OSTOMY COMPLICATIONS AND ASSOCIATED RISK FACTORS:

DEVELOPMENT AND TESTING OF TWO INSTRUMENTS

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ABSTRACT

Joyce A. Pittman

OSTOMY COMPLICATIONS AND ASSOCIATED RISK FACTORS:

DEVELOPMENT AND TESTING OF TWO INSTRUMENTS

Complications following intestinal ostomy surgery can diminish quality of life for individuals living with an ostomy, resulting in physical and psychosocial limitations. Risk factors contributing to ostomy complications are not well established in the literature. The purposes of this study were to: 1) identify risk factors contributing to the development of fecal ostomy complications; 2) describe the incidence and severity of early fecal ostomy complications; and 3) estimate the reliability and validity of two newly developed instruments, Ostomy Risk Factor Index (ORFI) and Ostomy Complication Severity Index (OCSI). Using a prospective longitudinal design, 71 adult patients who had undergone ostomy surgery were recruited from three acute care settings. Data were collected through self-administered surveys, medical record review, and direct observation prior to discharge and at 30 to 60 days post-operatively. Data were analyzed using descriptive statistics, analysis of variance, chi-square tests, correlation, and multiple regression. Psychometric properties of the Ostomy Risk Factor Index and the Ostomy Complication Severity Index were examined using content validity indices, Cohen coefficient kappa, Pearson correlation coefficient, and intra-class correlation. Two risk factors were found to be predictive of ostomy complications scores, stoma/abdomen characteristics (p= .007) and BMI (p= .002). Ostomy complications and ostomy adjustment were significantly inversely correlated (r= - 0.27, p=.04) and stoma care self-efficacy and ostomy adjustment were significantly correlated (r= .599, p= .01). The ORFI and OCSI demonstrated acceptable content validity (CVI= 0.9). ORFI demonstrated acceptable inter-rater reliability for 10 of the 14 items (k= 1.0) and excellent intra-class correlation of total scores between raters (r= .998, p= .001). The OCSI demonstrated acceptable inter-rater reliability for all of the items (k= .71- 1.0) and excellent intra-class

correlation of total scores between raters (r= .991, p= .000). The OCSI demonstrated acceptable internal consistency (Cronbach's alpha .68). In conclusion, this study provides new knowledge regarding risk factors, incidence and severity of ostomy complications, and provided support for the validity and reliability of two new instruments for the researcher and practitioner to reliably identify and describe important contributors (risk factors) and outcomes (complications) that affect care of the patient with an ostomy.

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CHAPTER ONE

THE NATURE OF THE STUDY

An ostomy is a surgically created exteriorization of the colon or ileum to the anterior abdominal wall of the body. There are many reasons for the creation of a fecal ostomy but the most common reasons include cancer, trauma, inflammatory bowel disease, or acute inflammatory processes (e.g. diverticulitis) (Pittman et al., 2008). The purpose of an ostomy is to provide a diversion for the elimination of waste material, either urine, feces or intestinal effluent. The most common types of ostomies include the colostomy (colon), ileostomy (small bowel), and the urostomy or ileal conduit (urinary) (United Ostomy Associations of America, 2005). Fecal diversions (colostomies or ileostomies) are more common than urinary diversions.

Creation of an ostomy significantly alters one's elimination pattern and can affect the individual both physically and psychologically. In addition, ostomy complications are a common problem (Smith, 1992). Research has shown that ostomy complications negatively affect the quality of life for individuals living with an ostomy, and often result in physical and psychosocial limitations for these individuals and their families (Pittman et al., 2008). Not only does the person with an ostomy have to cope with a serious and often life-threatening diagnosis, but the placement of an ostomy requires significant changes to one's lifestyle. Risk factors specific to ostomy complications have not been well established in the literature and research is needed to better understand the consequences of this common surgical procedure. Study design differences, inconsistent definitions and terminology, and timing of measurements make it difficult to accurately compare findings. In addition, the lack of an instrument to measure risk factors and severity of ostomy complications contributes to the paucity of evidence in the literature.

The purpose of this research study was two-fold: 1) to identify the most common risk factors that contribute to the development of fecal ostomy complications; and 2) to describe the incidence and severity of early fecal ostomy complications within 60 days post-operatively. A secondary objective was to examine the reliability and validity of two instruments that: a)

identified the risk factors for fecal ostomy complications, and b) identified the incidence and severity of fecal ostomy complications. The Pittman Ostomy Complications Conceptual Model was used to provide an innovative framework for conceptualizing the relationships among these variables.

In this chapter, the significance of the problem, the purpose of this study, the aims and hypotheses, the conceptual and operational definitions, and the theoretical framework are discussed.

Significance of the Problem

Complications following the surgical creation of an ostomy are a significant problem for many individuals. Ostomy complications can have both physiological and psychosocial aspects. The physiologic aspect of ostomy complications involve changes of the stoma and peri-stoma skin (Cottam, Richards, Hasted, & Blackman, 2007). The psychosocial aspect of having an ostomy involve the challenges individuals face living with, and adjusting to, the ostomy (Carlsson, Berglund, & Nordgren, 2001). In this section, the prevalence and incidence of fecal or intestinal ostomy complications and the potential risk factors that contribute to the development of these complications will be discussed. The psychosocial aspect of ostomy adjustment and the role of stoma self efficacy will be discussed briefly.

Ostomy Prevalence and Incidence

It has been estimated that there are over 800,000 individuals are currently living with an ostomy in North America and more than 120,000 new ostomies are created annually in the United States and Canada (Kelman & Minkler, 1989; Turnbull, 2003). The most common types of ostomies include the colostomy (colon), ileostomy (small bowel), and the urostomy or ileal conduit (urinary) (United Ostomy Associations of America, 2005). Fecal diversions (colostomies or ileostomies) are more common than urinary diversions. There are many reasons for the creation of a fecal ostomy but the most common reasons include cancer, trauma, inflammatory

bowel disease, or acute inflammatory processes (e.g. diverticulitis) (Pittman et al., 2008). In this research study, we are examining intestinal or fecal ostomies.

Risk Factors for Ostomy Complications

Few independent risk factors for the development of ostomy complications have been identified in the literature. Factors that have been investigated and have been shown to contribute to the risk for ostomy complications include higher body mass index (BMI), older age, emergent surgery, inflammatory bowel disease, having an ileostomy (versus colostomy), having had a diverting "loop" procedure, poor bowel quality, ischemic colitis, stomal retraction, inadequate pre-operative education and lack of involvement of a wound, ostomy, continence (WOC) nurse (Bass et al., 1997; Colwell, Goldberg, & Carmel, 2001; Duchesne, Wang, Weintraub, Boyle, & Hunt, 2002; Park et al., 1999; Pittman et al., 2008). Few studies have been conducted to estimate the relative strength of relationships between these risk factors and the development of ostomy complications. No studies were found that examined the relationship among risk factors and the severity of ostomy complications. Variability in study quality and design, lack of operational definitions, inconsistent timing of measurements, and lack of reliable and valid instruments limit the conclusions that can be drawn from existing research (Salvadalena, 2008).

Ostomy Complications

Studies have found that up to 71% of patients with an ileostomy and 43% of patients with a colostomy experience stomal complications (Colwell et al., 2001; Persson, Gustavsson, Hellstrom, Lappas, & Hulten, 2005; Ratliff, Scarano, & Donovan, 2005). The most common physical complications include peristomal irritant dermatitis, stoma pain, stoma bleeding, stoma necrosis, stoma prolapse, stoma stenosis, stoma mucocutaneous separation, herniation around or beside the stoma, infection, and stoma retraction (Colwell et al., 2001; Park et al., 1999; Ratliff et al., 2005). Complications are often categorized as those that develop early, within 30 days post surgery, and those that develop later, more than 30 days post surgery (Park et al., 1999). They also can be categorized into stomal and peristomal complications (Colwell & Beitz, 2007).

Definitions and terminology used to describe ostomy complications are often not consistent in the literature (Colwell et al., 2001; Salvadalena, 2008). The terms ostomy and stoma are often used interchangeably when referring to complications in the literature. Differentiating between stomal and peristomal complications is often not clearly described in the literature. These inconsistencies can make it difficult to compare studies and their findings.

Overall incidence rates of complications have been reported, although the ranges are very broad. Two comprehensive systematic reviews of the literature on ostomy complications indicated that 18-55% of patients with an ostomy experienced peristomal skin irritation, 1-37% experienced parastomal herniation, 2-25% experienced stomal prolapse, 2-10% experienced stenosis, and 1-11% experienced retraction of the stoma (Colwell et al., 2001; Salvadalena, 2008). Ratliff et al. (2005) reported that 10-70% of all patients with an ostomy develop complications. Putting this into a practical perspective, using the estimates above, stoma complications represent a significant problem with up to 560,000 individuals who receive an ostomy experiencing ostomy-related complications. If we use the annual incidence, up to 84,000 individuals with a new ostomy can be expected to develop ostomy-related complications annually.

Ostomy complications are a significant problem for individuals with an ostomy yet limitations in the literature are evident. Study design differences, inconsistent definitions and terminology, and timing of measurements make it difficult to accurately measure ostomy complication incidence (Salvadalena, 2008). In addition, research examining the severity of ostomy complications and reliable and valid instruments to measure ostomy complications and risk factors is lacking.

Self Efficacy

Self-efficacy is a concept in the Social Learning Theory developed by Bandura. Bandura defined self-efficacy as “the conviction that one can successfully execute the behavior required to produce certain outcomes” (Bandura, 1977). Bandura proposed “that expectations of personal efficacy determine whether coping behavior will be initiated, how much effort will be expended,

and how long it will be sustained in the face of obstacles and aversive experiences" (Bandura, 1977).

Stoma care self-efficacy is defined as the conviction by patients that they can successfully manage their stoma to minimize adverse outcomes (Simmons, Smith, Bobb, & Liles, 2007). Stoma care self-efficacy has been positively related to ostomy adjustment (Simmons et al., 2007). Higher self-efficacy after surgery predicted fewer psychosocial problems in the first year following ostomy surgery (Bekkers, 1996). In this research study, stoma care self-efficacy was examined as it relates to ostomy complications.

Ostomy Adjustment

Individuals with an ostomy have been referred to as a chronic illness population that frequently experience adjustment difficulties (Follick, 1984). Ostomy adjustment has been defined as "the overall impact of the stoma on psychological, social, and sexual functioning as perceived by patients" (Simmons et al., 2007). Not only does the person with an ostomy have to cope with a serious and often life-limiting diagnosis, but often there are significant modifications that the patient has to make to his/her lifestyle. Difficulty adjusting, coping, social restrictions, occupational considerations, and daily living concerns are challenges that most individuals with an ostomy face (Follick, 1984; Marquis, Marrel, & Jambon, 2003; Martinsson, Josefsson, & Ek, 1991; Simmons et al., 2007; Symms et al., 2008).

Many individuals with an ostomy have difficulty adjusting to the ostomy (Bekkers, 1995; Olbrisch, 1983; Simmons et al., 2007). One study examined the prevalence of adjustment problems and reported that 23% of the participants had emotional problems, 45% reported decreased social contacts, and 57% reported a decrease in libido after ostomy surgery (Bekkers, 1996). Follick (1984) found that significant numbers of ostomy patients reported technical (84%), emotional (50%), social (30%), marital/family (24%), and sexual (41%) difficulties post-surgery.

Individuals with an ostomy face a variety of complex psychosocial issues (Sirota, 2006). Bekkers identified six types of psychosocial problems: 1) emotional problems; 2) problems

related to social activities; 3) problems with interpersonal relationships; 4) sexuality problems, 5) occupational problems; and 6) general physical health problems (Bekkers, 1995). Other researchers have identified similar adjustment challenges including adapting to complicated ostomy management regimes, body image changes, alterations in sexual functioning and intimacy, interpersonal relationships, and occupational challenges. These challenges contribute to post-surgical ostomy adjustment difficulties (Follick, 1984; Marquis, et al., 2003; Martinsson et al., 1991; Simmons et al., 2007; Symms et al., 2008).

Psychosocial complications of having an ostomy, such as difficulty adjusting to an ostomy, often occur in conjunction with physiologic ostomy complications. Psychosocial ostomy complications present additional challenges for the individual with an ostomy. As a result, ostomy adjustment was examined as a factor that could be influenced by ostomy complications in this study.

Purpose

The purposes of this study were to: 1) identify risk factors that contribute to the development of ostomy complications; 2) describe the incidence and severity of ostomy complications within 60 days following surgery; and 3) estimate the reliability and validity of two instruments- the Pittman Ostomy Risk Factor Index (ORFI) and the Pittman Ostomy Complication Severity Index (OCSI). One instrument, the Pittman Ostomy Risk Factor Index (ORFI), was used to measure potential risk factors for the development of ostomy complications in the first 30 to 60 day post-operative period. A second instrument, the Pittman Ostomy Complication Severity Index (OCSI), was used to measure the frequency and quantify the severity of ostomy complications within 60 days following surgery. In addition, the relationships among ostomy adjustment, self-efficacy, and development of ostomy complications were explored.

Specific Aims and Hypotheses

Aim 1: Determine ostomy risk factors present at five to seven days post-operatively among adult patients who have fecal ostomy surgery at a large Midwestern health system.

Aim 2: Evaluate the content validity and inter-rater reliability of the Pittman Ostomy Risk Factor Index (ORFI).

Hypothesis 2a. The Ostomy Risk Factor Index and individual items demonstrate content validity as evidenced by content validity indices of at least 0.80 and acceptable scores on clarity, comprehensiveness, and appropriateness based on ratings from 10 national experts.

Hypothesis 2b. The ORFI demonstrates evidence of inter-rater reliability with Cohen's coefficient kappa greater than or equal to 0.60 (Wynd, Schmidt, & Schaefer 2003).

Aim 3: Determine the incidence and severity of ostomy complications within 60 days post-operatively among adult patients who have fecal ostomy surgery in a large Midwestern health system.

Aim 4: To evaluate the content validity, inter-rater reliability and construct validity of the Pittman Ostomy Complication Severity Index (OCSI).

Hypothesis 4a. The Ostomy Complication Severity Index and individual items demonstrate content validity as evidenced by content validity indices of at least 0.80 and acceptable scores on clarity, comprehensiveness, and appropriateness based on ratings from 10 national experts.

Hypothesis 4b. The OCSI demonstrates evidence of inter-rater reliability with Cohen's coefficient kappa greater than or equal to 0.60 (Wynd et al., 2003).

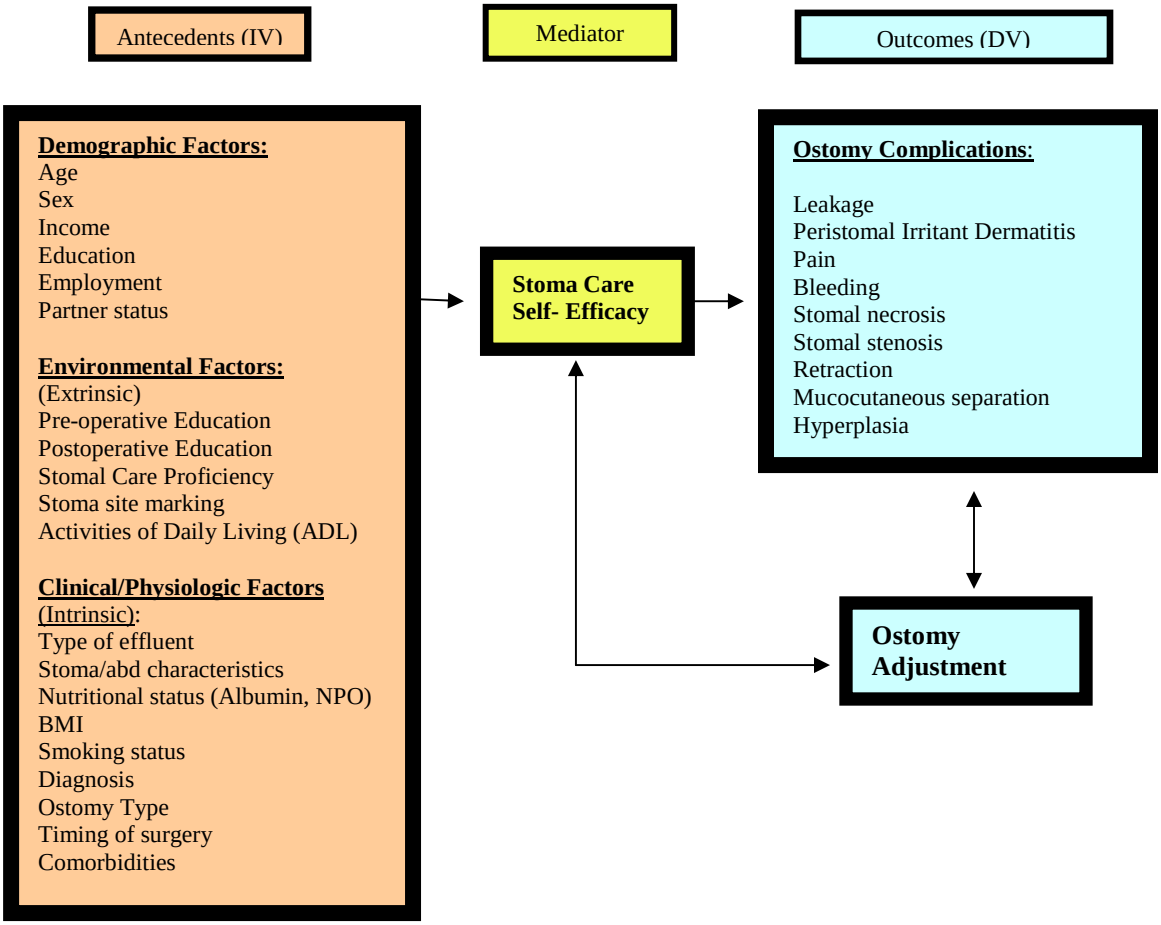
Hypothesis 4c. Total Ostomy Risk Factor Index (ORFI) scores at baseline (five to seven days post-operatively) and Stoma Care Self Efficacy scores at baseline (five to seven days post-operatively) will predict total Ostomy Complication Severity Index (OCSI) scores at follow-up (30 to 60 days post-operatively).

Hypothesis 4d. Pittman Ostomy Complication Severity Index (OCSI) scores and Stoma Care Self-Efficacy (SCSES) scores at baseline (five to seven days post-operatively) and follow-up (30 to 60 days post-operatively) will be correlated with Ostomy Adjustment scores (OAI-23) at follow-up (30 to 60 days post-operatively).

Theoretical Framework

Based on a comprehensive review of literature and extensive clinical experience, a conceptual model was developed by the investigator to guide this study (Figure 1). The Pittman Ostomy Complication Conceptual Model illustrates the relationship among antecedent (risk factors), mediator (stoma care self efficacy), and outcomes (early ostomy complications and ostomy adjustment). Antecedents or independent variables include demographic risk factors, environmental risk factors and clinical/physiologic risk factors. Stoma care self-efficacy is conceptualized as a mediator. The outcome or dependent variables are early ostomy complications and ostomy adjustment. The model demonstrates the interaction of potential predictors or risk factors and mediator that contribute to the occurrence of ostomy complications and ostomy adjustment (Figure 1).

Figure 1: Pittman Ostomy Complication Conceptual Model



Since no comprehensive models or frameworks were found that were relevant to guide the study of ostomy complications, the investigator developed one. Braden's conceptual schema for the etiology of pressure sores was identified as one model that, with modification, could be informative (Braden, 1987). Braden organized her framework into two critical components; duration/intensity of pressure and tissue tolerance. Tissue tolerance was further classified into extrinsic and intrinsic factors that contributed to the development of pressure ulcers (Braden, 1987). In Braden's model, extrinsic factors are those factors that influence tissue tolerance by affecting the skin surface. These factors include moisture, friction, and/or shear forces. Intrinsic factors are those that contribute to the underlying structure and integrity of the supporting features of skin, vascular, and lymphatic systems such as nutrition, age, and arterial pressure (Braden,

1987). Braden's concepts of extrinsic and intrinsic factors were considered relevant when examining ostomy complications and were used in the model developed for this study.

Antecedents (Risk Factors)

Demographic, environmental, and clinical/physiologic risk factors.

An antecedent precedes and is associated with a specific outcome (Crows, 2009). Braden's schema provided guidance for organizing knowledge about factors that may contribute to the development of ostomy complications. The concept of tissue tolerance, and the extrinsic and intrinsic factors that contribute to tissue tolerance, have been incorporated in the Pittman Ostomy Complication Conceptual Model. Extrinsic factors include those environmental risk factors that are external to the individual with an ostomy (perioperative education, stomal care proficiency, stoma site marking, and Activities of Daily Living (ADL) function). Intrinsic factors are those clinical/physiological risk factors that are internal to the patient with an ostomy and include type of effluent, stoma/abdomen characteristics, nutritional status, BMI, smoking status, diagnosis, ostomy type, timing of surgery, and comorbidities. Intrinsic factors influence the structure and integrity of the supporting structures of the skin and the internal organs. In addition, several concepts from the Stoma Management Ease Classification tool, originally developed for clinical use were reviewed, critiqued, revised and incorporated into the model (McCubbin, 2007).

In the Pittman Ostomy Complication Conceptual Model, antecedents are the risk factors that lead to the development of ostomy complications. These risk factors are categorized as demographic variables (age, gender, income, education, employment, partner status), environmental variables (pre-operative education, post-operative education, stoma care proficiency, stoma site marking by WOC nurse, and ADL functioning), and clinical/physiological variables (type of effluent, stoma/abdomen characteristics, nutrition, BMI, smoking status, diagnosis, ostomy type, timing of surgery, and comorbidities).

Several studies have identified that higher body mass index (BMI), older age, emergent surgery, inflammatory bowel disease, having an ileostomy (versus colostomy), a diverting "loop"

procedure, poor bowel quality, ischemic colitis, stomal retraction, pre-operative education and lack of involvement of a wound, ostomy, continence (WOC) nurse are associated with the development of ostomy complications (Bass et al., 1997; Colwell et al., 2001; Duchesne et al., 2002; Park et al., 1999; Pittman et al., 2008). As shown in the Pittman Ostomy Complication Conceptual Model, we hypothesized that these variables would be associated with the development of ostomy complications and conceptualized these variables as antecedents to ostomy complications.

Mediator: Self-efficacy

A mediating variable in the Ostomy Complication Conceptual Model is stoma care self-efficacy. Prior studies have linked stoma care self-efficacy and ostomy adjustment (Bekkers, 1996; Simmons et al., 2007; Wu, Chau, & Twinn, 2007). In the Ostomy Complications model, the mediator of stoma care self-efficacy is hypothesized to be associated with the development of ostomy complications and ostomy adjustment. This study examined relationships among stoma care self-efficacy, ostomy adjustment, and ostomy-related complications.

Self-efficacy is a concept of the Social Learning Theory developed by Bandura and is defined as "the conviction that one can successfully execute the behavior required to produce certain outcomes" (Bandura, 1977). Bandura hypothesized "that expectations of personal efficacy determine whether coping behavior will be initiated, how much effort will be expended, and how long it will be sustained in the face of obstacles and aversive experiences" (Bandura, 1977). Perceived self-efficacy is the belief in one's ability to perform a specific action to attain an outcome. Perceived self-efficacy reflects a broad sense of personal competence to deal effectively with a variety of stressful situations (Luszczynska, Scholz, & Schwarzer, 2005).

Bekkers (1996) studied psychosocial adaptation to stoma surgery and found that there was strong evidence for the important role of stoma care self-efficacy in the process of adapting to a stoma. Bekkers found that higher stoma care self-efficacy shortly after the ostomy operation predicted fewer psychosocial problems in the first post-operative year (Bekkers, 1996). Simmons

defined stoma care self-efficacy as “the conviction by patients that they can successfully manage their stoma to minimize adverse outcomes” (Simmons et al., 2007). Stoma care self-efficacy was positively associated with adjustment to a stoma (Bekkers, 1996; Follick, 1984; Olbrisch, 1983; Piwonka & Merino, 1999; Simmons et al., 2007; Wu et al., 2007).

Outcomes (Early Ostomy Complications and Ostomy Adjustment)

A comprehensive review of the literature was conducted to identify early complications of having an ostomy. Extensive clinical practice strengthened the evidence found in the literature. The outcomes in the Pittman Ostomy Complication Conceptual Model are early ostomy complications that commonly occur within 30 to 60 days post-operatively. Ostomy adjustment is a concept that is considered an outcome in the model because of its potential to be influenced by the development of early ostomy complications.

Ostomy complications.

One method of classifying ostomy complications is to separate them into early, within 30 days following surgery, and late complications, greater than 30 days following surgery (Duchesne et al., 2002; Park et al., 1999). In this study, early ostomy complications were the focus. The early ostomy complications that were examined included leakage, peristomal irritant dermatitis, stoma or peri-stoma pain, stoma or peri-stoma bleeding, stoma necrosis, stoma stenosis, stoma retraction, mucocutaneous separation, and hyperplasia (Colwell et al., 2001; Park et al., 1999; Ratliff et al., 2005). These complications are defined later in this chapter (pages 21-25).

Ostomy adjustment.

Adjustment to having an ostomy is defined as the acceptance of the illness and adapting life to accommodate it (Wright, 2008). Simmons (2007) states that adjustment is more than competence in self-care management and self-care management is insufficient by itself to promote adjustment. Ostomy adjustment is considered as an outcome in the conceptual model. Because of its potential to be influenced by ostomy complications, a uni-directional association between ostomy adjustment and the development of ostomy complications was expected. The

model also indicates that a uni-directional association may exist between ostomy adjustment and stoma care self-efficacy. This study examined relationships between risk factors for ostomy complications, ostomy complications, stoma care self-efficacy, and ostomy adjustment.

