be in approximately 2 weeks. The last time the surveys will be completed here if you are still a patient or the surveys can be taken home for you to complete and send back to me in a stamped, addressed envelope that I will provide to you. Each time you complete the surveys should take approximately 30 minutes so your total time will be approximately one and a half hours. If you would like to participate in this study, I will first have you sign the consent form and then I will review your medical record to see if you meet the conditions to participate. Once I have finished a review of your medical record, I will come back and let you know if you meet the conditions to participate or not. If you have met the conditions I will provide the surveys and pencils for you to complete the surveys. I want to assure you that I will not record any personal information that will identify you as I complete any part of this study. If you agree to participate in this study it will not change any of your current treatments".

If after reviewing the medical record, the person DOES NOT meet the criteria for the study, the following script will be used.

"Mr./Mrs./Ms./Miss _____ thank you for agreeing to participate in this study. I am sorry, but you did not meet the conditions to be included in this study. Please be assured that I did not record any personal information about you as I reviewed your medical record. Again, thank you for your time."

If after reviewing the medical record, the person DOES meet criteria for the study, the following script will be used.

"Mr./Mrs./Ms./Miss _____ thank you for agreeing to participate in this study. You have met the conditions necessary to participate in this study."

When a potential participant meets the criteria continue below -

Take the participant to the identified location for completion of the questionnaire. If appropriate ask the participant

"Is there anything I can do to make you more comfortable?"

Provide what you are able to for the comfort of the participant

Provide the respondent with the Symptom Intrusiveness Rating Scale and two pencils

Continue with -

"Please read the instructions and clearly mark you answer by circling the number which indicates the degree your pain interferes with the activity in the item. I will stay in the room until you have completed the questionnaire."

Questions you may answer during the survey include those related to the method to complete the questionnaire (e.g. How do I mark the answer I want to pick?). If a participant asks the meaning of a specific question respond by saying -

"I am not allowed to explain the questions, answer the questions as best you can."
Document in the study notes any questions participants ask.
After the participant has completed SyIRS, provide the respondent with the SF-36v2 –
"Please read the instructions and clearly mark you answer by completely filling in the circle to indicate your response. I will stay in the room until you have completed the questionnaire."
Questions you may answer during the survey include those related to the method to complete the questionnaire (e.g. How do I mark the answer I want to pick?). If a participant asks the meaning of a specific question respond by saying -
"I am not allowed to explain the questions, answer the questions as best you can."
After the respondent has completed the surveys -
"Mr./Mrs./Ms./Miss _____ I appreciate you taking the time today to participate in this study. Your answers will be combined with others in the study to look more closely at how symptoms can affect a person's HRQoL. I will return in 2-4 days for you to complete the surveys for the second part of this study.
Escort the respondent to their requested area.

*At the time of the **second administration** of the survey*

"Hello, Mr./Mrs./Ms./Miss _____ thank you again for agreeing to participate in the study being I am conducting about how your wound pain is impacting on your life. Is this a convenient time for you to complete the survey again?"
If the patient indicates that it is not a convenient time –
"What time would be more convenient for you?"
When determining a more convenient time note that the surveys are to be completed the second time within 2-4 days after the first completion.
If the patient indicates that the time is convenient provide the patient with a copy of SyIRS and a pencil and continue with -
"As you did when you first completed the surveys, please read the instructions and clearly mark you answer by circling the number which indicates the degree your pain interferes with the activity in the item. I will stay in the room until you have completed the questionnaire."
Questions I may answer during the survey include those related to the method to complete the questionnaire (e.g. How do I mark the answer I want to pick?). If a participant asks the meaning of a specific question respond by saying -
"I am not allowed to explain the questions, answer the questions as best you can."
I will document in the study notes any questions participants ask.
After the participant has completed SyIRS, provide the respondent with the SF-36v2 –
"Please read the instructions and clearly mark you answer by completely filling in the circle to indicate your response. I will stay in the room until you have completed the questionnaire."
Questions I may answer during the survey include those related to the method to complete the questionnaire (e.g. How do I mark the answer I want to pick?). If a participant asks the meaning of a specific question respond by saying -
"I am not allowed to explain the questions, answer the questions as best you can."
After the respondent has completed the surveys -