The Ostomy Complication Model depicts relationships among demographic, environmental (extrinsic), and clinical/physiological (intrinsic) risk factors to ostomy complications, stoma care self efficacy, early ostomy complications, and ostomy adjustment (Pittman & Rawl, 2007). Because no instruments were identified in the literature to measure the incidence and severity of ostomy complications or to assess risk factors for ostomy complications, two instruments were developed for this study. The model was used to guide the development of these two instruments, the Pittman Ostomy Risk Factor Index (ORFI) and the Pittman Ostomy Complication Severity Index (OCSI). The ORFI and the OCSI were used to measure the incidence of environmental and clinical/physiological risk factors and the incidence and severity of ostomy complications depicted in the Pittman Ostomy Complication Conceptual Model.

Conceptual and Operational Definitions

Independent Variables

Demographic factors.

Age, gender, ethnicity, race, income, education, employment, and partner status.

Conceptual definition. Demographic data refers to the characteristics of a selected population that were examined in this study such as age, gender, ethnicity, race, income, education, employment, and partner status. Participants' demographic characteristics were collected in order to provide a detailed description of the sample and to determine if any demographic factors were associated with the development of early ostomy complications.

Operational definition. An investigator-developed patient survey was used to measure demographic factors (Appendix C). The survey was administered five to seven days post-

operatively. The patient was provided the opportunity to complete the survey with assistance from the investigator. The patient was given the survey to complete. The investigator was available to offer assistance with reading the questions (see Appendix C).

The information was gathered using an open response for age, dichotomous response for gender, and categorical response items for partner status, ethnicity, race, education, income, and employment. In addition, the patient was asked to identify who will be primarily responsible for caring for the ostomy.

Environmental factors.

The environmental factors were defined as those factors external to the patient that may potentially influence the post-operative recovery of the patient and the development of ostomy complications. They were either provided to and reported by or were demonstrated by the patient during the pre-operative or post-operative period. These factors include: pre-operative education, post-operative education, stomal care proficiency, stoma site marking, ADL function, length of hospital stay, and disposition at discharge.

Pre-operative education.

Conceptual definition. The education that was provided to the patient by the WOC nurse prior to the scheduled ostomy surgery. This education typically includes a brief discussion of anatomy and physiology of the gastrointestinal tract, basics of the surgical procedure, introduction to the pouching systems, and a brief overview of lifestyle adjustment.

Operational definition. Pre-operative education was measured based on patient interview using the ORFI (Appendix A). Specifically, patients were asked the following three questions: "Did the ostomy nurse explain; 1) how your intestines or bowels work?; 2) what kind of surgery, or operation, you will have?; and 3) what you can expect after your surgery?" For each item, patient responses were "Yes" or "No".

Post-operative education.

Conceptual definition. The education that was provided to the patient by the WOC nurse during the post-operative hospital stay. Key components of post-operative education most often provided to the patient with a new ostomy are related to the specific type of ostomy surgery. This included physiological aspects (anatomy and function), a brief description of the surgery, technical aspects of ostomy management (pouching system procedure), nutrition, clothing, medications, body image, psychological issues (depression, anxiety, grief), social/recreation issues (work and play), interpersonal relationships (marriage, dating), sexual and intimacy issues, common complications (irritant dermatitis, leakage, stoma changes), and resources available (WOC nurse, support group, internet United Ostomy Association of America). The components of the post-operative education (items) that were included in this study are 1) brief description of the surgical procedure, 2) procurement of the ostomy supplies, 3) ostomy pouch emptying procedure, 4) ostomy pouch/wafer change procedure, and 5) dietary management after ostomy surgery.

Operational definition. Post-operative education was measured using the ORFI (Appendix A) five to seven days post-operatively and based on patient interview. Specifically, the patient was asked to answer the following questions, "Did the ostomy nurse explain: 1) the ostomy surgical procedure? (yes/no); 2) how to obtain your ostomy supplies? (yes/no); 3) how to empty the pouch? (yes/no); 4) how to change the pouch? (yes/no); and 5) your diet with an ostomy? (yes/no). The number of positive responses were tallied by the investigator and a categorical response was identified using the ORFI.

Stomal care proficiency.

Conceptual definition. The ability of the patient or caregiver in the technical management of the stoma; i.e., pouch/skin barrier changing procedure.

Operational definition. Stoma care proficiency was measured based on observation by the investigator/WOC nurse of the patient or caregiver's ability to change the ostomy pouching

system. The patient or caregiver demonstrated the pouching system change procedure. The investigator/WOC nurse tallied the number of verbal cues from the WOC nurse needed for the patient or caregiver to complete the task.

Stoma site marking.

Conceptual definition. The pre-operative marking by the WOC nurse of the most appropriate site for placement of the surgically created stoma.

Operational definition. Stoma site marking was measured by medical record review and patient interview using the ORFI. Specifically, the patient was asked, "Did you have the stoma site marked before surgery by the WOC nurse?" A dichotomous response was elicited where: 1= Yes, 2= No. This information was also measured by review of the medical record for documentation of stoma site marking by the WOC nurse.

Activities of daily living (ADL).

Conceptual definition. The functions that are normally done in daily living including functions performed for self-care such as bathing, dressing, toileting, transferring, continence (bladder), and feeding (Katz et al., 1963).

Operational definition. ADL function was measured based on information collected in the self-administered Patient Survey. Specifically, the patient was asked, "Do you need assistance in: bathing (1= Yes, 2= No), dressing (1= Yes, 2= No), toileting (1= Yes, 2= No), transferring (1= Yes, 2= No), continence (controlling their bladder) (1= Yes, 2= No) and feeding" (1= Yes, 2= No). The number of ADL functions were tallied by the investigator and a categorical response was identified using the ORFI.

Clinical/physiologic factors.

The clinical/physiologic factors are those factors that are intrinsic to the patient with a new ostomy. Intrinsic factors were defined as those factors that contribute to the underlying structure and integrity of the supporting features of skin, vascular, and lymphatic systems such as nutrition, age, and arterial pressure (Braden, 1987). Intrinsic factors influence the structure and

integrity of the supporting structures of the skin and the internal organs. In this study, clinical/physiologic factors included: type of effluent, stoma/abdomen characteristics, nutritional status, BMI, smoking status, diagnosis, ostomy type, and timing of surgery. Each of these factors is defined in the following sections.

Type of effluent.

Conceptual definition. Type of effluent refers to the consistency of the effluent in the pouch. The consistency of effluent, or drainage, from each type of ostomy will vary (colostomy versus ileostomy). The more proximal the ostomy, the more liquid the effluent.

Operational definition. Type of effluent was measured by investigator/WOC nurse observation of the patient's pouch contents prior to discharge from the hospital. A categorical response was identified where: 1= solid stool in pouch, 2= formed but soft stool in pouch, 3= thick liquid stool in pouch; or 4= liquid stool in pouch.

Stoma/abdomen characteristics.

Conceptual definition. Stoma characteristics refer to the shape and height of the stoma in relation to the skin. Abdominal characteristics refer to the presence of skin folds and creases at the stoma site.

Operational definition. Stoma/abdominal characteristics were measured by investigator/WOC nurse direct observation of the patient's stoma and abdomen prior to discharge from the hospital. A categorical response was identified where: 1= stoma that is above skin level, stoma is round, and surrounded by flat abdominal pouching surface, 2= stoma that is above skin level, is oval, and surrounded by minor alterations in abdominal pouching surface, 3= stoma that is skin level, is round or oval, and surrounded by abdomen that has skin folds/creases that are problematic, or 4= stoma that is below skin level, oval, and surrounded by deep abdominal skin folds/creases that are problematic.

Nutritional status.

Conceptual definition. The status of the patient's ability to assimilate food and use it for growth and body maintenance. Nutrition is the act or process of nourishing or being nourished; specifically**,** the sum of the processes by which an animal or plant takes in and utilizes food substances (National Library of Medicine, 2009c). Malnutrition is often defined as inadequate diet and nutrition.

Operational definition. The nutritional status of the participant was measured by investigator/WOC nurse review of the medical record using the ORFI. Two indicators of nutrition risk were extracted. This included a review of the dietary intake of the patient for the past week and the most recent serum albumin level. Unfortunately, there is no single, effective laboratory indicator for nutritional status, however, serum albumin is commonly used (Parrish, 2006). The most recently available albumin level was extracted from the medical record and categorized as 1= 3.0 g/dl or greater , 2= 2-2.9 g/dl ; 3= 1.0-1.9g/dl; and 4= 1.0 g/dl or less. In addition, the physician's dietary orders for the patient were extracted with the specific number of days the patient was restricted from eating (NPO). The number of days that the patient was restricted from eating was categorized as follows: 1= NPO less than 24 hours; 2= NPO 1-2 days; 3= NPO 3-4 days; 4= NPO greater than or equal to 5 days.

Body mass index (BMI).

Conceptual definition. The relative percentages of fat and muscle mass in humans. BMI is a relationship between weight and height that is associated with body fat and health risk (National Library of Medicine, 2009a).

Operational definition. BMI= body weight in kilograms/height in meters squared. Height and weight were obtained from the medical record. The investigator/WOC nurse divided weight in kilograms by height in meters squared to calculate BMI using SPSS. A categorical response using the ORFI was identified where: 1= BMI 18.5-24.9; 2= BMI 24.9- 29.9; 3= BMI 30-35; or 4= BMI less than 18.5 or greater than 35.

Smoking status.

Conceptual definition. The inhalation of the smoke of a burning tobacco product such as cigarettes, cigar, or pipe.

Operational definition. Smoking was measured by patient self report on the Patient Survey. Specifically, the patient was asked to circle the appropriate response to the following question, "Are you currently a smoker?" Response options were: 1= nonsmoker and has never smoked; 2= quit smoking greater than 2 months ago; 3= quit smoking less than 2 months ago; or 4= current smoker (Barrera, 2005).

Diagnosis.

Conceptual definition. The conclusion that is reached after a process of identifying a medical condition or illness by its signs and symptoms or through a variety of diagnostic procedures. Diagnosis is the art or act of identifying a disease from its signs and symptoms (National Library of Medicine, 2009b).

Operational definition. Diagnosis was measured by a review of the medical record. A categorical response was identified where: 1= colon cancer, 2= rectal cancer, 3= IBD (Crohn's or Ulcerative Colitis), or 4= other diagnosis (diverticulitis, trauma, or other).

Ostomy type.

Conceptual definition. An ostomy refers to a surgically created exteriorization of the colon or ileum to the anterior abdominal wall of the body. Fecal ostomies are classified according to the location of bowel that was diverted. An ostomy involving the small intestine is called an ileostomy. An ostomy involving the large intestine or colon is called a colostomy. More specific classification corresponds to the location of the bowel that is used to form the stoma, such as, sigmoid colostomy, transverse colostomy, ascending colostomy. Sigmoid and descending colostomies are usually on the left lower abdomen, transverse colostomies are usually higher and toward the middle of the abdomen, ascending colostomies and ileostomies are usually on the right lower abdomen (McGarity, 1992).

Operational definition. The type of ostomy was identified from the medical record. A categorical response was identified where: 1= sigmoid colostomy, 2= transverse colostomy, 3= ascending colostomy, or 4= ileostomy.

Timing of surgery.

Conceptual definition. If the ostomy surgery was performed electively (planned) or emergently.

Operational definition. Timing of surgery was identified through a review of the medical record. A dichotomous response was identified where: 1= planned or scheduled surgery or 4= emergent surgery.

Comorbidities.

Conceptual definition. Comorbidity refers to the presence of one or more diseases or disorders in addition to the primary disease; patient characteristics that independently affect outcomes. Comorbidity is often included in the description of the patient characteristics of a population. Research has shown that patients can accurately assess their current and past medical conditions including comorbidities (Sangha, Stucki, Liang, Fossel, & Katz 2003).

Operational definition. Comorbidities were measured by patient self-report using a modified version of the Self-Administered Comorbidity Questionnaire (SCQ). The modified SCQ was included in the Patient Survey. The original SCQ asks about the presence of the problem, if treatment is being received, and if the problem limits activities. Previous test-retest of the SCQ was 0.94 and overall agreement between Charlson Index and SCQ was greater than 78% (Sangha et al., 2003). In this study, only the presence of the problem was measured. Specifically, the patient was asked, "Has your doctor ever told you that you have: heart problems, high blood pressure, diabetes or high sugar, cancer (leukemia, skin, breast, lung, prostate, colon, rectal), rheumatoid arthritis, osteoarthritis or degenerative arthritis, breathing problems, kidney disease, ulcer of stomach problems, liver problems, anemia or blood disease, back pain or back problems, depression, and/or other". The patient checked the conditions that are present. The number of

conditions present was summed to compute a total comorbidity score using SPSS. A range of 0 to 14 was possible.

Mediator

Stoma care self-efficacy.

Conceptual definition. Self-efficacy is a concept of the Social Learning Theory developed by Bandura and is defined as "the conviction that one can successfully execute the behavior required to produce certain outcomes" (Bandura, 1977). Stoma care self-efficacy is task-specific and is defined as "the conviction by patients that they can successfully manage their stoma to minimize adverse outcomes" (Simmons et al., 2007).

Operational definition. In this study, stoma care self-efficacy was measured using the Stoma Care Self-Efficacy Scale (SCSES) (Bekkers, 1996) (see Appendix D). The Stoma Self-efficacy Scale is comprised of 2 subscales, stoma care self-efficacy and social self-efficacy. In this study, we used the stoma care self-efficacy subscale which had an internal consistency of .94 (Bekkers, 1996). This is a 13-item self-report questionnaire with a 5-point response scale where: 1= not confident, 2= slightly confident, 3= fairly confident, 4= highly confident, and 5= extremely confident. Higher scores indicate higher self-efficacy. The SCSES was completed by the patient or by the caregiver if the caregiver was responsible for ostomy care.

Dependent Variables

Ostomy complications.

Ostomy complications refer to those adverse events that are related to having an ostomy. These can include both physiological and psychosocial aspects of the consequences of having an ostomy.

Physiological Ostomy Complications.

Physiologic ostomy complications involve changes of the stoma and peri-stoma skin (Cottam et al., 2007). Physiological ostomy complications that were addressed in this study include leakage, peristomal irritant dermatitis, pain, bleeding, stomal necrosis, stomal stenosis,

retraction, mucocutaneous separation, and hyperplasia. Each of the complications is defined in the following sections.

Leakage.

Conceptual definition. Leakage occurs when effluent from the stoma undermines the adherence of the ostomy appliance to the skin causing interference with the adhesion of the skin barrier or pouching system.

Operational definition. Leakage was measured by self report and observation using the OCSI (see Appendix F). The investigator observed if there was any current leakage of the ostomy pouching system. If there was no current leakage, the patient or caregiver was asked, “Have you had any leakage of ostomy drainage that interfered with the adhesion of the skin barrier in the past 30 days?”. If yes, then the patient or caregiver was asked how often, “approximately 1-2 times in past 30 days, or approximately 1-2 times per week, or approximately 1-2 times per day?”. A categorical response was identified where: 0= no leakage; 1= leakage that occurred approximately 1-2 times in past 30 days; 2= leakage that occurred approximately 1-2 times per week; or 3= leakage that occurred approximately 1-2 times per day.

Peristomal irritant dermatitis.

Conceptual definition. Irritation and inflammatory changes of the skin surrounding the stoma due to contact (fecal, urinary, or chemical) or hypersensitivity to chemical elements (Colwell & Beitz, 2007). Severity ranges from mild redness or rash to complete skin loss or denudement.

Operational definition. Peristomal irritant dermatitis was measured by self report and observation using the OCSI. The investigator identified if there was any peristomal irritant dermatitis present. If there was none present, the patient or caregiver was asked, "Have you had any skin irritation around the stoma in the past week?" If yes, the patient or caregiver was asked to describe using the following descriptions, “redness, or rash but no skin loss and skin is intact; or redness, or rash with skin loss that is less than 50% around the stoma; or redness, or rash with

skin loss that is greater than 50% around the stoma?". A categorical response was identified where: 0= no peristomal irritation; 1= peristomal erythema, redness, or rash but no skin loss and skin is intact; 2= peristomal erythema, redness, or rash with less than 50% of peristoma skin loss; 3= peristomal erythema, redness, or rash with greater than 50% of peristoma skin loss.

Pain.

Conceptual definition. The current presence and severity of a physical hurt or unpleasant sensory experience at the stoma site as perceived by the patient.

Operational definition. Stoma pain was measured at follow-up using a 11-point numeric rating scale (NRS). The NRS has been identified as a standardized tool with established reliability and validity properties (Registered Nurses Association of Ontario, 2007). The patient identified the number that corresponded to their current level of stoma or peri-stomal pain, 0= no pain and 10= worst pain.

Bleeding.

Conceptual definition. The loss of blood from either the surface of the stoma or the skin surrounding the stoma.

Operational definition. Bleeding was measured by patient interview and observation using the OCSI. The investigator/WOC nurse observed the stoma site for the presence of bleeding at the stoma or around the stoma. If there was no bleeding present, the patient or caregiver was asked, "Have you had any bleeding from the stoma or around the stoma in the past week?" If yes, the patient or caregiver was asked how much: 1) superficial and stopped easily, 2) moderate and stopped after 10 minutes of pressure, or 3) severe and did not stop, had to see a doctor . A categorical response was identified where: 0= no stoma or peristoma bleeding; 1= stoma or peristomal bleeding that is superficial and stopped quickly; 2= stoma or peristomal bleeding that is persistent and requires either prolonged pressure, AgNO3 cauterization or hemostasis agent; 3= stoma or peristomal bleeding that requires advanced medical intervention (sutures or transfusion).

Stomal necrosis.

Conceptual definition. Death of the stoma tissue resulting from impaired blood flow (J. Colwell, Beitz, J., 2007). Impending tissue death is evidenced by a progression of discoloration of the stomal tissue from pink to black.

Operational definition. Stomal necrosis was measured by direct observation of the stoma by the investigator at follow-up using the OCSI. A categorical response was identified where: 0= no stomal necrosis, stoma is pink and moist; 1= dusky stoma; 2= stoma that is less than or equal to 50% black; 3= stoma that is greater than 50% black.

Stomal stenosis.

Conceptual definition. Impairment of effluent drainage due to narrowing or contracting of the stoma tissue at the skin or fascial level (Colwell & Beitz, 2007).

Operational definition. Stomal stenosis was measured by direct observation of the stoma by the investigator at follow-up using the OCSI. A categorical response was identified where: 0= stoma os that has no stenosis or narrowing; 1= stoma os that is less than 5th digit diameter, with no pain or discomfort and output is normal; 2= stoma os that is less than 5th digit in diameter, has ribbon-like output, and with occasional abdominal discomfort; 3= stoma os that is unable to accommodate the 5th digit, no output x 6 hours or greater, and with abdominal pain and distention.

Retraction.

Conceptual definition. The disappearance of stoma tissue protrusion in line with or below skin level (Colwell & Beitz, 2007).

Operational definition. Retraction was measured by direct observation of the stoma by the investigator at follow-up using the OCSI. A categorical response was identified where: 0= stoma is above skin level; 1= stoma is level with the skin; 2= stoma is below skin level; 3= stoma is greater than 2 centimeters below skin level or is unable to be visualized.

Mucocutaneous separation.

Conceptual definition. The detachment of stomal tissue from the surrounding peristomal skin (Colwell & Beitz, 2007).

Operational definition. Mucocutaneous separation was measured by direct observation of the stoma and peristomal skin by the investigator at follow-up using the OCSI. A categorical response was identified where: 0= no separation of the stoma from the mucocutaneous junction; 1= 1- 49% separation of the stoma from the mucocutaneous junction; 2= 50-74% separation of the stoma from the mucocutaneous junction; 3= 75-100% separation of the stoma from the mucocutaneous junction.

Hyperplasia.

Conceptual definition. Abnormal proliferation of granulation or abnormal tissue beyond that which is ordinarily seen on the skin surrounding a stoma. This could include mucosal seeding of viable intestinal mucosal tissue along the suture line onto the peristomal skin or wart-like lesions in the peristomal area related to chronic moisture exposure and irritation (Colwell & Beitz, 2007).

Operational definition. Hyperplasia was measured by direct observation of the stoma and peristomal skin by the investigator at follow-up using the OCSI. A categorical response was identified where: 0= no hyperplasia around the stoma; 1= hyperplasia that is 1-49% around stoma; 2= hyperplasia that is 50-74% around stoma; 3= hyperplasia that is 75-100% around stoma.

Psychosocial Aspect of Having an Ostomy

Psychosocial aspect of having an ostomy involve the challenges individuals face living with and adjusting to the ostomy (Carlsson, et al., 2001; Cottam et al., 2007). The psychosocial concept that was addressed in this study was ostomy adjustment.

Ostomy adjustment

Conceptual definition. Ostomy adjustment has been defined as "the overall impact of the stoma on psychological, social, and sexual functioning as perceived by patients" (Simmons et al., 2007).

Operational definition. Ostomy adjustment was measured by a 23-item scale (Ostomy Adjustment Inventory-23) using a 5-point Likert rating ranging from 1= strongly agree, 2= agree, 3= unsure, 4= disagree, to 5= strongly disagree (see Appendix E). This inventory was completed by the patient at follow-up using a self-administered written survey. The investigator was available to assist in reading the survey items. Higher scores indicate a better adjustment to having an ostomy. The Ostomy Adjustment Inventory-23 (OAI-23) had an internal consistency of .93 reported by Simmons (2008).

Summary

Ostomy-related complications are a significant problem for individuals with an ostomy. Due to the limited knowledge regarding relationships among antecedents (risk factors) and the incidence and severity of ostomy complications, this research study is a critical step in identifying risk factors of ostomy complications and evaluating the incidence and severity of ostomy complications in the immediate 30 to 60 days after surgery. This study also examined the psychometric properties of two instruments that were developed to measure the incidence of risk factors of ostomy complications and the incidence and severity of ostomy complications.

Studying the incidence and severity of ostomy complications and the factors that contribute to the development of such complications establish a foundation upon which to build future research. In addition, the development of clinically useful instruments will lead to further research and the development of interventions that will improve care and quality of life for individuals living with an ostomy.

CHAPTER TWO

REVIEW OF THE LITERATURE

The surgical creation of an ostomy is performed for many different reasons and conditions. Placement of an ostomy significantly alters one's elimination pattern and can affect the individual both physically and psychologically. In addition, ostomy complications are a common problem (Smith, 1992). Research has shown that ostomy complications negatively affect the quality of life for individuals living with an ostomy, and often result in physical and psychosocial limitations for these individuals and their families (Pittman et al., 2008). Not only does the person with an ostomy have to cope with a serious and often life-threatening diagnosis, but the placement of an ostomy requires significant changes to one's lifestyle. Risk factors specific to ostomy complications have not been well established and research is needed to better understand the impact of this common surgical procedure.

The purpose of this chapter is to describe the current state of the science related to risk factors that contribute to the development of fecal ostomy complications and to the development of ostomy complications. This chapter is divided into five sections: 1) ostomy surgery and conditions; 2) risk factors for ostomy complications; 3) stoma self-efficacy; 4) ostomy complications; and 5) ostomy adjustment.

Searches were conducted for literature regarding ostomy complications and risk factors using the databases of Ovid, EPM Full Text, Journals@Ovid Full Text, CINAHL, OVID, Healthstar, Lancet Archive, AARP Ageline, and Health and Psychosocial Instruments. Search words included ostomy complications, stoma, stomal complications, ostomy risk factors, ostomy adjustment, self efficacy, and ostomy surgery. A return of 123 sources were found. After careful review of titles, abstracts, ostomy type, and level of evidence, it was determined that 91 were appropriate for this review and synthesis. Thirty-six studies reported physical components of ostomy-related complications, 62 examined psychological aspects or quality of life, six presented information on the development of instruments to measure different aspects of ostomy adjustment

(coping, self-efficacy, quality of life), three were systematic reviews of the literature, and seven were intervention studies (two comparing pouching systems, one reporting on irrigation, one on relaxation, two on counseling, and one on surgical technique). Eighty-eight studies were quantitative, most were descriptive, 16 were experimental, 11 used qualitative designs, and two were systematic reviews. A table summarizing the review of literature is in Appendix G.

Overview of Ostomy Surgery and Conditions

The first part of this chapter provides an in-depth discussion of the conditions associated with an ostomy, the function and purpose of an ostomy, types of ostomies, and prevalence and incidence of ostomies. This information will provide the foundation for understanding ostomy complications and risk factors.

Conditions Associated with an Ostomy

There are several types of disorders that may require surgical creation of a fecal or intestinal ostomy for either palliation or cure. Common conditions in the adult include cancer, trauma, inflammatory bowel disease (Crohns disease or ulcerative colitis), and acute inflammatory processes such as diverticulitis (Bryant & Buls, 1992).

Colorectal cancer is the third most common cancer in both men and women and the second most common cause of cancer death in the United States (American Cancer Society [ACS], 2005). Estimates by the American Cancer Society report that there will be approximately 108,070 new cases of colon cancer and 40,740 new cases of rectal cancer diagnosed in 2008 (ACS, 2008). Most colorectal surgeries will involve some type of surgery and often will require having an ostomy created. Adenocarcinomas are the most common primary colon malignancy and the United States has one of the highest rates in the world. Surgical resection is the treatment of choice and is determined by the anatomic site of the lesion; the lower the lesion, the more likely a colostomy (Bryant & Buls, 1992). Therefore, a greater proportion of rectal cancer patients will have an ostomy compared to those with colon cancer. Approximately one in eight individuals diagnosed with rectal cancer will receive a permanent colostomy (ACS, 2005).

Trauma ranks as the leading cause of morbidity and mortality for all age groups under 60 years of age. More than 105,000 deaths in the United States were attributed to unintentional injuries in 2003 and nearly half a million hospital discharges in the United States were attributed to injury treatment (Steele, 2006). Blunt trauma to the abdomen occurs most often in motor vehicle accidents and results in tearing, crushing, or rupture of internal abdominal organs. Penetrating abdominal trauma is often the result of interpersonal violence such as a gunshot, stabbing, or sexual assault, and impalement. When the bowel is perforated, peritonitis and infection often result and an ostomy may be necessary (Steele, 2006).

Inflammatory bowel disease (IBD) involves chronic inflammation of the small and/or large intestine but is more commonly referred to as Crohn's disease and/or ulcerative colitis (Bryant & Buls, 1992). The annual incidence of Crohn's disease is seven new cases per 100,000 people. However, the incidence of Crohn's disease appears to be on the rise (Bryant & Buls, 1992). The incidence of ulcerative colitis is slightly higher at eight new cases per 100,000 persons per year (National Digestive Diseases Information Clearinghouse [NDDIC], 2005).

The cause of IBD is unknown but the focus of recent research has been on genetic, infectious, immunologic, and dietary causes. Both Crohn's disease and ulcerative colitis result in inflammation of the lining of the bowel, ulceration, bloody diarrhea, pain, gas, bloating, and sometimes hard stools (NDDIC, 2005). However, ulcerative colitis only involves the large intestine while Crohn's disease may involve both the large and the small intestine. Chronic inflammation results in scarring of the submucosa and muscular layers of the bowel in ulcerative colitis while the inflammation is transmural (submucosal, muscular, and serosal) in Crohns disease. Medical management of IBD consists of antidiarrheal agents, sulfasalazine, corticosteroids, and immunosuppressive agents. Surgery resulting in an ostomy is often the definitive treatment when medical management has been exhausted (Bryant & Buls, 1992).

An acute inflammatory process of the intestinal tract is another condition associated with the creation of an ostomy. Diverticular disease is one example of this and is defined as the

presence of diverticula, primarily in the sigmoid colon, in combination with muscular changes of the colon. The incidence of diverticular disease is 300,000 new cases per year and over 2.6 million people are known to be living with this condition. Approximately 576,000 individuals are hospitalized annually with diverticular disease (NDDIC, 2005). Diverticulitis is the acute inflammation of diverticular disease and often results in perforation and obstruction of the bowel (Bryant & Buls, 1992). These complications often are treated surgically with the creation of an ostomy.

Function and Purpose of an Ostomy

An ostomy refers to a surgically created exteriorization of the colon or ileum to the anterior abdominal wall of the body. The function and purpose of the ostomy is to provide a diversion for the elimination of urine, feces or intestinal effluent. Historically, there were sporadic accounts of ostomy surgery in the literature. It was recorded in the Book of Judges in the Bible and was noted by Hippocrates and Celsus of spontaneous fistula development following penetrating or blunt trauma to the abdomen (Abrams, 1984). The evolution of the procedures for the creation of a stoma have gone through phases; first, the exteriorization of the intestine following trauma, second, stoma formation alone, and finally stoma formation associated with bowel resection (Hardy, 1988). In 1793, a surgeon performed a colostomy on a 3-day old infant with imperforate anus. The surgery was successful and the patient lived to the age of 45 years.

Ostomy surgery became a more realistic treatment after the advent of anesthesia in the mid-1800’s. Surgeons used diverting colostomies to manage bowel obstruction and tried to cure patients with rectal cancer. In the 1900's, modifications were made to the procedure which improved outcomes and ostomies were found to protect distal anastomosis and to reduce post-operative complications. The history of ostomy surgery has been characterized by tremendous challenges, determined surgeons, and courageous patients (Doughty, 2008).

An ostomy is a surgical procedure creating an opening in the body for the discharge of body wastes (Gilles, 2008). Ostomies can be created to divert either fecal (colostomy, ileostomy)

or urinary contents. The differences in surgical technique and effluent characteristics make management of fecal and urinary ostomies very different from each other. In this study, we focused on intestinal or fecal ostomies in the adult, specifically, ileostomies and colostomies.

Intestinal or fecal diversions are often necessary due to an obstruction (cancer or mechanical), disease (cancer, inflammatory bowel disease, diverticulitis), perforation (trauma, inflammation), malformation (congenital disorders), malfunction of the intestine (neurogenic bowel), and for elimination management (spinal cord injury, mega colon) (Bryant & Buls, 1992). The purpose of a fecal or intestinal ostomy is to provide a diversion for the elimination of bowel contents.

Types of Fecal Ostomies

Fecal ostomies are classified according to the location of bowel that was diverted. For instance, an ostomy involving the small intestine is called an ileostomy. An ostomy involving the large intestine or colon is called a colostomy. Further classification can be even more specific, such as, sigmoid colostomy, transverse colostomy, ascending colostomy. With each type of ostomy, the location of the stoma on the abdomen and consistency of the effluent may vary. Sigmoid and descending colostomies are usually on the left lower abdomen, transverse colostomies are usually higher and toward the middle of the abdomen. An ascending colostomy is usually on the right side of the abdomen as is the ileostomy (McGarity, 1992).

Appropriate stoma site selection is critical and dependent on the type of ostomy created. Inappropriate stoma site placement is thought to be a potential risk factor in the development of ostomy complications (Bass et al., 1997). Complications may result due to inappropriate placement of the stoma in a deep skin fold or crease, along the beltline, close to the umbilicus, or not in the patient's visual field causing an inability of the patient to properly manage and care for the ostomy.

The consistency of effluent, or drainage, from each type of ostomy will also vary. This is important because the more proximal the ostomy, the more liquid the effluent and the more

caustic it is to peri-stomal skin. Therefore, type of ostomy, is a potential risk factor for the development of ostomy complications and will be examined in this study.

An ostomy can also be described by the type of surgical construction performed. A loop ostomy is constructed by bringing a loop of bowel to the abdominal surface, securing with a rod to hold above the skin level, and then surgically opening the anterior wall of the bowel. This creates one stoma with a proximal (functioning) opening and a distal (nonfunctioning) opening and an intact posterior wall that separates the two openings. The loop ostomy is usually temporary or created for emergent diversion (McGarity, 1992).

An end stoma is constructed by dividing the bowel and bringing the proximal portion out as a single stoma and securing to the exterior abdomen. The distal end may be oversewn and left in the abdomen. This procedure is referred to as a Hartmann's pouch. The distal end of the intestine, alternatively, may be brought to the exterior of the abdomen and called a mucous fistula. If the distal end is removed, the ostomy is permanent. If the distal end of the bowel is conserved, then the potential exists for the bowel to be reanastomosed and the stoma to be closed (McGarity, 1992).

Prevalence/Incidence of Ostomies

The demographics of the American ostomy population and the number and types of new ostomy surgeries performed each year remain elusive to accurately describe. This may be due, in part, to the reporting and coding mechanisms our country uses to track medical procedures. Regardless, estimates are that more than 800,000 individuals are currently living with an ostomy in North America and more than 120,000 new ostomies are created annually in the United States and Canada (Kelman & Minkler, 1989; Turnbull, 2003). More than 13,000 patients undergo stoma surgery in the United Kingdom each year (Simmons et al., 2007). The most common types of ostomies are the colostomy (colon), ileostomy (small bowel) and the urostomy or ileal conduit (urinary) (United Ostomy Associations of America [UOAA], 2005). There is a fairly even distribution of the three major ostomy types: colostomy 36.1%, ileostomy 32.2%, and urostomy

31.7%. Fecal diversions (colostomies and ileostomies) are more common than urinary diversions (68.3% to 31.7%) (Turnbull, 2003).

The average age of persons living with a colostomy is 70.6 years, those with an ileostomy are 67.8 years, and those with an urostomy are 66.6 years. There is no specific gender data available for the ostomy population, but one large study of 1400 individuals with an ostomy reported 57% were female (Turnbull, 2003).

The Center for Disease Control (CDC) reported that more females had operations of the digestive system than males (3.2 million compared with 2.4 million) and that the rate of digestive procedures was higher for females than for males (210.7 compared to 166.5 per 10,000 population) (DeFrances, 2007). Conversely, the American Cancer Society (ACS) reports that almost 149,000 new cases of colorectal cancer will be diagnosed in 2008, and will affect men more than women (77,250 versus 71,560) (ACS, 2008). Overall, the lifetime risk of developing colorectal cancer is approximately 1 in 19, or 5.4%, and is slightly higher in men than women (ACS, 2008). We know that a percentage of these individuals will have an ostomy, whether it is temporary or permanent. Temporary ostomies are created to allow the colon or rectum to heal from surgery. The duration of a temporary ostomy usually is for six to eight weeks. The intestine is then surgically reconnected and the stoma is closed. Approximately one in eight individuals treated for rectal cancer will result in a permanent colostomy (ACS, 2005). The inconsistencies and gaps in these statistics emphasize the lack of ostomy-specific information available.

The number of individuals with an ostomy is estimated to increase by 3-4% per annum (Zassi, 2008). Surgery resulting in stoma formation is often thought to be on the decline due to scientific and medical advancements yet one study found that stoma formation surgery actually increased over the eight year study period 1992 through 2000 (Harris et al., 2005). In addition, individuals who have an ostomy are expected to live longer as the number of people dying from colorectal cancer is decreasing (ACS, 2008). This is largely due to the improvement in screening,

early detection, and treatment. As a result, it is estimated that there are now over one million survivors of colorectal cancers in the United States (ACS, 2008).

Another factor affecting growth in the number of individuals with an ostomy is the aging population. As a result of nationwide improvements in health care, nutrition, education, and general living standards, the elderly account for an increasing percentage of the U.S. population. In 1997, one in eight Americans was elderly (age 65 and over). By 2030, one in five will be elderly (CDC, 2004). The "oldest old", those aged 85 and over, make up the fastest growing segment of the U.S. population. In 1996, an estimated 3.8 million persons were aged 85 or older and approximately 1.4 million were aged 90 or older. Between 1960 and 1994, the oldest old population increased 280 percent compared with a 100 percent increase for those 65 and older. Projections suggest that the population aged 85 and over will increase by 54 percent, from 3.7 million in 1996 to 5.7 million in 2010, and may reach 18.2 million in 2050 (CDC, 2004). Because of this increase in the aging population, it has been estimated that there will be a 3-4% per annum growth in the prevalence of ostomy surgery (Zassi, 2008).

Risk Factors for Ostomy Complications

Various patient characteristics have been identified in the literature as being associated with ostomy complications but studies with predictive analysis models are limited. The majority of ostomy studies have not evaluated a comprehensive set of predictors or risk factors for the development of ostomy complications. The Pittman Ostomy Complication Conceptual Model provides a framework for exploring ostomy complications and the risk factors that contribute to their occurrence. In this review, the rationale for both the inclusion and classification of specific risk factors in the Pittman Ostomy Complication Conceptual Model is provided. In the following section of this chapter, the evidence supporting relationships among demographic/psychosocial, environmental, and clinical/physiological factors that can influence the development of ostomy complications are presented.

Demographic Factors

In this study, the relationships among the demographic variables (age, sex, income, education, partner status) and ostomy complications were examined.

Age.

Age has been consistently found to be associated with the development of ostomy complications in the literature although the direction of the relationship has not been consistent. Five studies were identified that reported increased age was associated with increased risk of ostomy complications (Caricato, 2006; Harris et al., 2005; Helman, 1990; Mahjoubi, Moghimi, Mirzaeli, & Bijari, 2005; Park et al., 1999). One study in Iran found that compared to younger ostomy patients, persons older than 40 years of age had more bleeding (OR= 2.19), peristomal irritant dermatitis (OR= 3.14), and psychosocial problems (OR= 2.77) (Mahjoubi et al., 2005). In a study of 345 stomas from 1992 to 2000, Harris, et al., found that while increased age was associated with higher levels of morbidity and mortality ($p= 0.0001$), age was not significantly associated with complications (Harris et al., 2005). In another study of 132 subjects with fecal ostomies, younger patients and those with end colostomies had lower complication rates ($p= 0.01$) (Caricato, 2006). Park found that as age increased, so did the rates of stoma complications (OR= 1.098, $p= 0.0097$) (Park et al., 1999). Conversely, a study of 239 veterans found that age was inversely related to the severity of skin irritation ($p= 0.022$), leakage ($p= 0.007$), and difficulty adjusting to an ostomy ($p= \leq 0.001$). Younger veterans were more likely to report increased severity of all three of these complications (Pittman et al., 2008).

Employment and partner status.

The availability/presence of a supportive interpersonal relationship has been shown to be associated with improved adjustment to chronic disease. Among individuals with an ostomy, evidence suggests that adaptation is better in those who have access to supportive relationships (Simmons et al., 2007). Nine studies were identified that examined the influence of employment status, partner status, or supportive relationships on complications as they relate to having an

ostomy (Baldwin, 2008; Follick, 1984; Lucanova, 2003; Martinsson et al., 1991; Mitchell et al., 2007; Nichols & Riemer, 2008; Pittman et al., 2008; Piwonka & Merino, 1999; Simmons et al., 2007).

A survey of 1,495 individuals with an ostomy examined the relationship of stability of lifestyle forces and postoperative recovery from ostomy surgery. The investigator identified that occupational stability influenced overall recovery following ostomy surgery. Occupational stability was defined as a change in work habits or change in occupation as a result of ostomy surgery. Individuals who reported both a change in work habits and a change in occupation as a result of ostomy surgery were 4 times more likely to report lower life satisfaction scores than those with only a change in work habits (OR= 3.9) (Nichols & Riemer, 2008).

In a study that examined working capacity and health-related quality of life (HRQOL) in 53 persons with ulcerative colitis and Crohn's after ileostomy surgery, half the participants felt themselves to be handicapped to some extent. Most participants, though, felt that their working capacity had not been affected by the surgery (78%). Subjects also felt it was easier to plan both work and leisure time after the surgery (Martinsson et al., 1991). Follick examined adjustment difficulties after ostomy surgery in 131 patients, and reported that only 5% had to change employment due to ostomy surgery and that 96% reported that their fellow workers were helpful in their adjustment to the ostomy (Follick, 1984). Conversely, Pittman (2008) found that being employed was associated with more severe difficulty adjusting to an ostomy (p=.018). Likewise, in a study of 34 subjects with a stoma, 57% did not return to work after ostomy surgery (Lucanova, 2003).

Piwonka (1999) examined predictors influencing ostomy adjustment in 60 patients and found that adaptation following ostomy surgery was primarily affected by perceived support and support from family and significant others (p=.0002). In a study of 120 veterans with an ostomy, Baldwin reported that subjects who were married had higher spiritual HRQOL scores (p= < .0001) (Baldwin, 2008). Mitchell, in a sample of 239 veterans with an ostomy, found that

unpartnered veterans were more likely to be highly embarrassed about their ostomy (p= .001). High embarrassment was associated with higher anxiety (p= <.001), depression (p= <.001), more difficulty with intimacy (p= <.001), and feeling more isolated (p= <.001) (Mitchell et al., 2007). Simmons (2007) found that in a sample of 51 patients with a colostomy, having a partner was not significantly correlated with ostomy adjustment (p= 0.45). However, these investigators did find that interpersonal relationships (the ease with which one relates and interacts with other people) was correlated with ostomy adjustment (p=*.03)*. In another study, while partner status was not specifically addressed, 82% of subjects described social support as helpful to their adjustment (Follick, 1984). Another study of 239 veterans found that those who were married or had a partner reported less difficulty adjusting (p= <.001) (Pittman et al., 2008).

Income.

Only two studies were identified that examined associations between income or financial characteristics and ostomy complications (Coons, 2007; Pittman et al., 2008). Both studies reported negative associations between income and ostomy complications. In the study of 239 veterans, an annual income of less than $30,000 was related to severity of difficulty adjusting to an ostomy (p= .005) (Pittman et al., 2008). Coons (2007) examined the relationship between difficulty paying for ostomy supplies and overall quality of life in 511 veterans with an ostomy. These investigators found that subjects who had difficulty paying for ostomy supplies had overall lower HRQOL scores (p= .0002) (Coons, 2007).

No studies were identified that found gender or race/ethnicity to be associated with ostomy complications. Hellman and Lago, in their study of 93 ostomy patients, concluded that gender was not related to peristomal skin problems (Helman & Lago, 1990). In a study of 164 patients with an ostomy, gender was not associated with ostomy complications (Duchesne et al., 2002). Pittman and colleagues (2008) found no relationship between complications and gender. However, because there are differences in incidence of gastrointestinal disease and diagnosis

between males and females and conflicting evidence in the literature, gender was included in the Pittman Ostomy Complication Conceptual Model and was examined in this study.

In summary, the evidence is inconsistent regarding the relationships among demographic characteristics and ostomy complications. Age was the most consistent demographic factor associated with ostomy complications in the literature, but further research is needed to examine the direction of the association.

Environmental Factors

Environmental factors explored in this section are those extrinsic factors that affect the person with an ostomy. Extrinsic factors in the ostomy patient include those factors that occur externally to the individual with an ostomy. The Pittman Ostomy Complication Model postulates that potentially important environmental factors include pre-operative education, post-operative education, stoma care proficiency, stoma site marking by WOC nurse, and ADL functioning.

Pre-operative/post-operative education.

Thirteen studies were identified that described associations between pre-operative or post-operative ostomy education and development of ostomy complications. Five studies examined the association between pre-operative education and physiological ostomy complications (Bass et al., 1997; Duchesne et al., 2002; Millan, Tegido, Biondo, & Garcia-Granero, 2010; Park et al., 1999; Pittman et al., 2008). Eight studies examined the association between pre-operative or post-operative education and psychosocial ostomy complications or HRQOL (Beitz, 1999; Chaudhri, 2005; Edlund, 1981; Gulbiniene, Markelis, Tamelis, & Saladzinskas, 2004; Haugen, Bliss, & Slavik, 2006; Lynch, Hawkes, Steginaga, Leggett, & Aitken, 2008; Marquis et al., 2003; Notter & Burnard, 2006). In addition, one systematic review evaluated the influence of pre-operative education on surgical outcomes following ostomy surgery (Colwell & Gray, 2007).

In the pivotal retrospective study of 593 subjects at Cook County Hospital in Chicago, patients who received pre-operative education and stoma site marking by an enterostomal

therapist (Group 1) were compared to those who did not (Group 2). Of those in Group 1, 32.5% developed complications while 43.5% of those in Group 2 developed complications (p= <.0075) (Bass et al., 1997). Pre-operative education and stoma site marking by a WOC nurse often occur simultaneously in the clinical setting, therefore, it is difficult to evaluate the relative impact of each of these interventions. In a retrospective review of 1616 medical records of persons who had stoma surgery, stoma site marking by a enterostomal nurse decreased the incidence of stoma complications by half (OR= 0.57, p= .0089) (Park et al., 1999). Pre-operative education most likely occurred simultaneously in this situation.

Duchesne (2002), examined ostomy complications and risk factors associated with them in a sample of 164 participants. Although ostomy education was not specifically described, investigators found that enterostomal nursing care reduced complications by 85% (OR= 0.15, 95% CI= 0.03-0.69). In a study of 239 veterans, pre-operative ostomy education was associated with less severe skin irritation (p= .009) and less leakage (p= .009*)*. However, in this study, post-operative ostomy education was not associated with ostomy complications (Pittman et al., 2008). In a study of 270 subjects, those who received care from a stomatherapy nurse had significantly less irritant dermatitis compared to those who did not (p= <0.001) (Millan et al., 2010).

Eight studies examined associations between pre-operative education and psychosocial ostomy complications or HRQOL (Beitz, 1999; Chaudhri, 2005; Edlund, 1981; Gulbiniene et al., 2004; Haugen et al., 2006; Lynch et al., 2008; Marquis et al., 2003; Notter & Burnard, 2006). In one study of 4,739 patients with an ostomy, quality of life was examined using the Stoma Quality of Life Scale. HRQOL scores were higher in those patients who were satisfied with the care received (p= < .01). Patients who indicated that the stoma care nurse had a genuine interest in them as a person had higher HRQOL scores than those who had a poor relationship with their stoma care nurse (p= < .01) (Marquis et al., 2003). Likewise, in a study of 146 individuals with an ostomy, pre-operative education from a WOC nurse was positively associated with improved ostomy adjustment (*p=.03)* (Haugen et al., 2006). In a study done in Lithuania, investigators

examined the impact of adequate patient teaching on quality of life. These investigators found that patients who received adequate teaching had better emotional functioning, less gastrointestinal problems, and better sexual satisfaction (Gulbiniene et al., 2004). Due to the brevity of the English-language abstract, a more detailed analysis of the results of this study was not available.

In a small study of 15 subjects, investigators found that subjects who received a standardized ostomy education guide reported fewer problems following discharge. However, no statistical analyses were reported in this study (Edlund, 1981). In one of the few randomized controlled trials of pre-operative ostomy education, Chaudhri (2005) compared intensive pre-operative, community-based stoma education with conventional post-operative stoma education after colorectal surgery. These investigators found that all outcomes (time to stoma proficiency, hospital stay, and unplanned stoma-related interventions) improved in the experimental group compared to the control group. Time to stoma care proficiency decreased by 3.5 days ($p = .005$), hospital stay decreased by 2 days ($p = .029$), and interventions per patient decreased by 0.5 ($p = .03$) (Chaudhri, 2005). Conversely, in a study of 332 patients with an ostomy, investigators found no relationship among patients' satisfaction with the information provided to them by their healthcare providers and the number and severity of ostomy complications (Lynch et al., 2008).

Two qualitative studies confirmed the positive influence of pre-operative and post-operative education on quality of life or psychosocial aspects of living with an ostomy. These investigators identified themes related to adequacy of perioperative care/education or association with WOC nurse (Beitz, 1999; Notter & Burnard, 2006). Participants commented on the importance and value of the WOC nurse involvement in their care and the lack of information provided by staff nurses (Beitz, 1999; Notter & Burnard, 2006). In a study of seven young adults with ileostomy, frustration was verbalized about the lack of education offered by nurses and the lack of written information (Sinclair, 2009).

Finally, in a systematic review of the literature, Colwell and Gray (2007) identified three studies that evaluated the influence of pre-operative education on surgical outcomes following ostomy surgery (Chaudhri, 2005; Gulbiniene et al., 2004; Haugen et al., 2006). The outcomes in two of these studies were ostomy adjustment and health-related quality of life (Gulbiniene et al., 2004; Haugen et al., 2006). The outcomes in the third study were pouching proficiency, length of post-operative hospital stay, unplanned stoma-related interventions, and satisfaction with ostomy-related services. In all of these studies, pre-operative teaching by a WOC nurse was associated with better outcomes (Colwell & Gray, 2007).

In summary, due to the design and variability in the measurable outcomes, it is difficult to compare ostomy studies. None of the identified studies described the pre-operative or post-operative education components in detail. Therefore, a definitive statement regarding the relationship between ostomy education and the development of ostomy complications is not yet possible.

ADL function and stoma care proficiency.

No literature was found that examined the influence of ADL function or stoma care proficiency on the development of ostomy complications, even though technical management of the ostomy is a dominant theme in post-operative education that should be provided to persons with a new ostomy (Fleshman, 1988). An assessment of a person's ability to learn and perform ostomy management skills should be included when providing the education to the patient. Vision, hearing, dexterity and motor skills, language, cultural and spiritual beliefs, emotional and mental status, and psychosocial status should be part of this assessment (Carmel, 2004). This investigator's clinical experience supports the importance of the ability to care for personal needs, have adequate manual dexterity, and maintain adequate hygienic practices to avoid the development of ostomy complications. For this reason, ADL function was included in this study as a variable.

Stoma site marking.

Five studies were identified that examined associations between stoma site marking and ostomy complications (Arumugam, 2003; Bass et al., 1997; Gulbiniene et al., 2004; Park et al., 1999; Pittman et al., 2008). One of the most frequently cited studies is that of Bass and colleagues at Cook County Hospital in Chicago. In their retrospective study of 593 subjects, these investigators found that subjects whose stoma site was marked pre-operatively by the enterostomal therapist had fewer complications (32.5 compared to 43.5%, $p = < .0075$) (Bass et al., 1997). In a study of 553 stomas with complications, investigators found that 74% had not been pre-operatively marked by an enterostomal nurse. Logistic regression analysis demonstrated that pre-operative marking by the enterostomal nurse decreased the incidence of stoma complications by almost half (OR= 0.567, $p = .0089$) (Park et al., 1999).

In a study comparing the effect of pre-operative teaching and stoma site marking on HRQOL in two university-based hospitals in Lithuania, the investigators found that patients who received both pre-operative teaching and stoma site marking had higher scores on several HRQOL measures than patients who did not receive pre-operative stoma site marking or the control group (Gulbiniene et al., 2004). In a study of 239 veterans with an ostomy, researchers found that veterans who had their stoma site pre-operatively marked had less difficulty adjusting to an ostomy ($p = .038$) (Pittman et al., 2008). Finally, in one prospective study of 97 patients with an ostomy, investigators found no relationship between pre-operative stoma site marking and complications (Arumugam, 2003). The value of the findings in this study are limited, though, because of the combination of emergent and elective ostomy surgeries, combination of pre-operative siting done by "ostomy" nurses and "other" nurses, and the small number of stomas not pre-operatively sited (Colwell & Gray, 2007).