"Mr./Mrs./Ms./Miss _____ I appreciate you taking the time today to participate in this study. The next time the surveys are to be completed are in about 2 weeks. If you are discharged before that time, I will give you copies of the surveys with the week noted that I will need you to complete the surveys. I will also give you a stamped self addressed envelope to return the surveys to me in. If you are still in the hospital at the time for the surveys to be completed again, I will come to your room for you to complete them.
Escort the respondent to their requested area.

*At the time of the **third administration** of the survey, if the patient is an inpatient*

"Hello, Mr./Mrs./Ms./Miss _____ thank you again for agreeing to participate in the study being I am conducting about how your wound pain is impacting on your life. Is this a convenient time for you to complete the survey again?"
If the patient indicates that it is not a convenient time –
"What time would be more convenient for you?"
When determining a more convenient time note that the surveys are to be completed the second time within 2-4 days after the first completion.
If the patient indicates that the time is convenient provide the patient with a copy of SyIRS and a pencil and continue with -
"As you did when you completed the other surveys, please read the instructions and clearly mark you answer by circling the number which indicates the degree your pain interferes with the activity in the item. I will stay in the room until you have completed the questionnaire."
Questions I may answer during the survey include those related to the method to complete the questionnaire (e.g. How do I mark the answer I want to pick?). If a participant asks the meaning of a specific question respond by saying -
"I am not allowed to explain the questions, answer the questions as best you can."
I will document in the study notes any questions participants ask.
After the participant has completed SyIRS, provide the respondent with the SF-36v2 –
"Please read the instructions and clearly mark you answer by completely filling in the circle to indicate your response. I will stay in the room until you have completed the questionnaire."
Questions I may answer during the survey include those related to the method to complete the questionnaire (e.g. How do I mark the answer I want to pick?). If a participant asks the meaning of a specific question respond by saying -
"I am not allowed to explain the questions, answer the questions as best you can."
After the respondent has completed the surveys -
"Mr./Mrs./Ms./Miss _____ I appreciate you taking the time today to participate in this study. The next time the surveys are to be completed are in about 2 weeks. If you are discharged before that time, I will give you copies of the surveys with the week noted that I will need you to complete the surveys. I will also give you a stamped self addressed envelope to return the surveys to me in. If you are still in the hospital at the time for the surveys to be completed again, I will come to your room for you to complete them.
Escort the respondent to their requested area.

*If the patient is to be **discharged** in less than 2-4 weeks after the first administration of the surveys -*

"Hello, Mr./Mrs./Ms./Miss _____ thank you again for agreeing to participate in the study being I am conducting about how your wound pain is impacting on your life. I understand that you are being discharged. The last time for completing the surveys will be after you are at home. I have the surveys here for you with the week that I would like for you to complete the surveys. I would appreciate if you would complete the surveys the week of (indicate the date of the first day of the week to complete the surveys). Complete the surveys as you have already done by reading the instructions and circling your answer on the Symptom Intrusiveness Rating Scale and by completely filling in the circle on the SF-35v2 survey. I also have for you a stamped addressed envelope for you to return the surveys to me in. I would like to thank you very much for participating in this study. Your answers will be combined with others in the study to look more closely at how symptoms can affect a person's HRQoL."

***Reminder call** for subjects who are to complete the 2-4 week post first administration surveys after discharge*

"Hello, Mr./Mrs./Ms./Miss _____. I am calling from (hospital name) about the study you participated in while you were admitted here. I am calling to remind you to please complete the surveys and mail them to me in the envelope I sent home with you. Do you think you will be able to fill out the surveys?

If already completed

"Thank you very much Mr./Mrs./Ms./Miss _____. I appreciate your contribution to this study. Have a nice day"

If not yet completed

"I would appreciate if you could complete the surveys and mail them back to me this week. Your input is important to the results of this study. Thank you and have a nice day"

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