In summary, additional research is urgently needed to provide adequate evidence about the influence of environmental practices that affect the development of ostomy complications. Current healthcare practice and reimbursement strategies emphasize the need for post-operative

education for the person with an ostomy, rather than intervening in the pre-operative setting. Evidence in the literature supports the opposite practice, that of pre-operative education and involvement of the WOC nurse in order to positively prevent the development of ostomy complications. Further research is urgently needed in this area to demonstrate best practices related to provision of care of the person with an ostomy that result in prevention or reduction of ostomy complications.

Clinical/Physiological Factors

A variety of clinical and physiologic risk factors for the development of ostomy complications have been identified in the literature. The literature that supports the inclusion of each of the clinical/physiologic factors in the Pittman Ostomy Complication Conceptual Model (type of effluent, stoma/abdomen characteristics, nutrition, BMI, smoking, diagnosis, ostomy type, and timing of surgery) will be addressed in the following section.

Type of effluent and Ostomy type.

The amount and consistency of effluent is usually dependent on the type of ostomy. Other factors may also affect the output, such as, oral intake, medications, infection, and degree of ambulation (Colwell, 2004). Previously in this proposal, a discussion on the types of fecal ostomies has been presented. The effluent consistency from each type of ostomy will vary. This is important because the more proximal the ostomy, the more liquid the effluent and the more caustic it is to peri-stomal skin. For example, an ileostomy effluent is more liquid, higher in digestive enzymes, more caustic to skin, and more frequent as compared to colostomy effluent. Effluent from an ascending colostomy may be very similar to that of an ileostomy. High volume, liquid effluent is a factor when considering the pouching system in order to maintain an adequate seal and prevent leakage (Colwell, 2004). Herlufsen (2006) concluded in her study of 202 Danish individuals with an ostomy, that stoma effluent coming into contact with peristomal skin was the main cause of peristoma irritant dermatitis (Herlufson et al., 2006b).

There is overwhelming evidence that having an ileostomy versus a colostomy is associated with higher rate of complications (Caricato, 2006; Coons, 2007; Cottam, 2005; Courtney, 2009; Del Pino et al., 1997; Duchesne et al., 2002; Lefort, Closset, Sperduto, Houben, 1995; Leong, Londono-Schimmer, & Phillips, 1994; Park et al., 1999; Pittman et al., 2008). An actuarial analysis of complications of 150 permanent end ileostomies found that the stomal complication rate approached 76% for patients with ulcerative colitis and 59% for those with Crohn's disease (Leong et al., 1994). One study done in Chicago found that ileostomies created emergently had more complications than other types of ostomies ($p = .02$) (Del Pino et al., 1997). Another Chicago study found that descending end colostomies had the highest early complications (60%) followed by loop ileostomies (59%). Loop ileostomies were associated with more overall complications (early and late) than end configurations (74%) (Park et al., 1999). Having an ileostomy, rather than a colostomy, was associated with higher severity of skin problems and leakage in a study of 239 veterans with an ostomy ($p = .006$) (Pittman et al., 2008).

Cottam (2007) examined 1329 stomas with early ostomy complications, and found that loop ileostomies had the most problems (38.2%, $p = < .001$) compared to end colostomies (29.7%). Another study of 434 stomas that were identified as problematic found those with a loop ileostomy had the most problems (45/140, 32%) (Cottam, 2005). In a study of 50 persons with an ostomy, 43% of those with an ileostomy had skin irritation versus 17% of those with a colostomy (Lefort et al., 1995). In another study of 132 subjects with loop ileostomies, loop colostomies, and end colostomies, fewer complications were found in those with an end colostomy ($p = .026$) (Caricato, 2006). Recently, in a comparative study of 36 subjects, 14 out of 15 subjects with a traditional loop ileostomy were identified as problematic (Courtney, 2009). Conversely, in only one study of 164 patients in New Orleans, ostomy type was not predictive of ostomy complications (Duchesne et al., 2002).

Stoma/abdominal characteristics and BMI.

Three clinical factors will be addressed in this section because they are so closely related: 1) stoma characteristics; 2) abdominal characteristics; and 3) body mass index (BMI). Stoma characteristics refer to the height of the stoma above the skin level. Abdominal characteristics refer to the presence of skin folds and creases at the stoma site. The BMI of the person with an ostomy can have an effect on both the height of the stoma and the presence of skin folds and creases. This section will discuss the findings in the literature related to these clinical factors.

A flat pouching surface is the gold standard for every stoma. Unfortunately, a flat abdominal surface is not often present. Abdominal characteristics vary from one individual to another due to skin folds, skin wrinkles, flabby skin, or an abundance of adipose tissue (Abrams, 1984). Stoma height is also an important characteristic for an ideal stoma. Flush or retracted stomas create additional challenges in maintaining an adequate seal of the ostomy appliance to the skin surface (Colwell & Fichera, 2005).

There were 11 studies identified that included abdominal contours, BMI, or stoma characteristics as a variable (Arumugam, 2003; Cottam, 2005; Cottam et al., 2007; Duchesne et al., 2002; Leenen & Kuypers, 1989; Mahjoubi et al., 2005; Park et al., 1999; Pittman et al., 2008; Ratliff & Donovan, 2001; Richbourg, Fellows, & Arroyave, 2008; Richbourg, Thorpe, & Rapp, 2007).

In a multivariate analysis of stomal complications, Duchesne, et al., found that those subjects who were obese were two and half times more likely to develop stomal complications (OR= 2.64). The most common ostomy complications found in the obese patients were skin irritation (21%), prolapse (21%), and stomal necrosis (21%). Stenosis (14%), infection (14%), and bleeding (7%) were the next most common complications in these patients (Duchesne et al., 2002). Those subjects who had a BMI of 30-40 kg/m2, >25 kg/m2, were more than three times more likely to develop peristomal hernia and early dermal irritation (OR= 3.14) in 330 colostomy patients in Iran (Mahjoubi et al., 2005).

In a study of 97 patients with an ostomy, BMI was found to be associated with retraction ($p = .003$) peristomal irritant dermatitis ($p = .036$), and leakage ($p = .04$) (Arumugam, 2003). Richbourg, Thorpe, and Rapp (2007), examined difficulties experienced by the person with an ostomy. They found that those with a higher BMI had shorter wear-time of their pouching system (3.2 days versus 5 days) (Richbourg et al., 2007). Conversely, in another study of 551 individuals with an ostomy, no significance difference was found between ostomy pouch wear time and BMI (Richbourg et al., 2008).

Stomal necrosis has been associated with obesity and is a result of the traction that is placed on the mesentery and bowel wall (Colwell & Fichera, 2005). In a review of 266 patients with 345 stomas, stomal necrosis developed in 21% of patients with a BMI of 30 to 40 as compared to those who had lower BMI ($p = < .003$) (Leenen & Kuypers, 1989). Colwell, Goldberg and Carmel (2001) in their review of the literature of ostomy complications, concluded that increased body weight contributed to stoma complications and is an area in need of further research.

Flush or retracted stomas can be caused by a variety of factors including weight gain or increased BMI. Ratliff and Donovan found that 35 (16%) of 220 ostomy patients developed peristomal complications. Of these 35 patients with complications, 24 had irritant dermatitis (69%). Of the 24 subjects with irritant dermatitis, nine had flush or retracted stomas (38%) (Ratliff & Donovan, 2001). In Cottam's study of 1,329 problematic stomas, she found that if the stoma height was less than 10mm, the probability of having a problematic stoma was at least 35% ($p = < .0001$) (Cottam et al., 2007). Cottam reported that the incidence of stomal retraction (stoma below the skin level) more than doubled between 1996 and 2004 (22 versus 51%). Anecdotal evidence suggests that retraction occurs frequently in overweight patients with larger adipose layers. A shortened and fatty mesentery make adequate mobilization of the bowel difficult, thus producing tension on the stoma (Cottam, 2005).

Three studies reported no significant relationship between BMI and ostomy complications. In a study of 239 veterans with an ostomy, BMI was not found to be significantly related to severity of skin irritation, leakage, or difficulty adjusting to an ostomy (Pittman et al., 2008). In a study of 215 patients with ostomies in Chicago, no significant correlation between BMI and early or late or total complications was found (Park et al., 1999). Finally, in a study of 1329 problematic stomas, BMI was not associated with complications (Cottam et al., 2007).

The person who is obese has a higher risk of both wound and cardiopulmonary complications and presents a major challenge for stoma creation, stoma placement, and ostomy management (Colwell & Fichera, 2005). Stoma height and abdominal contours often present a challenge in the patient with a high body mass index (BMI). A multidisciplinary approach is necessary when planning surgery and education and caring for these patients post-operatively. Further research is needed to clarify and amplify the current evidence related to BMI and ostomy complications.

Nutritional status.

According to the 2002 Nutritional Screening Initiative, 40-60% of hospitalized elders are either malnourished or at risk for malnutrition and 20-60% of home care patients are malnourished. A BMI less than 18.5, low serum albumin, and low serum cholesterol are considered to be indicators for risk of poor nutrition. Malnutrition has been found to increase post-operative morbidity, mortality, as well as duration and cost of hospital stay (Chiang, 2007). Furthermore, healing has been found to be delayed with mild degrees of malnutrition or greater than 10% body weight loss. With 20-30% weight loss, wound healing is severely delayed and new wounds may develop (Chiang, 2007). Improving nutritional intake pre-operatively improves healing in those with nutritional deficiencies (Chiang, 2007).

Nutrition and dietary considerations are major components of pre and post-operative education provided to individuals with a new ostomy (Erwin-Toth, 1992; Fleshman, 1988; Fulham, 2008; Pontieri-Lewis, 2006). Persons undergoing gastrointestinal surgery resulting in an

ostomy are at particular risk for malnutrition as a result of prolonged fasting during the immediate pre-operative and post-operative period and their underlying disease process (Fulham, 2008). In addition, the effect of intestinal resection on nutrition is dependent on the length and function of the bowel removed and the amount of functional intestine remaining. At least 100-200 cm of absorptive small bowel is needed to maintain adequate nutrition in adults. Carbohydrates, proteins, lipids and specific vitamin absorption are altered in the person with an ostomy (Bryant, Doughty, & Fitzgerald, 1992). In spite of these recommendations, there are few research studies that examined relationships between nutrition and ostomy complications.

Although no studies were found that linked nutrition with ostomies, there is evidence of the benefit of improved nutrition and dietary intake in tissue and wound healing. Three studies were found that examined the impact of nutrition and dietary intake on morbidity and mortality. In a study examining the effect of improved nutrition and dietary intake among 318 subjects recovering from hip fracture, it was found that those subjects with additional nutritional support were less likely to die in the acute ward ($p = .048$). It was also found that nutritionally supported subjects had improved mean daily energy intake ($p = < .001$) and smaller reduction in mid-arm circumference ($p = .002$) during their inpatient stay (Duncan, Beck, Hood, & Johansen, 2006).

In a prospective randomized control trial of 100 subjects admitted for gastrointestinal surgery, the investigators compared the usual post-operative diet with a post-operative diet supplemented with an oral dietary supplement. The supplemented group demonstrated significantly improved nutritional intake ($p = < .001$), lost less weight ($p = .001$), and had fewer post-operative complications ($p = .05$) (Keele, Emery, Duncan, & Silk, 1997). Dempsey, in a review of the literature, found that the evidence is overwhelmingly in favor of a strong association between poor nutritional status and poor outcome in the surgical patient. Dempsey developed a predictive model between nutrition and post-operative complications. In 161 patients undergoing major surgery, these investigators found a significant increase in actual incidence of

death (p= < .0005), complications (p= < .0005), and sepsis (p= <.005) as predicted risk (prognostic nutritional index) increased (Dempsey et al., 1988).

In summary, nutrition is one of the intrinsic factors included in the Pittman Ostomy Complications Model because it contributes to tissue tolerance and health outcomes. Nutritional status influences the structure and integrity of the supporting structures of the skin and the internal organs and is an important variable that was examined in this study.

Smoking status.

The damaging effects of smoking on wound healing, oxygen delivery, and blood flow in tissues have been well documented in the literature. Mosely demonstrated that systemic administration of nicotine impaired wound healing (p= .05*)* (Mosely, Finseth, & Goody, 1978). A study examining the effect of smoking on cutaneous blood flow in habitual smokers and nonsmokers demonstrated that smoking a single cigarette acts on the cutaneous microcirculation reducing blood flow (p= < .01). These researchers also found that recovery time was significantly different between the nonsmokers and the habitual smoker groups (p= < .01) (Monfrecola, Riccio, Sacarese, Posterarao, & Procaccini, 1998).

Smoking has been identified as a risk factor for the development of post-operative complications in many types of surgery. Although, no studies were identified that specifically examined relationships between smoking and ostomy surgery, four studies were identified that examined smoking as a variable in relation to other surgical procedures (Barrera, 2005; Castillo, 2005; Delgado-Rodriguez et al., 2003; Padubidri et al., 2001)

Barrera (2005) examined the effect of smoking on post-operative pulmonary complications in a study of 300 patients undergoing thoracotomy. These investigators found that the overall pulmonary complication rate was significantly less in nonsmokers than smokers (p= .03) and average length of hospital stay was greater for smokers compared to nonsmokers (p= <.05). Relative risk of complications after surgery for smokers (>60 pack years) was double that

of nonsmokers (OR= 2.54, *p*=.0008). The risk of pneumonia for smokers (>60 pack years) was triple (OR= 3.10, *p*= .007) that of nonsmokers (Barrera, 2005).

In a study by Castillo, participants with unilateral open tibia fractures were divided into 3 groups: 1) never smoked; 2) previous smoker; and 3) current smoker. This study demonstrated that time to fracture healing, infection, and osteomyelitis were all associated with smoking. Current and previous smokers were less likely to achieve fracture union (*p*= .001). Current smokers were twice as likely to develop an infection (OR= 2.2, *p*= .05*)* and previous smokers were almost three times as likely to develop osteomyelitis (OR= 2.8, *p*= .07*)* (Castillo, 2005).

In a prospective cohort study of general surgery 2,989 patients admitted to a tertiary-care hospital for more than one day, the investigators analyzed whether smoking was related to nosocomial infection, admission to the intensive care unit, in-hospital death, and length of stay. Smoking was found to be associated with worse health status (*p*= .001), increased post-operative admission to the intensive care unit (*p*= < .001), surgical-site infection (*p*= < .001), and in-hospital mortality (OR= 2.56) (Delgado-Rodriguez et al., 2003). Finally, in a study of postmastectomy breast reconstruction patients, complications (mastectomy flap necrosis, fat necrosis , and abdominal wall necrosis) were significantly more frequent in smokers (*p*= .002) (Padubidri et al., 2001).

In an overview of the literature, Gurkan ranked smoking as eighth most important risk factor for surgical site infection. Obesity and nutrition were ranked sixth and seventh, respectively (Gurkan, 2006). Although no studies were identified that directly examined relationships between smoking and ostomy complications, there is ample evidence in the literature that smoking is associated with surgical complications and, as a result, warrants further investigation as a potential risk factor for the development of ostomy complications.

Diagnosis (conditions associated with an ostomy).

There are several types of disorders that may require surgical creation of an intestinal ostomy for either palliation or cure. Common conditions in the adult include cancer, trauma,

inflammatory bowel disease (Crohn's disease or ulcerative colitis), and acute inflammatory processes such as diverticulitis (Bryant & Buls, 1992). The most common diagnosis that requires ostomy surgery is colorectal cancer. However, there are many other benign diagnosis associated with ostomy surgery such as inflammatory bowel disease (IBD) and diverticulitis (Krouse et al., 2007).

While comparison of studies examining ostomy complications is challenging due to the variety of study design, different populations, and inconsistent measurable variables in each study, five studies were identified that examined relationships between diagnosis and the development of ostomy complications (Cottam et al., 2007; Duchesne et al., 2002; Harris et al., 2005; Leong et al., 1994; Pittman et al., 2008).

In a review of the literature, Colwell et al. (2001) found that pre-existing poor quality of the bowel contributed to stoma complications. In all of the literature identified, inflammatory bowel disease (IBD) is consistently associated with ostomy complications. A study of 164 patients in New Orleans, found that inflammatory bowel disease predisposed to complications (Duchesne et al., 2002). This multivariate analysis of stomal complications found that the presence of inflammatory bowel disease (OR= 4.49) and ischemic colitis (OR= 5.39) were positively associated with stomal complications (Duchesne et al., 2002). An actuarial analysis of complications in 150 permanent end ileostomies found that stomal complications approached 76% for those with ulcerative colitis and 59% for those with Crohn's disease ($p = < .05$) (Leong et al., 1994).

In a study of 345 stomas that were created over an eight year period, investigators examined relationships between diagnosis and complication rates; those subjects who had a stoma created due to cancer had more stoma complications than those subjects with a stoma created due to diverticular disease ($p = .025$) (Harris et al., 2005). In a study of 239 veterans with an ostomy, a rectal cancer diagnosis was associated with more severe skin problems ($p = .002$). A diagnosis of colon cancer ($p = .005$), rectal cancer ($p = .000$), and IBD ($p = .002$) were significantly associated

with more severe leakage. These investigators also found that those veterans who had "other" diagnosis (diverticulitis, trauma, familial polyposis, inflammatory processes) rather than colon cancer, rectal cancer, or IBD reported more problems adjusting to an ostomy ($p = .016$) (Pittman et al., 2008). Finally, Cottam found among 1329 patients who had problematic stomas, 68% had IBD ($p = < .001$) and 31% had colorectal cancer ($p = .009$) (Cottam et al., 2007).

Overall, the evidence indicates that, compared to other diagnosis necessitating the creation of an ostomy, inflammatory bowel disease is most consistently associated with ostomy complications. However, variability in study quality and design, operational ostomy complication definitions, and timing of measurements limit conclusions that can be made.

Timing of surgery.

The timing of ostomy surgery, whether it is performed electively or emergently, has been associated with ostomy complications. Emergent surgeries requiring an ostomy usually preclude the pre-operative assessment to identify the best stoma site and bypass pre-operative patient ostomy education. In addition, these surgeries are often performed in critically unstable patients (Del Pino et al., 1997). Four studies were identified that examined timing of surgery and its relationship to ostomy complications (Cottam et al., 2007; Del Pino et al., 1997; Harris et al., 2005; Park et al., 1999).

In a retrospective study of surgeries performed between 1976 and 1995, investigators examined whether ostomies created emergently were at greater risk for complications. No significant difference in ostomy complication rates between emergently and electively created stomas was found (35% versus 37%, $p = 0.15$). Yet, these investigators did find that ileostomies done emergently had more complications than other types of ostomies ($p = 0.02$) (Del Pino et al., 1997). A study by Park (1999) confirmed these findings. Comparing 1,022 emergently created stomas with 594 nonemergent stomas, no significant difference in comparison rates were found (35% versus 33%) (Park et al., 1999).

Urgency of surgery was associated with higher morbidity and mortality in a study of 320 subjects with 345 stomas. Compared to elective surgeries, emergent cancer and diverticular disease surgeries had a higher mortality rate (p=.007) (Harris et al., 2005). Timing of the surgery was also found to an important factor in the study of 3970 stomas in the United Kingdom. Those patients undergoing emergent surgery were more likely to have a problematic stoma (p= 0.02) (Cottam et al, 2007).

Comorbidities.

Measuring overall medical condition or presence of pre-existing conditions in patients is essential for health care research. Summarizing comorbidity information into an index or score provides an objective means of measuring this variable. One study was identified that specifically addressed the presence of comorbidities in subjects with an ostomy. In a study of 505 subjects, 237 with an ostomy and 268 controls, high comobidity influenced quality of life and predicted low QOL scores (Jain et al., 2007).

In summary, type of effluent, stoma and abdominal characteristics/BMI, nutritional status, type of ostomy (ileostomy or colostomy), smoking status, diagnosis, timing of surgery, and presence of comorbidities are clinical factors that have been associated with surgical complications and the development of ostomy complications. Relationships between these clinical and physiological risk factors and ostomy complications are hypothesized in the Pittman Ostomy Complication Model and were explored in this study.

Mediating Factor: Stoma care Self-Efficacy

The psychosocial impact of living with an ostomy is often a significant challenge to the post-operative adjustment of having an ostomy. Psychosocial adjustment is often the key to full recovery and return to pre-surgery level of functioning (Olbrisch, 1983). Self-efficacy has also been found to play a strong role in the process of adapting to a stoma (Bekkers, 1996). Self-efficacy is a primary factor for influencing behavior (Luszczynska et al., 2005). In this section literature related to stoma self-efficacy will be explored.

Self-efficacy, can be defined broadly or more narrowly. General self-efficacy is defined as the belief in one's competence to cope with a broad range of stressful demands (Luszczynska et al., 2005). Self-efficacy may explain a wide range of coping and behaviors when studying the adjustment of patients to multiple demands of illness or disease. Self-efficacy, or the "strength of one's convictions in his/her own effectiveness", is likely to affect whether the person will even try to cope with a stressful situation (Bandura, 1977). Task-specific self-efficacy is defined as the expectation regarding one's ability to perform a specific task or behavior (Bekkers, 1995). In this study, we explored stoma care self-efficacy and its mediating effect on ostomy complications and ostomy adjustment.

Three studies were identified that examined stoma care self-efficacy (Bekkers, 1995; Simmons et al., 2007; Wu et al., 2007). In a study of 59 individuals with an ostomy, those with higher self-efficacy after surgery had fewer psychosocial problems in the following year ($p = < .001$) (Bekkers, 1996). A study of 96 patients with a new ostomy in Hong Kong found that there were positive correlations between self-efficacy and quality of life ($p = .039$ to $<.001$) (Wu et al., 2007). These investigators also reported that age was negatively correlated with overall stoma self-efficacy scores ($p = .02$) indicating that older individuals with an ostomy had lower self-efficacy. Self-efficacy scores were higher for male participants compared to females ($p = .04$) (Wu et al., 2007). In a study of 51 subjects with colostomies, self-efficacy was strongly associated with ostomy adjustment ($p = .002$). Stoma care self-efficacy accounted for 57.5% of the variance in a multiple regression analysis predicting ostomy adjustment (Simmons et al., 2007).

In summary, self-efficacy may explain a wide range of coping and behaviors that predict adjustment of ostomy patients to the demands of their disease. This review suggests a complex relationship between risk factors for the development of ostomy complications, ostomy complications, stoma care self-efficacy, and ostomy adjustment. In this study, we examined the

role of stoma care self-efficacy in the development of ostomy complications and ostomy adjustment.

Ostomy Complications

In section of the chapter, literature related to ostomy complications are presented. This section will focus on: 1) definitions/classification of ostomy complications; and 2) prevalence and incidence of ostomy complications.

Ostomy Complications: Definitions and Classification

Complications following ostomy surgeries (both stomal and peristomal) are a significant problem to many individuals. There has been some attempt at classification of complications but consistent definitions in the literature are lacking (Colwell & Beitz, 2007). Studies reporting ostomy complications are difficult to compare due to the variety of design, types and severity of outcomes, and inconsistency in defining and measuring complications (Porter, Salvati, Rubin, & Eisenstat, 1989). Three common classifications of ostomy complications are presented: 1) Early and late complications; 2) stomal and peristomal complications; and 3) physiological and psychosocial complications.

Early and late complications.

One method of classifying ostomy complications is to separate them into early, within 30 days following surgery, and late complications, greater than 30 days following surgery (Duchesne et al., 2002; Park et al., 1999). Park classified stoma complications according to time of occurrence but the investigators did not provide specific rationale for the specified time of occurrence of the complications. Similarly, Duchesne classified stoma complications as either early or late but without specific rationale or evidence to justify this classification. Both of these investigators identified skin irritation and necrosis as the most common early complications. Individually, these investigators categorized retraction, pain, and bleeding as early complications (Duchesne et al., 2002; Park et al., 1999). Clearly, some complications can occur at any time in

the post-operative period, both early and late. Both Duchesne and Park identified peristomal irritant dermatitis as a commonly occurring early and late complication.

Steel defined late complications as those that occur “after the initial rehabilitation of the patient with a stoma” (Steel & Wu, 2002). This definition is very broad and can be interpreted in a variety of ways. Inconsistent definitions and classifications make comparing studies difficult. Nevertheless, late complications often include prolapse, stomal stenosis, infection, skin irritation, necrosis, bleeding, herniation, obstruction, stricture (Duchesne et al., 2002; Park et al., 1999; Steel & Wu, 2002). Prolapse and herniation usually occur with increased body mass index (Cingi, 2006; Duchesne et al., 2002). The individual with IBD or chronic intestinal conditions may experience weight gain over time following surgical treatment. Herniation also can occur due to the necessary surgical construction of the stoma and creation of a defect in the abdominal wall (Steel & Wu, 2002). A defect in the fascial layer is created by the surgeon in order to accommodate the portion of the intestine to form the stoma and over time, this defect enlarges (Hampton, 1992). Stomal stenosis, stricture, and obstruction can be the consequence of scar maturation and fascial contraction over time. Stomal stenosis can also be caused by disease, trauma resulting from improperly fitting appliance, hyperplasia, or chronic irritant dermatitis of the peri-stomal skin (Hampton, 1992). See Chapter One for definitions of these terms.

Some complications can occur at any time, early or late. For example, both Duchesne and Park identified peristomal irritant dermatitis as a commonly occurring early and late complication (Duchesne et al., 2002; Park et al., 1999). Fecal effluent contact with peristomal skin, over time, often initiates this process and may be due to poor ostomy management technique, change in the effluent consistency, weight gain or loss, mechanical irritation (appliance), and infection (fungal or bacterial) (Hampton, 1992; Herlufson et al., 2006b). Leakage may also occur at any time, early or late, and often leads to peristomal irritant dermatitis. Leakage may be due to poor ostomy management technique, effluent consistency, appliance nonadherence, and dietary intake changes that increase flatus or change the consistency of the effluent (Duchesne et al., 2002; Herlufson et

al., 2006b). Research demonstrates that the elderly and those without adequate pre-operative ostomy management education are at an increased risk for late complications (Steel & Wu, 2002).

Stomal/peristomal complications.

Ostomy complications have also been categorized into stomal and peristomal complications (Colwell & Beitz, 2007). In a survey of 686 Wound, Ostomy, and Continence (WOC) nurse clinicians, experts were asked to validate the classification scheme of stomal and peristomal complication definitions. This classification scheme demonstrated a content validity of .91. In this study, *stomal* complications were defined as parastomal hernia, stoma prolapse, stomal necrosis, mucocutaneous separation, stomal retraction, stomal stenosis, stoma fistula, and stoma trauma. *Peristomal* complications were defined as peristomal varices, peristomal candidiasis, peristomal folliculitis, mucosal transplantation, pseudo verrucuous lesions, peristomal pyoderma gangrenosum, peristomal suture granulomas, peristomal irritant contact dermatitis, peristomal allergic contact dermatitis, and peristomal trauma. Respondents commented that there were some stomal and peristomal complications that were not included on the list (Colwell & Beitz, 2007).

Physiological and psychosocial ostomy complications.

Ostomy complications can be classified as physiological and psychosocial. Physiologic ostomy complications involve changes of the stoma and peri-stoma skin (Cottam et al., 2007). Psychosocial ostomy complications involve the challenges individuals face living with and adjusting to the ostomy (Carlsson et al., 2001; Cottam et al., 2007). Physiological ostomy complications include peristomal irritant dermatitis, leakage, pain, bleeding, stomal necrosis, stomal stenosis, retraction, mucocutaneous separation, hyperplasia, prolapse, herniation. These complications have been discussed previously in this proposal.

Ostomy adjustment has been defined as “the overall impact of the stoma on psychological, social, and sexual functioning as perceived by patients” (Simmons et al., 2007). Psychosocial ostomy complications include emotional, social, marital/family, and sexual

adjustment difficulties (Follick, 1984). A study comparing psychosocial functioning found that depression, loneliness, low self-esteem, suicidal thoughts, feelings of stigma, and sexual impairment were more common in persons with an ostomy than in those without an ostomy (Simmons et al., 2007). These difficulties can result in profound alterations in the person's functioning and well-being (Mohler et al., 2008).

In this study, the dependent variables examined were nine physiological ostomy complications that commonly occur in the first thirty days following surgery: leakage, peristomal irritant dermatitis, pain, bleeding, stomal necrosis, stomal stenosis, retraction, mucocutaneous separation, and hyperplasia. Definitions for each of these ostomy complications are presented in Chapter One. In addition, the psychosocial outcome of ostomy adjustment of the individual with an ostomy were examined.

Prevalence and Incidence of Ostomy Complications

Literature shows a broad range in the estimates of prevalence and incidence of ostomy complications following ostomy surgery. Much of the literature reports ostomy complications in the aggregate. For example, studies show that up to 71% of patients with an ileostomy experience complications and 43% of patients with a colostomy experience complications (Persson et al., 2005). Systematic reviews of the literature have found that between 18-55% of patients with an ostomy experienced peristomal skin irritation, 1-37% experienced parastomal herniation, 2-25% experienced stomal prolapse, 2-10% experienced stenosis, and 1-11% experienced retraction of the stoma (Colwell et al., 2001; Ratliff & Donovan, 2001; Ratliff et al., 2005).

In the landmark retrospective study conducted by Bass at Cook County Hospital in Chicago, complication rates were compared between patients who received pre-operative education and stoma site marking by an enterostomal therapist and those who did not (Bass et al., 1997). They found that, among those who received pre-operative education and stoma site marking by an enterostomal therapist, 32.5% developed complications compared to 43.5% of those who did not receive these clinical interventions (p= 0.05). In a prospective audit of nine

stoma care services, Cottom audited 3,970 stomas and reported that 34% were reported as problematic (needing one or more accessories to keep the patient clean and dry). The most common complications in this study were retraction (40.1%) and mucocutaneous separation (24%) (Cottam et al, 2007).

Thirteen studies were identified that report the incidence of specific complications. In a study of 599 cancer and non-cancer patients with colostomies, it was found that 21% of the cancer patients had leakage and 20% had skin problems around the colostomy. The investigators also found that, among the non-cancer patients with a colostomy, 30% had leakage problems and 35% had skin problems around the colostomy (Krouse et al., 2007). In a study of 332 colorectal cancer patients at five months following surgery, 40% had skin difficulties and 30% had leakage (Lynch et al., 2008). These findings were confirmed in a study of the difficulties experienced by individuals with an ostomy after hospital discharge. Two of the top difficulties reported were skin irritation (76%) and leakage (62%) (Richbourg et al., 2007).

In a retrospective study of 150 permanent end ileostomies created over a 10 year period, an actuarial analysis reported that by 20 years the incidence of stomal complications approached 76% in patients with ulcerative colitis and 59% in those with Crohn's disease (Leong et al., 1994). The four most common complications were skin problems (34%), intestinal obstruction (23%), retraction (17%), and herniation (16%) (Leong et al., 1994). Cheung reported an overall complication rate of 66.8% in 316 patients with 322 stomas; 156 were end-sigmoid colostomies. Specifically, 31.1% had parastomal herniation, 10.2% had stenosis, and 6.8% developed prolapse (Cheung, 1995). Porter reported a complication rate of 44% in 130 end colostomies over a six year period. In this population, 17% experienced skin excoriation, 14% developed a hernia, 11% developed a stricture (stenosis), 9% experienced an obstruction, 11% developed an infection, 4% developed prolapsed stoma, and 1% developed a peristomal fistula (Porter et al., 1989).

In a study of 202 persons with an ostomy, 45% had a peristomal irritant dermatitis that was diagnosed by a dermatologist while only 38% of the participants reported that they had a skin

disorder (Herlufson et al., 2006a). This demonstrates that complications may be under-reported by persons with an ostomy. This study also found that 56% of those diagnosed with peristomal irritant dermatitis reported leakage within the 14 days prior to the skin examination. Peristomal skin problems were significantly related to leakage ($p = 0.01$) in this study (Herlufson et al., 2006a, 2006b). Ratliff examined 220 new ostomy patients and found a 16% incidence rate for peristomal complications. Of these 35 complications, 69% were irritant dermatitis, 25% had retraction, and 14% had a peristomal hernia (Ratliff et al., 2005).

In a study of 330 patients with an end colostomy, 69.4% had at least one early or late complication. These investigators reported that 56.4% experienced psychosocial complications, 34.5% had mucosal bleeding, 23.5% had peristoma irritant dermatitis, and 11.2% developed a hernia (Mahjoubi et al., 2005). Follick (1984) examined 131 ostomy patients who reported a significant number of technical (84%), emotional (50%), social (30%), marital/family (24%), and sexual (41%) difficulties post-surgically.

In a three year retrospective study of 164 patients that had surgery resulting in an ostomy, the overall complication rate was 25%. Thirty-nine percent of these were early complications, including prolapse (22%), necrosis (22%), stenosis (17%), peristomal irritant dermatitis (17%), infection (15%), bleeding (5%), and retraction (5%) (Duchesne et al., 2002). In a retrospective study of 1,616 medical records from 1976-1995 of patients that had received ostomy surgery, Park reported that 34% developed ostomy complications with 28% occurring early (within 1 month post-operatively). Of the most common early complications, 12% developed peristomal irritant dermatitis, 7% had pain, and 3% had necrosis. The most common late complications were peristomal irritant dermatitis (6%), prolapse (2%), and stenosis (2%) (Park et al., 1999).

Finally, in a study of 1,758 stomas constructed over a 19 year period at Cook County Hospital in Chicago, 59% were created for emergent situations. Thirty-five per cent of these patients developed complications, including peristomal irritant dermatitis (55%), parastomal

problems (12%), retractions (11%), stenosis (4%), necrosis (12%), prolapses (3%), and herniation (3%) (Del Pino et al., 1997).

In summary, whether complications following ostomy surgeries are classified as stomal or peristomal, early or late, physiological or psychosocial, they are a significant problem for many individuals. Yet the literature does not adequately describe the variability in the severity of these complications. One of the purposes of this study was to measure the incidence and severity of nine common early ostomy complications. But in addition, we also examined the relationship among complications and the psychosocial ostomy aspect of ostomy adjustment.

Ostomy Adjustment

The psychosocial effect of living with an ostomy is often a significant challenge to the post-operative adjustment of having an ostomy. Often, successful psychosocial adjustment is the key to full recovery and return to pre-surgery level of functioning (Olbrisch, 1983). Ostomy adjustment has been described as the overall impact of the stoma on psychological, social and sexual functioning, as perceived by the patient (Simmons et al., 2007). Follick, Smith, and Turk (1984) report that ostomy patients are a population with a chronic illness that frequently experiences adjustment difficulty. This population is at risk for significant psychological and social difficulties that often affects long-term adjustment. The biopsychosocial model of adjustment is prominent in Follick's work and states that the biological, psychological, and social difficulties encountered by the patient are closely interrelated and affect ostomy adjustment (Follick et al., 1984).

The Pittman Ostomy Complication Model hypothesizes that ostomy adjustment is influenced by demographic, environmental, and clinical/physiological factors. The model also postulates that there is a bi-directional relationship between ostomy adjustment and ostomy complications. In this section, literature that examines ostomy adjustment are presented. Four studies were identified that examined the concept of ostomy adjustment (Follick, 1984; Pittman et al., 2008; Piwonka & Merino, 1999; Simmons et al., 2007).

A study of 60 patients who had ostomy surgery in Chile, found that successful adjustment to a colostomy was associated with increased age (p= .03), higher education (p= .00), occupational level (p= .00), more social support from friends (p= .00), time since surgery (p= .00), higher level of ostomy self-care (p= .00), body image (p= .01), and social support (p= .00) (Piwonka & Merino, 1999). These investigators concluded that successful adjustment to a colostomy was most likely to occur if instruction in self care and appropriate psychological support was given (Piwonka & Merino, 1999).

Follick et al. (1984) confirmed these findings and in addition found that ostomy patients experienced difficulty adjusting to an ostomy in several domains: technical management of the ostomy (84%); emotional adjustment (50%); social adjustment (44%); family/marital adjustment (24%); and sexual adjustment (41%). Technical difficulties of managing the ostomy were the most frequently encountered problem area (84%) and negatively correlated with psychosocial adjustment. The greater the frequency of technical difficulties (higher scores) in managing their ostomy, the worse was the emotional (p= < .02), social (p= < .02), and marital difficulties (p= < .001). These investigators found that adequate preparation was associated with fewer technical problems and better patient adjustment (p= < .001). Adequate preparation was also associated with better emotional adjustment (p=< .001) and social adjustment (p= < .02). The researchers in this study concluded that information provided pre-operatively may be an important component in intervention development for ostomy patients (Follick et al., 1984).

A study of 239 veterans examined the relationship between ostomy adjustment, demographic, and clinical factors, and HRQOL (Pittman et al., 2008). These researchers found that greater difficulty adjusting to an ostomy was associated with younger age (p= < .001), not having a partner (p= < .001), and being employed (p= .018). Increased ostomy adjustment difficulty was also associated with less time (<5 years) since surgery (p= .016) and having had the stoma site marked pre-operatively (p=.038). An important finding in this study was that

severe difficulty adjusting to an ostomy was predictive of HRQOL (p= < .001) (Pittman et al., 2008).

Finally, in a study examining ostomy adjustment and its relationship with stoma acceptance and social interaction, the investigators found that ostomy adjustment was associated with stoma care self-efficacy (p= .0001), stoma acceptance (p= .0001), interpersonal problems (p= .008), and type of stoma (p= .001). Stoma care self-efficacy accounted for 57.5% of the variance in adjustment (Simmons et al., 2007).

In summary, the literature offers some limited evidence of the relationship between ostomy adjustment and various demographic factors, psychosocial factors, clinical factors and HRQOL. Therefore, the concept of ostomy adjustment is an important variable for inclusion in this dissertation study.

Summary

The literature demonstrates that ostomy complications occur frequently and that adjustment can be difficult for individuals living with an ostomy. Not only does the individual have to cope with a serious and often life-threatening diagnosis but the placement of an ostomy requires significant changes to one's lifestyle. People with ostomies face difficulties adjusting to and coping with their ostomy, social isolation, occupational changes and challenges in daily living. Complications can make adjustment even more difficult, necessitate complex ostomy management techniques, require additional use of costly ostomy equipment and supplies, and cause interruption of daily, occupational, social, and physical activities. Despite the many improvements that have occurred in the management of an ostomy, including advanced surgical techniques/procedures and innovative new ostomy equipment, ostomy complications continue to commonly occur. In addition, prevention of these complications remains a challenge to the patient, the surgeon, the Wound, Ostomy, and Continence (WOC) nurse, and others caring for the patient.

The literature clearly demonstrates inconsistencies in our knowledge of ostomy complications and associated risk factors. From standard definitions of ostomy complications to identifying specific risk factors for the development of the complications, there are gaps in the current state of the science. In addition, research examining the severity of ostomy complications is lacking. Further research is needed to fill this void and generate new knowledge so that nursing interventions can be developed to decrease the development of ostomy complications and to improve adjustment for those individuals with an ostomy.

CHAPTER THREE

METHODOLOGY

In this chapter, the methodology used in this study to examine risk factors for the development of ostomy complications, the incidence and severity of early ostomy complications, and the evidence of reliability and validity of two newly developed instruments is presented. This chapter consists of five sections: 1) design; 2) sample and setting; 3) study procedures; 4) measures; and 5) data analysis.

Design

A prospective longitudinal study design was used to examine the incidence and severity of early ostomy complications that occurred within the first 30 to 60 days after surgery. Risk factors for the development of early ostomy complications were identified and relationships among variables depicted in the Pittman Conceptual framework were examined.

Sample and Setting

A convenience sample of 71 adult patients who had undergone surgery to create a new fecal ostomy, either colostomy or ileostomy, was recruited from a large health care system in the Midwest United States. To be eligible for this study, patients had to: 1) be 18 years of age or older; 2) be undergoing surgery involving the creation of a fecal ostomy during their hospital stay; 3) be willing and able to return for follow-up visit 30 to 60 days post-operatively; and 4) be able to speak and read English. Patients were excluded from participation if they had any diagnosis indicating cognitive impairment or if they were unable to participate in the consent process. No participants were excluded based on ethnicity, race, or socioeconomic status.

A sample of 66 participants was the goal for enrollment. Anticipated enrollment was estimated to be 95% of those subjects determined to be eligible; accounting for a refusal rate of 5%. A low refusal rate was anticipated due to the complexity of ostomy management and patient desire for post-operative ostomy management assistance. Average number of ostomy surgeries performed at the primary study location site was estimated to be 10-15 per month. Recruiting a

sample consisting of 66 subjects was considered feasible given the number of ostomy surgeries performed each month at the primary study site. It was anticipated that the sample of 66 patients would be enrolled in approximately 5-7 months with completion of the follow-up assessments requiring one additional month. If recruitment was slower than anticipated, the study sites would be expanded to include two additional acute care settings within the healthcare system. Each of these additional acute care settings performed three to five ostomy surgeries per month.

An important component of any study design is whether the study will have adequate power (Tabachnick & Fidell., 2001). There are four factors that are involved in determining statistical power: the statistical test being used, the alpha level, the sample size, and the effect size (Lipsey, 1990). In this study, there may have potentially been a limited number of subjects; therefore, power was an important concept to consider.

Considering the most stringent statistical test used in this study, testing for multiple regression (research aim 4), a common rule to follow is $N \geq 50 + 8m$ (where m is the number of independent variables) (Tabachnick & Fidell., 2001). In this study, two independent variables (risk factors and stoma care self efficacy) were examined. Using the above rule, $N \geq 50 + 8(2) = 66$, a minimum sample size of 66 was deemed adequate to observe a moderate effect size, power of .80, and alpha of .05. A sample size of 66 would meet the guidelines for any of the other statistical tests conducted in this study.

Study Procedures

In this section, study procedures regarding human subjects protection, recruitment, data collection, measures, and limitations are presented.

Protection of Human Subjects

Indiana University and Purdue University/Indiana University Health Institutional Review Board (IUPUI/ IUHealth IRB) approval was obtained prior to the onset of data collection.

Recruitment was conducted in a private setting. Eligible patients were enrolled in the study only after they were fully informed and signed the written informed consent form and

authorization. Subjects were informed that they could refuse to answer any of the questions and could stop at any time without negative consequences. Subjects were informed that they could rest during data collection if so desired.

Data collection occurred in a private setting during the subjects' hospital stay and during the follow-up clinic visit. All paper documents were secured in a locked location and will be shredded after the study is completed. All electronic data were secured with a confidential password. All confidential information was managed by the investigators and kept in a secured location with access only by the investigators. Data were de-identified upon entry into the data base and reported as group data with no individual identifying information.

Recruitment

Subjects were recruited from a large health care system in the Midwestern United States. Recruitment began at two acute care sites that had the largest volume of ostomy surgeries. Because recruitment was slower than expected, recruitment was expanded to one additional acute care site within this healthcare system.

Each of three acute care settings within this large healthcare system has a Wound/Ostomy Team. Each team consists of one or more certified wound, ostomy, continence (WOC) nurses. All patients who undergo ostomy surgery are seen and managed by the WOC Team. Eligible patients who were undergoing ostomy surgery were identified by the Wound/Ostomy Team and/or physician. Potential subjects were informed of the opportunity to participate in the study while receiving standard inpatient care from the Wound/Ostomy Team. The patient was asked if they would be interested in hearing more about the study and, if so, for permission to give their name to the Principal Investigator (PI). If the patient agreed, the Principal Investigator met with the patient to provide written and verbal information about the study and answer questions. A pamphlet briefly describing the study was given to all potential subjects (Appendix H). Written

consent was obtained by the PI after an in-depth discussion of all aspects of the study and all questions were answered.

Data Collection

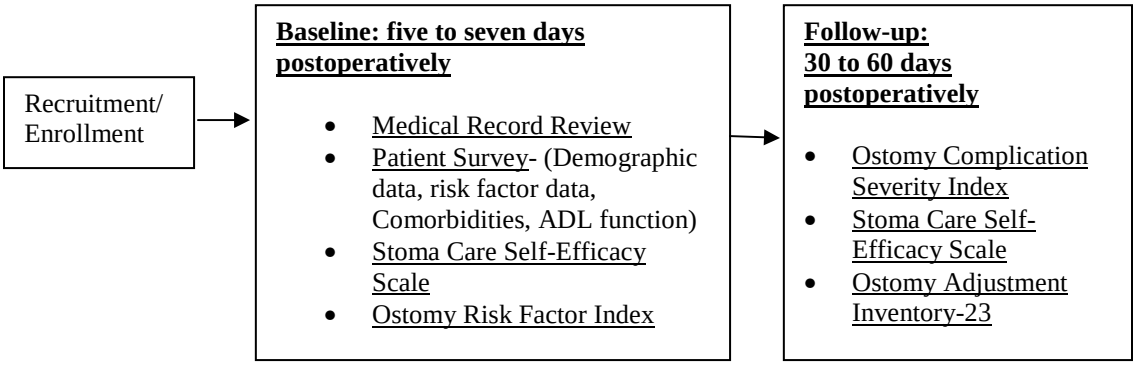
There were two data collection points; baseline data were collected at five to seven days post-operatively or prior to discharge and follow-up data were collected at 30 to 60 days post-operatively. The typical length of stay following ostomy surgery without complication is approximately five to seven days. Therefore, the goal for completion of the baseline data was within that timeframe or prior to discharge. The data was collected through self-administered surveys, medical review, and direct observation. Baseline data included demographic data, risk factor data, and stoma-care self-efficacy. Demographic and risk factor data were collected using the Ostomy Risk Factor Index (ORFI) (Appendix A), medical record review (Appendix B), and the Patient Survey (Appendix C). Stoma care self-efficacy was measured at both time points, baseline and at follow-up using the Stoma Care Self-Efficacy Scale (Appendix D). At follow-up, data regarding ostomy complications and ostomy adjustment was collected in addition to stoma care self efficacy. Ostomy complication data were collected using the Ostomy Complication Severity Index (OCSI) (Appendix F) and ostomy adjustment was collected using the Ostomy Adjustment Inventory (OAI-23) (Appendix E).

The PI collected all data at site 1 and 2 and the majority of data at site 3. To ensure subjects were not missed and all data were collected when recruitment expanded to site 3, an expert, certified, WOC nurse was trained to assist with data collection. Training included information regarding human subjects protection, study procedures forms, instruments, and data collection. The PI made frequent visits to site 3 for contact with the WOC nurse, ongoing training, and data collection. In order to examine inter-rater reliability of each instrument, an expert WOC nurse completed the ORFI at baseline and the OCSI at follow-up on a random sampling of participants.

To summarize, baseline data collection included: 1) Medical record review form; 2) Patient Survey; 3) Stoma Care Self-Efficacy Scale (SCSES); and 4) the Ostomy Risk Factor Index (ORFI).

Follow-up data collection included: 1) Ostomy Adjustment Inventory-23 (OAI-23); and 2) the Ostomy Complication Severity Index (OCSI).

Figure 2: Data Collection Timeline:



Measures

This section, using the framework of the Ostomy Complications Conceptual Model, describes the measurement of the antecedents or independent variables (demographic, environmental, and clinical risk factors), the mediating variable (stoma care self-efficacy), and the outcomes or dependent variables (ostomy complications and ostomy adjustment).

Antecedents/Independent Variables- Demographic, Environmental, and Clinical/Physiologic Risk Factors.

Antecedents/independent variables in this study included demographic variables (age, gender, income, education, employment, partner status), environmental variables (pre-operative education, post-operative education, stoma care proficiency, stoma site marking by WOC nurse, and ADL functioning), and clinical/physiological variables (type of effluent, stoma/abdomen characteristics, nutrition, BMI, smoking status, diagnosis, ostomy type, timing of surgery, and comorbidities). Data related to risk factors (demographic, environmental, and clinical/physiological) were collected at baseline using the Ostomy Risk Factor Index (ORFI) (Appendix A), medical record review form (Appendix B), and Patient Survey (Appendix C).

Demographic Data.

Demographic data regarding patient characteristics including age, gender, marital status, ethnicity, education, income, employment were collected primarily using Patient Survey (Appendix C). This self-administered patient survey was developed by the investigator and was used to facilitate the collection of demographic information. The Patient Survey was intended to be self-administered by the subject, however, the investigator was available to assist in reading questions when needed. In addition to demographic questions, patients were asked to identify who would be primarily responsible for caring for the ostomy (1= self, 2= spouse/partner, or 3= other), comorbities, ADL function, and smoking status. See specific items and complete Survey in Appendix C.

Environmental and Clinical/Physiologic Risk Factors.

Environmental and clinical/physiologic factors for development of ostomy complications included in this study were measured using the Ostomy Risk Factor Index (Appendix A), medical record review form (Appendix B), or the Patient Survey (Appendix C). Environmental risk factors included pre-operative education, post-operative education, stomal care proficiency, stoma site marking, and ADL function. Clinical/physiological risk factors included type of effluent, stoma/abdomen characteristics, nutritional status (albumin and NPO status), BMI, smoking status, diagnosis, ostomy type, timing of surgery, and comorbidities.

After a thorough search of the literature, no instruments were found to measure risk factors for the development of ostomy complications. Therefore an instrument was developed by this investigator for use in this study, specifically, the Ostomy Risk Factor Index (ORFI). Guidelines for developing instruments, established by DeVellis (2003), were followed for the development of the ORFI. These guidelines recommend a step-wise approach that begins with: 1) clearly identifying the construct to be measured; 2) choosing items that reflect the instrument's purpose; 3) determining the format for measurement; and 4) including expert review of the items (DeVellis, 2003).

The concept to be measured was clearly identified; risk factors for the development of ostomy complications. Fifteen items for the Ostomy Risk Factor Index (ORFI) were generated from an extensive review of the research and clinical literature related to risk factors and ostomy complications. Several items from the Stoma Management Ease Classification (SMEC) tool were modified and incorporated into the new instrument. The SMEC is an unpublished tool that was originally developed to aid the Wound, Ostomy, Continence (WOC) nurse in identifying the patient with an ostomy for additional discharge needs (McCubbin, 2007). In addition, results from previous studies conducted by the investigator were used to inform generation of ORFI items.

The format for the ORFI instrument contains a likert-like rating providing an individual item score and a total score (Appendix A). The ORFI consists of 15 items: age, diagnosis, timing of surgery, ostomy type, type of effluent, stoma/abdomen characteristics, stoma care proficiency, ADL function, preoperative education, stoma site marking, NPO status, serum albumin, BMI, smoking status, and postoperative education. Each item rating ranges from 1-4 with 1 being the least risk and 4 being the greatest risk. Maximum total score possible is 60 and the minimum total score possible is 15. Potentially, the higher the score the more at risk the patient is for the development of ostomy complications.

Finally, an expert review was conducted of each instrument as described by Pittman and Bakas (2010). A panel of 10 Wound, Ostomy, Continence (WOC) nurse experts participated in a survey to establish the content validity of the instrument. Three of these experts were doctorally-prepared, six were master's-prepared advanced practice nurses, and all were nationally recognized experts in the WOC field. Each reviewer was given a packet of information that included: purpose of the study, hypotheses of the study, conceptual definitions, operational definitions, survey instructions, content validity survey for the ORFI. Each reviewer completed the survey and returned them to the PI electronically, by facsimile, or by mail. Details of the evidence of content validity are presented in Chapter Four: Results section.

In addition to the variables measured using the ORFI, self-reported comorbidities were assessed using the Patient Survey. A modified version of the Self-Administered Comorbidity Questionnaire (SCQ) was incorporated into the Patient Survey. The original SCQ asks about the presence of the health problem, if treatment is being received, and if the health problem limits activities. Test-retest of the SCQ was 0.94 and overall agreement between Charlson Index and SCQ was greater than 78% (Sangha et al., 2003). In this study, only the presence of the health problem was measured. Specifically, patients were asked, "Has your doctor ever told you that you have: heart problems, high blood pressure, diabetes or high sugar, cancer (leukemia, skin, breast, lung, prostate, colon, rectal), rheumatoid arthritis, osteoarthritis or degenerative arthritis, breathing problems, kidney disease, ulcer or stomach problems, liver problems, anemia or blood disease, back pain or back problems, depression, or other." The patient checked the appropriate conditions. The investigator tallied the number of conditions present for a total comorbidity score. A range of 0 to 14 was possible.

Age.

Age was collected as a continuous variable using the Patient Survey. The investigator used the participant's response of number of years and marked the appropriate category on the ORFI: 1= 18-49 years; 2= 50-59 years; 3= 60-69 years; 4= 70 years or greater.

Pre-operative education.

Specifically, patients were asked the following three questions: “Did the ostomy nurse explain: 1) how your intestines or bowels work?; 2) what kind of surgery, or operation, you will have?; and 3) what you can expect after your surgery?” For each item, patient responses were “Yes” or “No”. The investigator tallied each “yes” response and marked the appropriate category on the ORFI where: 1= all items explained; 2= 2 items explained; 3= 1 item explained; 4= no items explained.

Post-operative education.

Specifically, the patient was asked to answer the following questions, “Did the ostomy nurse explain: 1) the ostomy surgical procedure (yes/no); 2) how to obtain your ostomy supplies (yes/no); 3) how to empty the pouch (yes/no); 4) how to change the pouch (yes/no); and 5) your diet with an ostomy (yes/no)?”. The number of topics the patient responded “yes” was tallied by the investigator and a categorical response on the ORFI was identified where: 1= all items; 2= 3-4 items; 3= 1-2 items; or 4= no items.

Stomal care proficiency.

Stoma care proficiency was measured based on direct observation by the investigator/WOC nurse of the patient or caregiver’s ability in changing the ostomy pouching system. The patient or caregiver (if the caregiver was responsible for the care of the ostomy) demonstrated the pouching system change procedure. The investigator/WOC nurse tallied the number of verbal cues from the WOC nurse needed for the patient or caregiver to complete the task. The appropriate categorical response was indicated on the ORFI where: 1= independent/competent and needs 0 verbal cues; 2= requires 1-2 verbal cues to complete the task; 3= requires 3 or more verbal cues to complete the task; or 4= unable to complete the task without hands-on assistance by the WOC nurse.

Stoma site marking.

Stoma site marking was measured by medical record review and patient interview using the ORFI. Specifically, the patient was asked, “Did you have the stoma site marked before surgery by the WOC nurse?” A dichotomous response was elicited where: 1= Yes; 2= No. If the patient could not remember, this information was collected by reviewing the documentation in the medical record. The appropriate categorical response was indicated on the ORFI where: 1= no and 4= yes.

ADL Function.

ADL function was assessed using the Patient Survey. These activities of daily living are the functions that are normally done in daily living including functions performed for self-care such as bathing, dressing, toileting, transferring, continence (bladder), and feeding (Katz et al., 1963). Specifically, patients identified whether they needed assistance in: bathing (1= Yes, 2= No); dressing (1= Yes, 2= No); toileting (1= Yes, 2= No); transferring (1= Yes, 2= No); continence (controlling their bladder) (1= Yes, 2= No); and feeding (1= Yes, 2= No). The number of ADL functions was tallied by the investigator and a categorical response was then identified on the ORFI where: 1= independent in all 6 ADL functions; 2= dependent in 1-2 ADL functions; 3= dependent in 3-4 ADL functions; or 4= dependent in 5-6 ADL functions.

Type of effluent.

Type of effluent was measured by investigator/WOC observation of the patient's pouch contents. A categorical response was indicated on the ORFI where: 1= solid stool in pouch; 2= formed but soft stool in pouch; 3= thick liquid stool in pouch; or 4= liquid stool in pouch.

Stoma/abdomen characteristics.

Stoma/abdominal characteristics was measured by investigator/WOC nurse direct observation of the patient's stoma and abdomen. A categorical response was indicated on the ORFI where: 1= stoma that is above skin level, stoma is round, and surrounded by flat abdominal pouching surface; 2= stoma that is above skin level, is oval, and surrounded by minor alterations in abdominal pouching surface; 3= stoma that is skin level, is round or oval, and surrounded by abdomen that has skin folds/creases that are problematic; or 4= stoma that is below skin level, oval, and surrounded by deep abdominal skin folds/creases that are problematic.

Nutritional status- Albumin.

The nutritional status of the participant was measured by investigator/WOC nurse review of the medical record using the ORFI. The most recently available albumin level was extracted

from the medical record and indicated on the ORFI where: 1= 3.0 g/dl or greater; 2= 2-2.9 g/dl; 3= 1.0-1.9g/dl; or 4= 1.0 g/dl or less.

Nutritional status- NPO Status.

Physicians' dietary orders for the patient was extracted from the medical record with the specific number of days the patient was restricted from eating (NPO). The number of days that the patient was restricted from eating was indicated on the ORFI where: 1= NPO less than 24 hours; 2= NPO 1-2 days; 3= NPO 3-4 days; or 4= NPO greater than or equal to 5 days.

Body mass index (BMI).

BMI = body weight in kilograms/height in meters squared. Height and weight was obtained from the medical record. The investigator/WOC nurse divided weight in kilograms by height in meters squared to calculate BMI. A categorical response was selected on the ORFI where: 1= BMI 18.5-24.9; 2= BMI 24.9- 29.9; 3= BMI 30-35; or 4= BMI less than 18.5 or greater than 35.

Smoking status.

Smoking status data was collected using the Patient Survey. Specifically, the patient was asked the following question with the answer choices, “Are you currently a smoker?” A categorical response was selected on the ORFI where: 1= nonsmoker and has never smoked; 2= quit smoking greater than 2 months ago; 3= quit smoking less than 2 months ago; or 4= current smoker.

Diagnosis.

Diagnosis was measured by a review of the medical record. A categorical response was identified on the ORFI where: 1= colon cancer; 2= rectal cancer; 3= IBD (Crohn’s or Ulcerative Colitis); or 4= other diagnosis (diverticulitis, trauma, or other).

Ostomy type.

The type of ostomy was identified from the medical record. The categorical response was selected on the ORFI where: 1= sigmoid colostomy; 2= transverse colostomy; 3= ascending colostomy; or 4= ileostomy.

Timing of surgery.

Timing of surgery was identified through a review of the medical record. A dichotomous response was identified on the ORFI where: 1= planned or scheduled surgery; or 4= emergent surgery.

Mediator: Stoma Care Self-Efficacy.

Stoma care self-efficacy was measured using the Stoma Care Self-Efficacy Scale (SCSES). The Stoma Self-Efficacy Scale was developed by Bekkers and colleagues (1996) and tested in a sample of 59 patients in the Netherlands. In the development of the scale, two factors emerged that explained 61% of the variance of the psychosocial adaptation to having a stoma. Two sub-scales were constructed; Stoma Care Self-Efficacy (13 items, Cronbach's alpha= 0.94) and Social Self-Efficacy (9 items, Cronbach's alpha= 0.95) (Bekkers et al., 1996).

Wu and colleagues used the Stoma Self-Efficacy Scale in their study of 96 patients in Hong Kong. Cronbach's alpha for the Chinese Stoma Care Self-Efficacy subscale was 0.97 and 0.89 for the Social Self-Efficacy subscale. These investigators found a strong correlation between stoma care self-efficacy and the SF-36 (Wu et al., 2007). In this study we used the stoma care subscale of the Stoma Self-Efficacy Scale.

In our study, stoma care self-efficacy was measured at two points in time; baseline and follow-up. The patient or the caregiver, depending who performed stoma care, completed the instrument. The Stoma Care Self-Efficacy Scale Cronbach's alpha at baseline was .96 and at follow-up was .95.

Outcomes/Dependent Variables- Ostomy Complications and Ostomy Adjustment.

Ostomy Complications.

The dependent variables examined in this study were early ostomy complications and ostomy adjustment. Ostomy complications included leakage, peristomal irritant dermatitis, stoma pain, stoma bleeding, stomal necrosis, stomal stenosis, retraction, mucocutaneous separation, and hyperplasia. Because there were no instruments found that adequately measured incidence and severity of ostomy complications, the investigator developed the Pittman Ostomy Complication Severity Index (OCSI, Appendix F). The OCSI development was similar to that of the ORFI; specifically, a specific concept was identified, items that reflected the scale's purposes were chosen, a format for measurement was determined, and expert review of the items was accomplished and the OCSI was developed to measure the incidence and severity of ostomy complications.

OCSI items were generated from an extensive review of the research and clinical literature related to ostomy complications. The OCSI format uses a likert-like scale with individual item score and a total score. The OCSI consists of nine items, ranging 0-3, with 0 being not severe and 3 being the most severe. The maximum total score possible is 27 and the minimum possible score is 0. The higher the score the more severe the ostomy complications.

The panel of 10 Wound, Ostomy, Continence (WOC) nurse experts participated in a survey to establish the content validity of the instrument. Each reviewer was given a packet of information that included: purpose of the study, hypotheses of the study, conceptual definitions, operational definitions, survey instructions, content validity survey for the OCSI and the OCSI instrument. Each reviewer completed the survey and returned it to the PI electronically, by facsimile, or by mail. The CVI for the OCSI was 0.91. The details of the evidence of content validity are presented in the Results portion of the study manuscript.

The complications included in the OCSI are leakage, peristomal irritant dermatitis, pain, bleeding, stomal necrosis, stomal stenosis, retraction, mucocutaneous separation, and hyperplasia. Each of these items is discussed in the following section.

Leakage.

Leakage was measured by self report and observation using the OCSI at follow-up(Appendix F). The investigator observed if there was any leakage of the ostomy pouching system. If there was no leakage, the patient or caregiver was asked, “Have you had any leakage of ostomy drainage that interfered with the adhesion of the skin barrier in the past 30 days?”, if yes, then the patient or caregiver was asked how often leakage occurred. A categorical response was selected where: 0= no leakage; 1= leakage that occurred approximately one to two times in past 30 days; 2= leakage that occurred approximately one to two times per week; or 3= leakage that occurred approximately one to two times per day).

Peristomal Irritant Dermatitis.

Peristomal irritant dermatitis was measured by self report and observation using the OCSI at follow-up. The investigator first identified if there was any peristomal irritant dermatitis present. If there was none present, the patient or caregiver was asked, “ Have you had any skin irritation around the stoma in the past week?” If yes, the patient or caregiver was asked to describe using the following descriptions: “redness, or rash but no skin loss and skin is intact; or redness, or rash with skin loss that is less than 50% around the stoma; or redness, or rash with skin loss that is greater than 50% around the stoma?”. A categorical response was identified where: 0= no peristomal irritation; 1= peristomal erythema, redness, or rash but no skin loss and skin is intact; 2= peristomal erythema, redness, or rash with loss that is less than 50% of peristoma skin; 3= peristomal erythema, redness, or rash with loss that is greater than 50% of peristoma skin.

Pain.

Stoma pain was measured at follow-up using a 11-point numeric rating scale (NRS). The patient identified the number that corresponded to their current level of stoma or peri-stomal pain, 0= no pain and 10= worst pain. The NRS has been identified as a standardized tool with established reliability and validity properties (RNAO, 2007). A single item question of stoma

pain using the NRS was incorporated onto the self-administered OAI-23 instrument. The investigator transferred that response into the OCSI identifying the appropriate categorical response where: 0= no stoma pain; 1= stoma pain 1, 2, 3; 2= stoma pain 4, 5, or 6; or 3= stoma pain 7, 8, 9, or 10.

Bleeding.

Bleeding was measured by patient interview and observation using the OOCI at follow-up. The investigator/WOC nurse observed the stoma site for the presence of bleeding at the stoma or around the stoma. If there was no bleeding present, the patient or caregiver was asked, "Have you had any bleeding from the stoma or around the stoma in the past week?" If yes, the patient or caregiver was asked whether bleeding was: 1) superficial and stopped easily; 2) moderate and stopped after 10 minutes of pressure; or 3) severe and did not stop, had to see a doctor . A categorical response was identified by the investigator where: 0= no stoma or peristoma bleeding; 1= stoma or peristomal bleeding that is superficial and stopped quickly; 2= stoma or peristomal bleeding that is persistent and requires either prolonged pressure, AgNO3 cauterization or hemostasis agent; 3= stoma or peristomal bleeding that requires advanced medical intervention (sutures or transfusion).

Stomal necrosis.

Stomal necrosis was measured by direct observation of the stoma using the OCSI at follow-up. A categorical response was identified where: 0= no stomal necrosis, stoma is pink and moist; 1= dusky stoma; 2= stoma that is less than or equal to 50% black; or 3= stoma that is greater than 50% black.

Stomal stenosis.

Stomal stenosis was measured by direct observation of the stoma using the OCSI at follow-up. A categorical response was identified where: 0= stoma os that has no stenosis or narrowing; 1= stoma os that is less than 5^{th} digit diameter, with no pain or discomfort and output is normal; 2= stoma os that is less than 5^{th} digit in diameter, has ribbon-like output, and with

occasional abdominal discomfort; or 3= stoma os that is unable to accommodate the 5th digit, no output x 6 hours or greater, and with abdominal pain and distention.

Retraction.

Retraction was measured by direct observation of the stoma using the OCSI at follow-up. A categorical response was selected where: 0= stoma is above skin level; 1= stoma is level with the skin; 2= stoma is below skin level; 3= stoma is greater than 2 centimeters below skin level or is unable to be visualized.

Mucocutaneous separation.

Mucocutaneous separation was measured by direct observation of the stoma and peristomal skin using the OCSI at5 30 to 60 days post surgery. A categorical response was selected where: 0= no separation of the stoma from the mucocutaneous junction; 1= 1- 49% separation of the stoma from the mucocutaneous junction; 2= 50-74% separation of the stoma from the mucocutaneous junction; or 3= 75-100% separation of the stoma from the mucocutaneous junction.

Hyperplasia.

Hyperplasia was measured by direct observation of the stoma and peristomal skin using the OCSI at follow-up. A categorical response was selected where: 0= no hyperplasia around the stoma; 1= hyperplasia that is 1-49% around stoma; 2= hyperplasia that is 50-74% around stoma; or 3= hyperplasia that is 75-100% around stoma.

Ostomy Adjustment.

The Ostomy Adjustment Inventory-23 (OAI-23) (Appendix E) was used to measure ostomy adjustment. The OAI-23 was developed in 2005 by Simmons and colleagues and was designed to measure social and psychological adjustment of patients with a fecal ostomy. The OAI-23 is a 23-item, multidimensional, self-report scale that consists of four subscales; acceptance, self-esteem, social engagement, and anger (Simmons et al., 2008). Simmons (2008) reported that the OAI-23 demonstrated evidence of validity in a large sample of 570 British subjects with an ostomy.

Cronbach's alpha ranged from .93 for the overall inventory to .64 for the Anger subscale. Test-retest reliability was found to be 0.83 (Simmons et al., 2008). Permission was obtained for use of the OAI-23 in this study. In our study, the OAI-23 was measured at follow-up and demonstrated evidence of reliability with a Cronbach's alpha of .91.

Data Analysis

Frequencies were used to examine all patient demographics and were summarized and tabulated. Continuous measures were summarized using means and standard deviations and were compared using analysis of variance (ANOVA). Categorical measures were summarized using frequencies and percentages and were compared using chi-square tests. Data were checked and rechecked for accuracy and completeness prior to data entry. Analyses were performed using SPSS statistical software. Specific analytic procedures used to address each study aim are described in detail below.

Aim 1. Determine ostomy risk factors present at baseline, five to seven days post-operatively, among adult patients who have intestinal ostomy surgery at a large Midwestern health system.

One of the important research aims that was addressed in this study was the identification of risk factors for ostomy complications that are present among adult patients that undergo intestinal or fecal ostomy surgery. The frequencies and percentages of risk factors present were reported. Frequencies were used to examine all patient demographic, environmental, and clinical/physiological risk factors. Continuous measures were summarized using means and standard deviations and were compared using analysis of variance (ANOVA). Categorical measures were summarized using frequencies and percentages and were compared using chi-square tests.

Aim 2. Evaluate the content validity and inter-rater reliability of the Pittman Ostomy Risk Factor Index (ORFI).

The Ostomy Risk Factor Index (ORFI) was developed for use in this study. A main focus of this study was to determine the quality of the items, inter-rater reliability, and content validity of the instrument. Content validity index was calculated to determine content validity of the instrument.

A systematic approach was used to conduct and evaluate inter-rater reliability of the ORFI. A second trained WOC nurse expert, in addition to the principal investigator, independently completed the ORFI at baseline, five to seven days post-operatively, on three participants. Training of this WOC nurse required one hour and focused on the content of the instrument, use of the instrument, and application of scoring rules. Subjects were randomly selected to be examined by the second WOC nurse in order to determine inter-rater reliability. Cohen's coefficient kappa was computed to estimate inter-rater reliability on each item and Pearson correlation coefficient was computed to estimate total score agreement between raters.

Aim 3. Determine the incidence and severity of ostomy complications at follow-up, 30 to 60 days post-operatively, among adult patients who have fecal ostomy surgery in a large Midwestern health system.

Frequencies and percentages of participants experiencing early overall and individual ostomy complications were reported. The frequencies and percentages of the severity of each ostomy complication were also reported. Continuous measures were summarized using means and standard deviations and were compared using analysis of variance (ANOVA). Categorical measures were summarized using frequencies and percentages and were compared using chi-square tests.

Aim 4. To evaluate the content validity, inter-rater reliability and construct validity of the Pittman Ostomy Complication Severity Index (OCSI).

The Ostomy Complication Severity Index (OCSI) was developed for use in this study. One of the primary goals of this study was to determine the quality of the items, inter-rater reliability, and content validity of the instrument. Item and total analysis included reporting item means, medians, standard deviations, percentage ceiling and floor effects, inter-item correlations, and item-to-total correlations. Multicollinearity was examined by identifying the squared multiple correlation (SMC). This identified variables that were highly correlated or redundant (Tabachnick & Fidell, 2001). In addition, content validity index was calculated to determine content validity of the instrument.

Content validity is defined as the determination of the content representativeness of the items of an instrument and that those items adequately sample the research domain of interest when attempting to measure phenomena (Polit & Beck, 2006; Wynd et al., 2003). Content validity was examined using a two stage methodology: 1) Developmental stage in which a thorough literature review and generation of instrument items was performed, and 2) Judgment/quantification stage in which a select panel of content experts evaluates and rates the instrument item relevance to the domain of interest (Lynn, 1986). The content validity index was computed for the proportion of experts who are in agreement on item.

A systematic approach was used to conduct and evaluate inter-rater reliability of the OCSI. A trained WOC nurse expert independently completed the OCSI at follow-up, 30 to 60 days post-operatively. Training of the expert included a minimum of one hour training on the content of the instrument, use of the instrument, and applying the scoring rules. Random selection of the subjects were included for determining inter-rater reliability. Cohen's coefficient kappa was computed to estimate inter-rater reliability on each item and Pearson correlation coefficient was computed to estimate total score agreement between raters.

Multiple regression was conducted to determine if the independent variables, measured by the ORFI and SCSES, predicted OCSI total scores. For normally distributed continuous data, Pearson correlation coefficients were computed to determine the relationship among OCSI, SCSES, and OAI-23 total scores.

Summary

This research study is a critical step in evaluating the incidence and severity of early ostomy complications in the immediate 30 to 60 days after surgery and in identifying risk factors of early ostomy complications. This study examined the validity and reliability of two new instruments that have been developed to measure: 1) risk factors that contribute to the development of early ostomy complications, and, 2) incidence and severity of ostomy complications. Relationships, correlations, and risk factors that predict early ostomy complications were examined. The methodology presented in this chapter establishes the rigor carried out in this study.

Studying the incidence and severity of ostomy complications and the factors that contribute to the development of such complications establish a foundation upon which to build future research. This, in turn, may lead to the development of interventions that will improve care and quality of life for individuals living with an ostomy.

CHAPTER FOUR

RESULTS

The results of this study are presented in this chapter. The purposes of this study were to: 1) identify risk factors that contribute to the development of early fecal ostomy complications; 2) describe the incidence and severity of early fecal ostomy complications within 60 days post-operatively; and 3) estimate the reliability and validity of two newly developed instruments to measure risk factors and ostomy complications. The findings will be presented in two sections. In the first section, a brief summary of the sample and setting are presented. The second section consists of the findings addressing each specific research aims.

Sample Description

A sample of 71 adult patients who had undergone surgery to create a new fecal ostomy, either colostomy or ileostomy, were recruited from a large health care system in the Midwest United States. Seventy-one subjects were included in the baseline data and 58 subjects in the follow-up data. Thirteen (18%) subjects were lost to follow-up and did not complete the second data collection visit. Two participants did not show up for follow-up appointments, two participants expired, and nine participants did not return repeated phone calls to schedule the follow-up visit.

Participants were recruited from three hospital sites within a single healthcare system. One site was a 750-bed Level I Trauma hospital, the second site was a 350-bed university academic teaching hospital, and the third site was a 189-bed community hospital. Data regarding risk factors and stoma care self-efficacy were collected at baseline. Data regarding ostomy complications, stoma care self-efficacy, and ostomy adjustment were collected at follow-up.

Demographic Characteristics.

Demographic characteristics that were examined included age, gender, income, education, employment, and partner status. The age distribution of the sample ranged from 22 to 86 years (M= 56.7, sd 15.09). Age was grouped into categories with the largest category being

those participants 18-49 years of age (n= 22, 31%). There were 17 (24%) participants in the 50-59 year old age group, 15 (21%) participants in the 60-69 year old age group, and 16 (23%) participants in the 70 years and older age group. The sample was almost evenly distributed by gender with 37 males (52%) and 34 females (48%). To assess adequacy of income, participants were asked, “Considering your household income from all sources, would you say you are comfortable, just have enough to make ends meet, or do NOT have enough to make ends meet”. Twenty-three (34%) participants stated they were financially “comfortable”, 26 (39%) participants stated they had “just enough”, and 18 (27%) participants stated that they did “not have enough”. Twenty-nine (43%) participants had a high school education or less and 38 (57%) participants had some college or more education. Forty-eight (70%) participants were not employed. More than half of the participants were single (n=38, 55%). No statistically significant differences in demographic risk factors were identified across sites (see Table 1).

Table 1. Description of demographic characteristics

Demographic Risk Factors		SITE 1	SITE 2	SITE 3	TOTAL			
		n= 18 n (%)	n= 42 n (%)	n= 11 n (%)	N= 71 n (%)	*Chi square*	F	*p*
Age	Mean (sd)	61 (12.5)	54 (15.4)	60 (16.8)	57 (15.1)		1.42	.249
	18-49	3 (18)	16 (38)	3 (27)	22 (31)	5.75		.451
	50-59	3 (18)	10 (24)	4 (36)	17 (24)			
	60-69	6 (35)	8 (19)	1 (9)	15 (21)			
	70+	5 (30)	8 (19)	3 (27)	16 (23)			
Gender								
Female		6 (33)	22 (52)	6 (55)	34 (48)	2.06		.356
Male		12 (67)	20 (48)	5 (46)	37 (52)			
Income								
Comfortable		8 (53)	10 (24)	5 (46)	23 (34)	6.70		.153
Just enough		6 (40)	17 (42)	3 (27)	26 (39)			
Not enough		1 (7)	14 (34)	3 (27)	18 (27)			
Education								
High School or less		3 (20)	21 (51)	5 (46)	29 (43)	4.39		.112
College or more		12 (80)	20 (49)	6 (55)	38 (57)			
Employment								
Yes		4 (25)	11 (26)	6 (55)	21 (30)	3.60		.165
No		12 (75)	31 (74)	5 (46)	48 (70)			
Partnered Status								
No		10 (59)	22 (52)	6 (60)	38 (55)	0.32		.853
Yes		7 (41)	20 (48)	4 (40)	31 (45)			

Aims, Hypotheses, and Research Questions

Data were analyzed to address four specific aims and results are presented by each aim in this section.

Aim 1. Determine ostomy risk factors present at five to seven days post-operatively among adult patients who have fecal ostomy surgery at 3 sites in a large Midwestern health system.

The Ostomy Complication Conceptual Model was used to guide the choice of ostomy risk factors examined in this study. Frequencies were used to examine all patient demographic, environmental and clinical/physiological risk factors as depicted in the conceptual model. Continuous measures were summarized using means and standard deviations and were compared across study sites using analysis of variance (ANOVA). Categorical measures were summarized using frequencies and percentages and compared across study sites using chi-square tests. Data were checked and rechecked for accuracy and completeness prior to data entry.

Ostomy risk factors were examined by study site due to the diversity of populations and services provided at each site. Each study site was located in a different area and served different patient populations. Two sites were downtown urban settings which provide to care to a diverse urban population, many of whom are indigent poor. One of these urban sites is a university medical academic/teaching setting and the other is designated as a Level I Trauma center. The third site was an outlying community setting located in an affluent suburban area. In addition, the types of surgeries performed and the patients served at each site differ greatly. For example, because site 1 is a Level I Trauma center, often patients require complex abdominal surgery that results in an ostomy. Site 1 also has many of the leading vascular surgeons in the region. These complex vascular abdominal surgeries sometimes result in the creation of an ostomy. Site 2 is an academic teaching setting and provides complex colorectal surgeries and multi-visceral transplant surgeries. Often these surgeries result in an ostomy. In addition, both site 1 and 2 provide surgical services for critically ill patients with complex surgical and medical conditions. Site 3 provides surgical services to less complicated patients; i.e., uncomplicated colon surgeries, in a community

healthcare setting. Demographic characteristics, including several potential risk factors, were presented in the preceding section and in Table 1.

Environmental risk factors.

Environmental risk factors examined included whether the participant: 1) had received pre-operative education from the Wound, Ostomy, Continence (WOC) nurse, 2) had received post-operative education from the WOC nurse, 3) was proficient in stomal care, 4) had their stoma site marked by the WOC nurse, and 5) was independent in Activities of Daily Living (ADL). Only 27 (39%) of participants reported they received at least two of three components of pre-operative ostomy education while 50 (73%) reported they received at least three of five components of post-operative ostomy education from the WOC nurse. Within seven days following surgery, 33 (47%) of the participants were observed to be proficient in stoma care (needing minimal assist with only one to two cues) with 37 (53%) not proficient in stoma care (needing moderate assist or greater with three or more cues). Although proficiency rates were not found to be statistically significantly different across study sites, a trend toward significance was noted (p= .065). Only four of 17 (24%) participants at site 1 were proficient in stoma care (needing minimal assist with only one to two cues) , while 22 of 42 (52%) at site 2, and 7 of 11 (64%) at site 3 were proficient.

The stoma site was marked pre-operatively for 37 of 69 (54%) participants and significant differences were observed across study sites (p=.000). Few participants had their stoma site marked pre-operatively at sites 1 and 3, three of 17 participants (18%) and three of 11 participants (27%), respectively. In contrast, the majority of participants at site 2 had their stomas marked pre-operatively (n= 31, 76%). Forty-two (60%) participants were independent in ADL. Data related to environmental characteristics are summarized in Table 2.

Table 2. Description of Environmental Risk Factors five to seven days post ostomy surgery by study site

Environmental Risk Factors	**SITE 1** n= 18 n (%)	**SITE 2** n= 42 n (%)	**SITE 3** n= 11 n (%)	**TOTAL** N= 71 n (%)	*Chi square*	*p*
Pre-operative Education by WOC nurse						
- 2 of 3 components received	5 (29)	18 (44)	4 (36)	27 (39)	1.10	.577
- 1 or less component received	12 (71)	23 (56)	7 (64)	42 (61)		
Post-operative Education by WOC nurse						
- At least 3 of 5 components received	14 (82)	26 (63)	10 (91)	50 (73)	4.39	.111
- 2 or less components received	3 (18)	15 (37)	1 (9)	19 (28)		
Participant Stoma Care Proficiency						
- Needed minimal assist (2 cues or less)	4 (24)	22 (52)	7 (64)	33 (47)	5.47	.065
- Needed moderate assist (3 cues or more)	13 (77)	20 (48)	4 (36)	37 (53)		
Stoma marked by WOC nurse						
- **Yes**	**3 (18)**	**31 (76)**	**3 (27)**	**37 (54)**	**19.89**	**.000**
- **No**	**14 (82)**	**10 (24)**	**8 (73)**	**32 (46)**		
Participant Independent in ADL Function						
- Yes (independent in all 6 ADL functions)	8 (47)	28 (67)	6 (55)	42 (60)	2.10	.350
- No (dependent in at least 1 ADL function)	9 (53)	14 (33)	5 (46)	28 (40)		

Clinical risk factors.

Clinical risk factors that were examined included type of effluent, stoma/abdominal (stoma height above skin) characteristics, nutritional status (albumin, NPO), BMI, smoking status, diagnosis, ostomy type, timing of surgery, and number of comorbidities. These data are summarized in Table 3.

Overall, about half of participants had liquid effluent from their ostomy (n= 36, 51%). For 51 (73%) participants, stoma height was above skin level, while 19 (27%) participants had a stoma height at or below skin level. Eight (11%) participants had been NPO for less than 24 hours post surgery, 31 (44%) were NPO for one to two days post surgery, 12 (17%) were NPO for three to four days post surgery, and 19 (27%) were NPO for more than five days post surgery. Significant differences in nutritional status were observed across sites (p= .000). Eleven of 17 participants (65%) at site 1 were NPO for more than five days post surgery compared to only four of 42 (10%) at site 2 and four of 11 (36%) at site 3. In addition, 28 of 42 (67%) participants at site 2 and seven of 11 (63%) at site 3 were NPO for two or less days compared to only four of 17 (24%) at site 1.

Only 15 (21%) participants had a normal body mass index (BMI) ranging from 18.5-24.9. Six (9%) participants were underweight with a BMI less than18.5. Twenty-four (34%) participants were overweight with a BMI ranging from 25-29.9, 12 (17%) were severely obese with a BMI ranging 30-35, and 15 (22%) were morbidly obese with a BMI ranging greater than 35. Thirty-three (47%) participants were nonsmokers, 19 (27%) were ex-smokers (quit more than two months ago), eight (11%) participants had recently quit smoking (within 2 months) and 10 (14%) were current smokers (see Table 3).

With regard to primary diagnosis, 24 (34%) participants had colorectal cancer, 15 (21%) had inflammatory bowel disease (IBD), and 31 (44%) had other diagnoses including diverticulitis, trauma, or other. There were significant differences in primary diagnosis observed across sites (p= .029). At site 1, 12 (71%) participants were in the “other” category compared to

14 (33%) at site 2 and five (46%) at site 3. Only two (12%) participants at site 1 had colorectal cancer while 18 (43%) at site 2 and four (36%) at site 3 had colorectal cancer.

More than half of the participants had ileostomies (n= 39, 56%) and 31 (44%) had colostomies. Again, ostomy type was significantly different (p= .003) by study site. About two-thirds of participants at site 2 and 3 had an ileostomy, 28 (67%) and 7 (64%) respectively, while only four (24%) participants at site 1 had an ileostomy.

Significant differences were observed across study sites regarding timing of surgery (p= .000). Overall, most ostomy surgeries were planned (n= 45, 64%) versus emergent (n=25, 36%). However, when examined by site, 14 (82%) of participants at site 1 had emergent surgery compared to only six (14%) at site 2. At site 3, timing of surgery was evenly distributed with five (46%) participants undergoing emergent surgery and six (55%) undergoing planned surgery. Comorbidity scores ranged from zero to nine with a mean of 3.84 co-morbidities. No significant differences in comorbidity scores were observed across sites (p= .186).

The overall Ostomy Risk Factor Index total scores ranged from 23 to 45 with a mean of 34 (sd= 5.7) with a significant difference observed across sites (p=.000). Participants at Site 1 scored a ORFI total score mean of 39 (sd= 4.8). At site 2, participants scored an ORFI total score mean of 32 (sd= 5.1) and at site 3, the mean was 34 (sd= 5.4). Post-hoc Bonferroni analysis showed that site 1 was significantly different from sites 2 (p= .000) and 3 (p= .05).

In summary, important environmental and clinical risk factors were identified. More than 60% of participants did not receive adequate pre-operative education from the WOC nurse regarding their ostomy. Sixty-four percent of the surgeries were planned but only 54% of stoma sites were marked pre-operatively, indicating 10% of stoma sites potentially could have been marked but were not. The majority of ostomies were ileostomies. Forty-five percent of participants had a BMI of 25 or greater and almost 30% of stomas were at skin level or below.

Important site differences were observed on stoma site marking, diagnosis, timing of surgery, ostomy type, nutrition, and total ORFI scores. Some of these differences can be explained based on the population differences and types of surgeries performed at each site. For example, 82% of participants at site 1 did not have their stoma site marked. Most likely this is because 82% of the ostomy surgeries at site 1were emergent. Conversely, 86% of the ostomy surgeries at site 2 were planned. This may be because site 2 is the location where the majority of the colorectal surgeons practice and elective surgeries occur. Forty-three percent of the participants at site 2 had a primary diagnosis of colorectal cancer. Sixty-five percent of participants at site 1 were NPO greater than five days. Total ORFI scores were highest at site 1.

Table 3. Description of clinical risk factors five to seven days post ostomy surgery by study site

Clinical Risk Factors	**SITE 1** n= 18 n (%)	**SITE 2** n= 42 n (%)	**SITE 3** n= 10 n (%)	**TOTAL** n (%)	*Chi square*	F	*p*
Diagnosis							
Colon Cancer	0 (0)	1 (2)	2 (18)	3 (4)	14.05		**.029**
Rectal Cancer	2 (12)	17 (41)	2 (18)	21 (30)			
IBD	3 (18)	10 (24)	2 (18)	15 (21)			
Other (diverticulitis, trauma, emergent)	12 (71)	14 (33)	5 (46)	31 (44)			
Timing of surgery							
Planned	3 (18)	36 (86)	6 (55)	45 (64)	24.96		**.000**
Emergent	14 (82)	6 (14)	5 (46)	25 (36)			
Ostomy type							
Sigmoid Colostomy	7 (41)	13 (31)	2 (18)	22 (31)	15.80		**.003**
Transverse Colostomy	6 (35)	1 (2)	2 (18)	9 (13)			
Ileostomy	4 (24)	28 (67)	7 (64)	39 (56)			
Type of Effluent							
Solid	0	0	0	0	0.69		.953
Formed, soft	1 (6)	2 (5)	0	3 (4)			
Thick liquid	7 (41)	19 (45)	5 (46)	31 (44)			
Liquid	9 (53)	21 (50)	6 (55)	36 (51)			
Stoma/Abdominal Characteristics (stomal height above skin)							
Yes	13 (77)	31 (74)	7 (64)	51 (73)	0.60		.739
No	4 (24)	11 (26)	4 (36)	19 (27)			
BMI							
Normal (18.5-24.9)	4 (24)	8 (19)	3 (27)	15 (21)	1.42		.965
Overweight (25-29.9)	5 (29)	15 (36)	4 (36)	24 (34)			
Severe Obesity (30-35)	4 (24)	7 (17)	1 (9)	12 (17)			
Underweight or Morbidly obese (<18.5 or >35)	4 (24)	12 (29)	3 (27)	19 (27)			

Smoker							
Nonsmoker	5 (29)	19 (45)	9 (27)	33 (47)	9.96		.126
Past ex-smoker	8 (47)	10 (24)	1 (9)	19 (27)			
Recent ex-smoker	2 (12)	6 (14)	0	8 (11)			
Current smoker	2 (12)	7 (17)	1 (9)	10 (14)			
Nutrition							
NPO < 24 hrs	1 (6)	4 (10)	3 (27)	8 (11)	24.70		**.000**
NPO 1-2 days	3 (18)	24 (57)	4 (36)	31 (44)			
NPO 3-4 days	2 (12)	10 (24)	0	12 (17)			
NPO > 5 days	11 (65)	4 (10)	4 (36)	19 (27)			
Number of Comorbidities							
Mean (sd)	4.69 (2.4)	3.71 (2.1)	3.09 (2.6)	3.84 (2.3)		1.72	.186
Median	4.50	3.50	3.00	3.00			
ORFI Total Score							
Mean (sd)	39 (4.8)	32(5.1)	34(5.4)	34(5.7)		9.53	**.000**

Aim 2. Evaluate the content validity and inter-rater reliability of the Ostomy Risk Factor Index (ORFI).

Hypothesis 2a. The Ostomy Risk Factor Index and individual items will demonstrate content validity as evidenced by content validity indices of at least 0.80 and acceptable scores on clarity, comprehensiveness, and appropriateness based on ratings from 10 national experts.

Due to the lack of reliable and valid instruments to measure ostomy risk factors, the Ostomy Risk Factor Index was developed for use in this study. Using guidelines established by DeVellis (2003), a systematic step-wise approach was followed. The first three steps in this process, identifying the construct to be measured, choosing items that reflect the instrument's purpose, and determining the format for measurement were described in Chapter Three. The fourth step, expert review of the items, will be described in this section (DeVellis, 2003).

The content validity index (CVI) was chosen for this study as an objective method for quantitatively measuring the content validity of this instrument. The CVI, or proportion agreement method, is calculated based on the ratings of item relevance by a panel of content experts (Wynd et al., 2003). A CVI of .80 or higher is considered acceptable (D. Polit, Beck, C., 2006). In this study, a panel of 10 WOC nurse experts participated in establishing the content validity of the ORFI using a content validity survey. Three experts were doctorally-prepared, seven were master's-prepared advanced practice nurses, and all were nationally recognized experts in the WOC field. Each reviewer was given a packet of information that included: purpose of the study, hypotheses, conceptual definitions, operational definitions, survey instructions, and a content validity survey for the ORFI (see Appendix I). The content validity survey format was developed using the recommendations of Wynd, Lynn and Sacks (Lynn, 1986; Sacks; Wynd et al., 2003). Each expert was given specific instructions by which to determine the relevance of each of the 14 individual risk factors (age, diagnosis, ostomy type, type of effluent, stoma/abdomen characteristics, stoma care proficiency, care giver support, pre-operative

education by WOC nurse, stoma site marking by WOC nurse, current nutritional status, prior nutritional status, BMI, smoking status, and post-operative education by WOC nurse) and of the instrument as a whole. In addition to relevance, the experts evaluated the clarity, comprehensiveness, and appropriateness of each item. The experts also ranked each item in the order of importance as a risk factor for ostomy complications. Each expert reviewer completed the survey and returned it to the principal investigator electronically, by facsimile, or by mail.

Item and total content validity analyses included reporting means and standard deviations of expert ratings for each individual item. In addition to the CVI ratings, clarity, comprehensiveness, appropriateness, and rank of importance of each ORFI item is reported. These findings are presented in Table 4.

The items were rated on a 4-point ordinal scale with the exception of comprehensiveness which was a 2-point nominal scale. The mean for item clarity was above 3 (out of 4) for all 14 items. The mean rating for item comprehensiveness was 1.6 (out of 2) or higher for all items and the mean for item appropriateness was 3 (out of 4) or higher for all items. Stoma/abdominal characteristics were ranked as the most important risk factor of all 14 items and smoking was ranked the least important risk factor by the experts. Because of the expert ratings and comments on instrument content (relevance, clarity, comprehensiveness, and appropriateness), revisions were made to the original instrument. Age scoring was reversed to indicate increased age represented higher risk. The wording of the two nutrition items (prior nutrition status and current nutrition status) were revised to "serum albumin" (instead of prior nutrition) and "NPO status" (instead of current nutrition). The caregiver support item was revised into an item measuring ADL status. Finally, timing of surgery was added as an item. The original ORFI evaluated by the contents experts is in Appendix I (Content Expert Packet), The revised ORFI instrument is in Appendix A.

Table 4. Ostomy Risk Factor Index: Panel of Experts Mean Ratings

	Mean (SD)				
	Relevance as a Risk Factor for Ostomy-related Complications	**Clarity of item**	**Comprehensive-ness of item**	**Appropriateness of numeric rating scale for each item**	**Average Rank**
ORFI					
Age	3.6 (0.97)	3.6 (0.31)	1.9 (0.32)	3.1 (0.38)	10.2
Diagnosis	3.2 (1.14)	3.5 (0.31)	2.0 (0)	3.0 (0.33)	10.0
Ostomy Type	4.0 (0)	3.7 (0.15)	2.0 (0)	3.7 (0.15)	5.5
Type of Effluent	3.9 (0.32)	3.4 (0.22)	2.0 (0)	3.9 (0.10)	4.7
Stoma/Abd characteristics	4.0 (0)	3.6 (0.22)	2.0 (0)	3.5 (0.27)	2.6
Stomal care proficiency	3.7 (0.48)	3.3 (0.34)	1.9 (0.32)	3.6 (0.27)	5.7
Caregiver Support	3.4 (0.70)	3.6 (0.22)	1.9 (0.32)	3.5 (0.27)	9.1
Pre-operative Ostomy Education	3.5 (0.97)	3.7 (0.15)	1.8 (0.42)	3.6 (0.22)	7.4
Stoma site marked	4.0 (0)	3.8 (0.20)	2.0 (0)	3.6 (0.16)	4.7
Prior Nutritional Status:(Albumin level)	3.4 (0.97)	3.6 (0.22)	1.9 (0.32)	3.8 (0.20)	8.3
Current Nutritional status:(NPO duration)	3.5 (0.97)	3.8 (0.20)	1.9 (0.32)	3.6 (0.22)	10.2
BMI	3.7 (0.67)	3.7 (0.15)	1.9 (0.32)	3.8 (0.13)	8.2
Smoker	3.0 (1.30)	3.3 (0.40)	1.6 (0.50)	3.6 (0.17)	11.7
Post-operative Ostomy Education	4.0 (0)	3.3 (0.34)	2.0 (0)	3.5 (0.24)	6.7
Total (mean)	3.6	3.6	1.8	3.6	

Two types of CVI scores were calculated; 1) content validity of individual items and 2) content validity of the overall scale. The item ratings were on a 4-point ordinal scale. The individual item CVIs were computed by determining the number of items considered to be relevant (rated 3 or 4) by the experts divided by the total number of experts (Polit & Beck, 2006). The individual item content validity (proportion of agreement of experts) index results are presented in Table 5.

The total scale CVI is defined as the "proportion of items on an instrument that achieved a rating of 3 or 4 by all the content experts" (Polit & Beck, 2006). In this study, the total ORFI CVI was calculated by summing the individual CVI scores and dividing by the number of items (Polit & Beck, 2006; Sacks, ND). Twelve of the 14 item CVI scores ranged from 0.9-1.0. Two items (smoking and diagnosis) scored below .80 (Polit & Beck, 2006) and were revised according to experts' recommendations. The total ORFI CVI was 0.9, demonstrating acceptable content validity of the instrument (Polit & Beck, 2006). The content validity index of the overall scale are presented in Table 5.

Table 5. Ostomy Risk Factor Index: Item and Total CVI Scores from number of Experts rating Item Relevance as 1 or 2 and 3 or 4

	Rated:		
ORFI ITEM	**1 or 2**	**3 or 4**	**Item CVI**
Age	1	9	0.9
Diagnosis	3	7	0.7
Ostomy Type	0	10	1.0
Type of Effluent	0	10	1.0
Stoma/abd characteristics	0	10	1.0
Stoma care Proficiency	0	10	1.0
Caregiver Support	1	9	0.9
Pre-operative education by WOC nurse	1	9	0.9
Stoma site marked	0	10	1.0
Prior Nutrition	1	9	0.9
Current Nutrition	1	9	0.9
BMI	1	9	0.9
Smoker status	4	6	0.6
Post-operative education by WOC nurse	0	10	1.0
TOTAL CVI score			0.9

In summary, the Ostomy Risk Factor Instrument and individual items demonstrated acceptable content validity as evidenced by content validity indices of 0.9 and acceptable scores on clarity, comprehensiveness, and appropriateness based on ratings from 10 national experts.

Hypothesis 2b. The ORFI demonstrates evidence of inter-rater reliability with Cohen's coefficient kappa greater than or equal to 0.60.

A systematic approach was used to evaluate inter-rater reliability of the ORFI whereby the scoring of the ORFI was completed by two independent and experienced WOC nurses five to seven days after ostomy surgery for their initial data collection visit. Inter-rater reliability for the individual categorical ORFI items was determined using Cohen's coefficient kappa (Wynd et al., 2003). A minimally acceptable kappa of 0.60 is recommended (Wynd et al., 2003). The total ORFI instrument score was a continuous score, thus, the strength of agreement between the two raters was analyzed using Pearson's correlation and an Intra Class Correlation coefficient (ICC).

At the onset of the study, the goal was to collect inter-rater reliability data on one-third of the participants. Unfortunately, due to unforeseen circumstances this was not feasible and ORFI inter-rater reliability was able to be evaluated on only three participants by two raters. Examining the proportion of agreement between the two raters, 10 items (age, diagnosis, timing of surgery, ostomy type, stoma/abdomen characteristics, pre-operative education by the WOC nurse, stoma site marked by WOC nurse, NPO status, serum albumin, smoking status) had a Cohen's coefficient kappa of 1.0 and 100% agreement between raters. The remaining five items (type of effluent, stoma care proficiency, ADL function, BMI, and post-operative education by the WOC nurse) had a Cohen's coefficient kappa below 0.60 with 66% agreement between raters. The total scoring between raters of the ORFI had a Pearson's correlation of .999 (p= .035) and an Intra Class Correlation coefficient of .998 (p= .001) thus demonstrating acceptable overall inter-rater reliability. The findings are presented in Table 6.

Table 6. Ostomy Risk Factor Index Inter-rater reliability analysis (n=3)

Item	% of agreements	kappa
Age	100%	1.0
Diagnosis	100%	1.0
Timing of surgery	100%	1.0
Ostomy Type	100%	1.0
Type of Effluent	66%	0.4
Soma/Abd characteristics	100%	1.0
Stoma care proficiency	66%	0.4
ADL function	66%	0.4
Pre-operative Education by WOC nurse	100%	1.0
Stoma site marked by WOC nurse	100%	1.0
NPO Status	100%	1.0
Serum Albumin	100%	1.0
BMI	66%	0.4
Smoking status	100%	1.0
Post-operative Education by WOC nurse	66%	0.4
ORFI Total score		
Pearson's correlation (*p)*		.999 (.035)
Intra-Class correlation (*p*)		.998 (.001)

In summary, the findings of this rigorous content analyses were used to examine, modify, and improve the ORFI. The ORFI demonstrated acceptable content validity (CVI= 0.9). Mean expert ratings provided evidence of content validity for relevance (3.6), clarity (3.6), comprehensiveness (1.8), and appropriateness (3.6). The ORFI demonstrated acceptable inter-rater reliability for 10 of the 15 items (k=1.0) and an excellent correlation of total scores between raters (ICC .998, p= .001).

Aim 3. Determine the incidence and severity of ostomy complications within 60 days post-operatively among adult patients who have intestinal ostomy surgery at 3 sites in a large Midwestern health system.

Ostomy complications examined at follow-up included leakage, peristomal irritant dermatitis, stomal pain, stomal bleeding, stomal necrosis, stomal stenosis, stomal retraction, mucocutaneous separation, and hyperplasia. The incidence and severity of each ostomy complication are presented in Table 7. Continuous measures were summarized using means and standard deviations and were compared across sites using analysis of variance (ANOVA).

Categorical measures were summarized using frequencies and percentages and were compared across sites using chi-square tests.

Almost 60% of participants reported leakage of their pouching system at follow-up. Thirty-one (50%) participants reported having, or were observed to have, peristomal irritant dermatitis at follow-up. Twenty-six (42%) participants reported having stoma pain. The mean pain score was 1.7 (range 1-10 numeric scale) among all participants. Twenty (32%) participants reported having, or were observed to have, stomal bleeding at follow-up. Only one (2%) participant had stomal *necrosis* and three (5%) participants had stomal *stenosis*. At follow-up, 39 (62%) participants had a stoma that was above skin level versus 24 (39%) participants had stomal retraction or a stoma that was at skin level or below. Across sites, stomal retraction approached significance (p= .052). Twenty-seven (73%) participants at site 2 had a stoma above skin level versus only six (40%) at site 1 and six (55%) at site 3. Eight (13%) participants had mucocutaneous separation. Three (5%) participants had hyperplasia present at the stoma site. Participants' OCSI total scores ranged from 0 to 13 with a mean of 3.9 (SD 3.5). There were no difference in OCSI scores among sites.

Table 7. Incidence and severity of ostomy complications at 30-60 days by study site

Ostomy Complications	**SITE 1** n= 18 n (%)	**SITE 2** n= 42 n (%)	**SITE 3** n= 10 n (%)	**TOTAL** n= 70 n (%)	*Chi square*	*p*
Leakage						
None	5 (36)	13 (35)	7 (64)	25 (40)	7.52	.276
1-2x/mo	3 (21)	9 (24)	1 (9)	13 (21)		
1-2x/wk	6 (43)	10 (27)	1 (9)	17 (27)		
1-2x/day	0	5 (14)	2 (18)	7 (11)		
Peristomal Irritant Dermatitis						
None	9 (64)	15 (41)	7 (64)	31 (50)	6.15	.407
Mild	2 (14)	12 (32)	3 (27)	17 (27)		
Moderate	3 (21)	6 (16)	1 (9)	10 (16)		
Severe	0	4 (11)	0	4 (7)		
Stomal Pain						
None	7 (50)	21 (57)	8 (73)	36 (58)	4.48	.612
1-3	3 (21)	8 (22)	3 (27)	14 (23)		
4-6	1 (7)	4 (11)	0	5 (8)		
7-10	3 (21)	4 (11)	0	7 (11)		
Mean (SD)	1.25 (2.5)	1.89 (2.9)	1.64 (2.7)	1.71 (2.8)		.794
Stomal Bleeding						
None	8 (57)	25 (68)	9 (82)	42 (68)	8.71	.191
Superficial	4 (29)	12 (32)	1 (9)	17 (27)		
Moderate	1 (7)	0	1 (9)	2 (3)		
Severe	1 (7)	0	0	1 (2)		
Stomal Necrosis						
None	15 (100)	36 (97)	11 (100)	62 (98)	0.71	.700
Stoma Dusky	0	1 (3)	0	1 (2)		
Stoma 50% black	0	0	0			
Stoma >50% black	0	0	0			
Stomal Stenosis						
None	14 (93)	36 (97)	10 (91)	60 (95)	3.71	.447

<5th digit diameter, no discomfort	0	1 (3)	0	1 (2)		
<5th digit diameter, occasional discomfort	1 (7)	0	1 (9)	2 (3)		
Unable to insert 5th digit, no output	0	0	0	0		
Stomal Retraction						
Stoma above skin	6 (40)	27 (73)	6 (55)	39 (62)	12.48	.052
Stoma skin level	6 (40)	9 (24)	2 (18)	17 (27)		
Stoma below skin level	3 (20)	1 (3)	2 (18)	6 (10)		
Stoma >2cm below skin level	0	0	1 (9)	1 (2)		
Mucocutaneous Separation						
None	11 (73)	35 (95)	9 (82)	55 (87)	10.17	.118
1-49%	2 (13)	1 (3)	0	3 (5)		
50-74%	1 (7)	0	0	1 (2)		
75-100%	1 (7)	1 (3)	2 (18)	4 (6)		
Hyperplasia						
None	13 (87)	36 (97)	11 (100)	60 (95)	3.33	.190
1-49%	2 (13)	1 (3)	0	3 (5)		
50-74%	0	0	0	0		
75-100%	0	0		0		
Ostomy Complications present						
No	1 (7)	6 (16)	3 (30)	10 (16)		
Yes	13 (93)	31 (84)	8 (73)	52 (84)	1.85	.397
OCSI Total Score	5 (3.5)	4 (3.5)	3 (3.8)	4 (3.5)		.546

To summarize, 52 (84%) participants had developed at least one ostomy complication at follow-up. Leakage was one of the most commonly occurring complication with almost 60% of the participants experiencing this problem. Peristomal irritant dermatitis was the next most commonly occurring complication with 50% of the participants experiencing it. Stomal pain (42%), retraction (39%), and stomal bleeding (32%) were the next most common complications found in our study. There was no significant difference in the incidence or severity of ostomy complications across study sites although rates of stomal retraction were approaching significance (p=.052).

Aim 4. Evaluate the content validity, inter-rater reliability and construct validity of the Ostomy Complication Severity Index (OCSI).

Hypothesis 4a. The Ostomy Complication Severity Index and individual items will demonstrate content validity as evidenced by content validity indices of at least 0.80 and acceptable scores on clarity, comprehensiveness, and appropriateness based on ratings from 10 national experts.

As stated in Aim 2, because of the lack of reliable and valid instruments to measure ostomy complications, the Ostomy Complication Severity Index (OCSI) was developed for use in this study. Using the guidelines established by DeVellis (2003), a systematic step-wise approach was followed. The first three steps in this process, identifying the construct to be measured, choosing items that reflect the instrument's purpose, and determining the format for measurement are described in Chapter Three. The fourth step, expert review of the items, will be described here (DeVellis, 2003).

The same panel of 10 WOC nurse experts who participated in establishing the content validity of the ORFI participated in establishing the content validity of the OCSI. Each reviewer was given a packet of information that included the: purpose of the study, hypotheses, conceptual definitions, operational definitions, survey instructions, and the content validity survey for the OCSI (see Appendix I). The content validity survey format was developed using the

recommendations of Wynd, Lynn and Sacks (Lynn, 1986; Sacks; Wynd et al., 2003). In addition to item relevance, the experts evaluated clarity, comprehensiveness, and appropriateness of each item. The item ratings were on a 4-point ordinal scale with the exception of comprehensiveness which was a 2-point nominal scale. Each reviewer completed the survey and returned it to the Principal Investigator electronically, by facsimile, or by mail.

Item and total content validity analyses included calculating means and standard deviations of the expert ratings of relevance for each individual item (see Table 8). The means and standard deviations for ratings of clarity, comprehensiveness, and appropriateness of each OCSI item are also reported in Table 8.

The mean rating for item clarity was 3 (out of 4) or above for eight of the nine items. The average item comprehensiveness rating was 1.8 (out of 2) or higher for all items. Eight of the nine items' mean rating for item appropriateness was 3 (out of 4) or higher. The item (stomal bleeding) that rated lower on clarity (2.4) and appropriateness (2.5) was revised based on experts' recommendations. In summary, the results of the rigorous content validity analyses demonstrated acceptable content validity for the OCSI.

Table 8: Ostomy Complication Severity Index: Panel of Experts Mean Ratings

OCSI	**Mean (SD)**			
	Relevance as a Risk Factor for Ostomy-related Complications **1. Item is NOT relevant** **2. Item needs MAJOR revision to be relevant** **3. Item needs MINOR revision to be relevant** **4. Item IS relevant**	**Clarity of item** **1. Item is NOT clear** **2. Item needs MAJOR revision to be clear** **3. Item needs MINOR revision to be clear.** **4. Item IS clear**	**Comprehensiveness of item** **1. Item should be deleted.** **2. Item should be retained.**	**Appropriateness of numeric rating scale for each item** **1. Rating scale is NOT appropriate.** **2. Rating scale needs MAJOR revision to be appropriate.** **3. Rating scale needs MINOR revision to be appropriate.** **4. Rating scale is appropriate.**
Leakage	3.6 (0.97)	3.2 (1.23)	1.9 (0.32)	3.4 (0.97)
Peristomal Irritant Dermatitis	4.0 (0)	3.9 (0.33)	2.0 (0)	3.3 (0.95)
Pain	3.3 (0.95)	3.0 (1.15)	1.9 (0.32)	3.2 (1.03)
Bleeding	3.0 (1.15)	2.4 (1.13)	1.8 (0.42)	2.5 (1.01)
Stomal Necrosis	3.8 (0.63)	3.9 (0.33)	2.0 (0)	3.5 (0.71)
Stomal Stenosis	3.8 (0.63)	3.3 (1.00)	1.9 (0.32)	3.0 (1.12)
Retraction	3.8 (0.63)	3.4 (1.13)	1.9 (0.32)	3.7 (0.71)
Mucocutaneous Separation	3.8 (0.63)	3.6 (0.73)	2.0 (0)	3.4 (0.97)
Hyperplasia	3.6 (0.97)	3.8 (0.67)	2.0 (0)	3.7 (0.67)
Total (mean)	3.6	3.4	1.9	3.3

Table 9. Ostomy Complication Severity Index: Item and Total CVI Scores from number Experts rating Item Relevance as 1 or 2 and 3 or 4

	Rated:		
OCSI	**1 or 2**	**3 or 4**	**Item CVI**
Leakage	1	9	.90
Peristomal Irritation	0	10	1.00
Pain	1	9	.90
Bleeding	2	8	.88
Stoma Necrosis	1	9	.90
Stoma Stenosis	1	9	.90
Retraction	1	9	.90
MC Separation	1	9	.90
Hypergranulation	1	9	.90
TOTAL CVI			.91

Two types of CVI were calculated; 1) content validity of individual items and 2) content validity of the overall scale. The individual item CVI was computed by determining the number of items considered to be relevant (rated 3 or 4) by the experts divided by the total number of experts (Polit & Beck, 2006). The individual item content validity (proportion of agreement of experts) results are presented in Table 9.

The total scale CVI is defined as the "proportion of items on an instrument that achieved a rating of 3 or 4 by all the content experts" (Polit & Beck, 2006). In this study, the total OCSI CVI was calculated by summing the individual CVI scores and dividing by the number of items (Polit & Beck, 2006). All of individual item CVI scores were acceptable ranging from .88 to 1.0. The total OCSI CVI score was .91, which demonstrates acceptable content validity of the instrument (Polit & Beck, 2006). The content validity scores of individual items and content validity score of the overall scale are presented in Table 9.

In addition to the above analyses, internal consistency reliability analysis using Cronbach's alpha was conducted. Item and total scores obtained from study participants were examined to report item means, medians, standard deviations, percentage floor and ceiling effects, inter-item correlations and item-to-total correlations. These findings are presented in Table 10. Item means ranged from 0.02 (stomal necrosis) to 1.10 (leakage). There was good

variability in relation to the mean with standard deviations ranging from 0.13 to 1.07. The median was 0, indicating little variability in severity on seven of nine items; pain, bleeding, stomal necrosis, stomal stenosis, retraction, mucocutaneous separation, and hyperplasia. The item-to-total correlations varied with five of nine items demonstrating acceptable item-to-total correlation (.30 to .70). Items with item-to-total correlations less than .30 (stomal necrosis, stomal stenosis, mucocutaneous separation, and hyperplasia) were those items with low incidence in this sample. These analyses may indicate that the OCSI could be revised to include fewer items. The highest ceiling effect was 11.3 % (leakage) and the highest floor effect was 98.4% (stomal necrosis). Item means indicated that stomal necrosis was the least severe and leakage was the most severe complication in these participants.

Table 10. Ostomy Complication Severity Index: Item-to-total reliability analysis

OCSI Item	Mean (SD)	Range	% Ceiling	% Floor	Item-to-total Correlation	Cronbach's α if deleted
Leakage	1.10 (1.07)	0-3	11.3	40.3	.60	.59
Peristomal Irritant Dermatitis	0.79 (0.94)	0-3	6.5	50.0	.59	.60
Pain	0.73 (1.03)	0-3	11.3	58.1	.53	.61
Bleeding	0.39 (0.64)	0-3	1.6	67.7	.41	.65
Stomal Necrosis	0.02 (0.13)	0-1	1.6	98.4	.23	.69
Stomal Stenosis	0.08 (0.38)	0-2	3.2	95.2	.09	.69
Retraction	0.52 (0.74)	0-3	1.6	61.9	.35	.66
Mucocutaneous Separation	0.24 (0.76)	0-3	6.3	87.3	.21	.69
Hyperplasia	0.05 (0.22)	0-1	4.8	95.2	.19	.69

In summary, the findings of this rigorous content analyses were used to examine, modify, and improve the OCSI. The OSCI demonstrated acceptable content validity (CVI= 0.9). Mean expert ratings provided evidence of content validity for relevance (3.6), clarity (3.4), comprehensiveness (1.9), and appropriateness (3.3). The item-to-total correlations varied with five of the nine items demonstrating acceptable item-to-total correlation (.30 to .70). Internal consistency reliability for the OCSI was supported by a Cronbach's alpha of .68 (n= 9).

Hypothesis 4b. The OCSI demonstrates evidence of inter-rater reliability with Cohen's coefficient kappa greater than or equal to 0.60 (Wynd et al., 2003).

A systematic approach was used to evaluate inter-rater reliability of the OCSI whereby the OCSI was completed by two independent and experienced WOC nurses 30 to 60 days after ostomy surgery. At the onset of the study, the goal was to collect inter-rater reliability data on one-third of the participants. Unfortunately, due to unforeseen circumstances this was not feasible and OCSI inter-rater reliability was able to be evaluated by both expert raters on only six participants.

Inter-rater reliability of the individual OCSI items was determined using Cohen's coefficient kappa (Waltz, Strickland, & Lenz, 2005). All individual items had a Cohen's coefficient kappa of .71 to 1.0 which demonstrates acceptable inter-rater reliability (Polit & Hungler, 1999). Pearson's correlation and Intra Class Correlation coefficient were used to examine the strength of agreement between the two experts rating the total OCSI score. The total score of the OCSI had a Pearson's coefficient of .999 (p=.000) and Intra Class Correlation coefficient of .991 (p= .000). The OCSI demonstrated acceptable inter-rater reliability on individual items and total score. These findings are presented in Table 11.

Table 11. Ostomy Complication Severity Index: Inter-rater reliability analysis (n=6)

OCSI Item	% Agreement	Kappa
Leakage	100%	1.0
Peristomal irritant dermatitis	100%	1.0
Pain	75%	0.7
Bleeding	100%	1.0
Stomal necrosis	100%	1.0
Stomal stenosis	100%	1.0
Retraction	100%	1.0
Mucocutaneous separation	100%	1.0
Hyperplasia	100%	1.0
Total OCSI score		
Pearson's Correlation *(p)*		.999 (.000)
Intra-Class Correlation (*p*)		.991 (.000)

In summary, the OCSI demonstrated acceptable inter-rater reliability for individual items (*k*= .71- 1.0) and almost perfect agreement of total scores between raters (ICC .991, *p*= .000).

Hypothesis 4c. Total Ostomy Risk Factor Index (ORFI) scores at baseline (five to seven days post-operatively) and Stoma Care Self Efficacy scores at baseline (five to seven days post-operatively) will predict total Ostomy Complication Severity Index (OCSI) scores at follow-up (30 to 60 days post-operatively).

Univariate analyses were performed initially using Pearson coefficient and a significance level of $p<.25$ was used to determine variables to be entered in later multivariate models. Significant relationships were found between ORFI total scores and Stoma Care Self-Efficacy scores at baseline ($p= .04$). However, no significant relationships were observed between ORFI total scores, Stoma Care Self-Efficacy scores at baseline and OCSI total scores at follow-up, 30-60 days post-operatively.

Table 12. Univariate analyses of Ostomy Risk Factor Index total scores, Stoma Care Self-Efficacy Scale total scores related to Ostomy Complication Severity Index total scores using Pearson Correlation

Variables	SCSES1.Tot r (*p*)	ORIFTot r (*p*)	OCSITot r (*p*)
SCSES1.Tot	---	-.254 (.040)	-.097 (.466)
ORIFTot	-.254 (.040)	---	.069 (.598)
OCSITot	-.097 (.466)	.069 (.598)	---

Although no significant relationships were found in the univariate analysis, in order to examine this hypothesis as stated, multiple regression analysis was also performed. Univariate and multivariate regression analyses were conducted to examine relationships among ORFI total score, baseline SCSES and OCSI total scores. These findings are presented in Table 13.

Univariate regression analysis indicated no significant correlations between ORFI total score and OCSI total score or SCSES and OCSI total score. The multiple regression analysis confirmed this when both independent variables (ORFI total score and SCSES total score) were entered into the model.

Table 13. Multivariate regression analysis of predictors of Ostomy Complications

Outcome	**Covariate**	**Univariate**				**Multivariate**			
		B	SE	Beta	*p*	B	SE	Beta	*p*
OCSI Total score	ORFI Total score	.042	.080	.069	.598	.013	.085	.021	.878
	SCSES Total score	-.024	.033	-.097	.466	-.021	.035	-.084	.546

Unfortunately, Ostomy Risk Factor Index total scores did not predict overall Ostomy Complication Severity Index scores. Therefore, the findings in this study do not support the use of the total score derived from the ORFI to predict ostomy complications. However, when examined individually, specific independent risk factors were found to be significantly related to ostomy complications.

In order to examine relationships among individual risk factors and individual ostomy complications, univariate analyses were completed using Pearson correlation coefficients. This information is summarized in Table 14. Several risk factors were significantly correlated with specific ostomy complications. Type of ostomy was correlated with leakage (r= .31, p= .05) and peristomal irritant dermatitis (r= .26, p= .05). These findings indicate that those participants with an ileostomy had more leakage and more peristomal irritant dermatitis. Stoma/abdomen characteristics was significantly correlated with pain (r= .30, p= .05), bleeding (r= .28, p= .05), stomal necrosis (r= .28, p= .05), retraction (r= .57, p= .01), mucocutaneous separation (r= .30, p= .05), and overall OCSI total score (r= .43, p= .01). These findings indicate that those participants with flatter stomas and problematic skin folds/creases had more pain, more bleeding, more stoma necrosis, more retraction, more mucocutaneous separation, and more overall ostomy complications.

ADL function was significantly correlated with pain (r= -.32, p= .05), bleeding (r= -.25, p= .05), and stomal stenosis (r= .29, p= .05). This indicated that those participants who needed more assistance in ADL had less pain, less bleeding, and more stomal stenosis. Those participants whose stoma site was not marked pre-operatively by the WOC nurse had greater retraction (r= .32, p= .01) and mucocutaneous separation (r= .30, p= .05).

NPO status was negatively correlated with bleeding (r= -.35, p= .01) and overall OCSI total score (r= -.25, p=.05). This indicated that participants who went longer without food had less bleeding, and fewer or less severe ostomy complications. BMI as measured on the ORFI is nonlinear, therefore correlation was examined using Spearman's coefficient and was significantly correlated with leakage (r= .44, p= .01), peristomal irritant dermatitis (r= .29, p= .01), and overall OCSI total score (r= .36, p= .01). Recognizing that analysis using the continuous variable is preferred when available, analysis was completed using the continuous BMI data. BMI as a continuous variable was found to be significantly correlated with leakage (r=36, p= .01), retraction (r= .28, p= .05), mucocutaneous separation (r=26, p= .05), and ostomy complication

total score (r= 32, p= .05). These findings indicated that those participants with higher BMI had more leakage, more retraction, more mucocutaneous separation, and higher ostomy complication severity scores.

In addition to the risk factors included on the ORFI, relationships among demographic characteristics and ostomy complications were examined, including gender, education, employment, marital status, race, and comorbidities total score. Analyzing the data using Pearsons correlation coefficient, only gender was associated with ostomy complications, specifically, more leakage (r= .324, p= .05), more pain (r= .269, p= .05) and higher ostomy complication total scores (r= .320, p= .05). When comparing ostomy complications total scores between males and females using analysis of variance, females had significantly higher mean ostomy complication scores (p= .02).

Table 14. Correlations among Risk factors (ORFI items) and Ostomy complications (OCSI items)

Variables	Leakage	Peri-stomal dermatitis	Pain	Bleed-ing	Stomal Necrosis	Stomal Stenosis	Retrac-tion	MC Sep	Hyper Plasia	Total score
Gender	**.324***	.198	**.269***	.249	.138	.090	.110	.027	-.207	**.32***
Age	-.15	-.08	-.01	.03	-.15	-.03	-.01	.04	.20	-.06
Diagnosis	.05	-.05	-.09	-.03	-.01	.17	-.09	.02	.07	-.03
Timing of surgery	-.16	-.18	-.12	.04	-.10	.02	.14	.13	.15	-.07
Ostomy Type	**.31***	**.26***	.20	-.07	.11	-.01	-.16	.06	-.09	.19
Type of Effluent	-.03	.03	-.05	-.08	.12	.05	-.08	-.12	.07	-.06
Stoma/abd characteristics	.22	.11	**.30***	**.28***	**.28***	.05	**.57****	**.30***	-.10	**.43****
Stoma care proficiency	.02	-.15	.01	.05	.20	-.03	.09	.14	.04	.03
ADL function	-.07	-.20	**-.32***	**-.25***	.17	**.29***	-.11	-.14	.08	-.23
Pre-operative education by WOC nurse	-.13	-.12	-.13	.01	-.17	-.10	.10	.15	.02	-.05
Stoma site marked by WOC nurse	-.02	-.12	-.02	.03	-.13	.13	**.32****	**.30***	.07	.11
NPO status	-.21	-.22	-.11	**-.35****	-.08	-.04	-.02	-.08	.10	**-.25***
Albumin	**-.46***	-.45	.04	-.10	---	----	.19	.10	-.10	-.22
BMI (Spearman *r*)	**.42****	**.29****	.20	.22	.17	.05	.25	.22	.13	**.36****
BMI2 (continuous)	**.36****	.11	.13	.17	.14	.03	**.28***	**.26***	-.10	**.32***
Smoking status	-.04	.03	-.01	-.12	-.11	-.09	-.22	-.01	.18	-.09
Post-operative education by WOC nurse	-.11	-.09	-.13	-.03	.15	-.12	-.05	-.14	-.06	-.14

**p<.01, *p<.05

In order to further examine relationships among individual risk factors and overall OCSI total scores, univariate and multivariate regression analyses were completed. (see Table 15) Univariate regression analysis identified two individual risk factors in the ORFI that were significantly associated with the development and severity of ostomy complications, stoma/abdomen characteristics (p= .000) and BMI (p= .000). It is worthwhile to mention that NPO status approached significance (p= .054) but in the opposite direction. When all risk factors were entered into the multivariate model, stoma/abdomen characteristics (p= .007) and BMI (p= .002) remained independent predictors of total ostomy complication scores. These important findings indicated that having flatter stomas and/or problematic skin folds around stoma at baseline predicted ostomy complication scores at 30-60 days post operatively. Higher BMI was related to higher ostomy complication scores 30-60 days post operatively. Older age (p= .053) and needing more assistance with ADL functions (p= .057) at baseline were approaching significance as predictors of ostomy complications. These findings are presented in Table 15.

Table 15. Univariate and Multivariate regression analyses of Risk factors (Ostomy Risk Factors Index) and Ostomy Complications (Ostomy Complications Severity Index)

Outcome	Covariate	Univariate				Multivariate			
		B	**SE**	**Beta**	***p***	**B**	**SE**	**Beta**	***p***
OCSI Total score	Age	-.177	.404	-.057	.663	.948	.476	.302	**.053**
	Diagnosis	-.107	.490	-.028	.828	1.202	.644	.320	.068
	Timing of surgery	-.160	.319	-.065	.619	-.856	.528	-.348	.112
	Ostomy type	.487	.331	.188	.147	-.007	.395	-.003	.985
	Type of effluent	-.341	.811	-.055	.676	.997	.855	.159	.250
	Stoma/abd characteristics	**1.503**	**.407**	**.433**	**.000**	**1.269**	**.445**	**.365**	**.007**
	Stoma care proficiency	.119	.479	.032	.805	-.256	.507	-.070	.616
	ADL	-.796	.439	-.230	.075	-.819	.420	-.236	**.057**
	Pre-operative education by WOC	-.136	.329	-.054	.681	-.196	.377	-.078	.605
	Stoma site marked by WOC	.256	.306	.109	.408	.566	.375	.241	.138
	NPO status	-.882	.449	-.248	**.054**	-.496	.532	-.139	.356
	BMI	**1.375**	**.370**	**.435**	**.000**	**1.412**	**.427**	**.441**	**.002**
	Smoking	-.322	.447	-.093	.474	.122	.403	.035	.764
	Post-operative education by WOC	-.527	.480	-.143	.277	-.376	.525	-.102	.478

In conclusion, Ostomy Risk Factor Index total scores and Stoma Care Self-Efficacy scores at baseline were not found to predict Ostomy Complication Severity Index total score at follow-up. However, Stoma Care Self-Efficacy scores at follow-up were found negatively associated with Ostomy Complication Severity scores (r= -300, p=.05). These findings indicate that patients with lower stoma care self efficacy at 30 to 60 days had higher incidence and severity of ostomy complications.

Ostomy Risk Factor Index total scores did not predict overall Ostomy Complication Severity Index scores. Therefore, findings do not support the use of the ORFI total score to predict ostomy complications. However, specific individual risk factors were related to the incidence and severity of ostomy complications, suggesting that assessing individual risk factors contained in the ORFI may be helpful to identify individuals at risk for ostomy complications and develop and target specific interventions for these at risk individuals.

Hypothesis 4d. Pittman Ostomy Complication Severity Index (OCSI) scores and Stoma Care Self-Efficacy (SCSES) scores at baseline and follow-up will be correlated with Ostomy Adjustment scores (OAI-23) at 30 to 60 days post-operatively.

Construct validity of the newly developed ostomy complications instrument (OSCI), was evaluated by examining the relationships among ostomy complications, stoma care self-efficacy, and ostomy adjustment. In order to examine the relationship among OCSI total scores, Stoma Care Self-Efficacy scores, and OAI-23 total scores, analyses using Pearson correlation coefficients were conducted.

Forty-six percent of the participants scored below the mean (55.2) on the Ostomy Adjustment Index-23. Higher scores on the OAI-23 indicated better ostomy adjustment. A significant negative correlation of r= - 0.27 (p=.04) was observed between total scores on the OCSI and the OAI-23. These results indicate that participants with higher incidence and severity

of ostomy complications, had more difficulty adjusting to having an ostomy. These findings are presented in Table 16.

Table 16. Correlations between Ostomy Complication Severity Index and Ostomy Adjustment Inventory-23 total scores

Variables	OCSI Total score	OAI Total score	*p*
OCSI Total score	---	-.27	**.04**
OAI-23 Total score	-.27	----	**.04**

Stoma Care Self-Efficacy scores at baseline (r= .402, p= .002) and at follow-up (r= .599, p= .000) were positively associated with Ostomy Adjustment scores. This indicates that participants who were more confident in caring for their stoma, both at baseline and at follow-up, had higher ostomy adjustment scores, indicating better adjustment. Stoma care self-efficacy and factors that influence it may be an important area that warrants further investigation. These findings are presented in Table 17.

Table 17. Pearsons Correlations between Stoma Care Self-Efficacy Scale total scores at baseline and follow-up, and Ostomy Adjustment Inventory-23 scores

Variables	**SCSES Total score (baseline)**	**SCSES Total score (follow-up)**	**OAI Total score**	*p*
SCSES Total score (baseline)	---	.474	.402	**<.002**
SCSES Total score (follow-up)	.474	---	.599	**.000**
OAI-23 Total score	.599	.599	----	**.000**

In summary, there was a significant inverse relationship between the development of ostomy complications and ostomy adjustment in this study. The higher the OCSI total score, the lower the OAI-23 score, indicating that the higher the incidence and severity of ostomy complications, the poorer the participants adjustment to having an ostomy. In addition, there was a significant relationship between stoma care self-efficacy and ostomy adjustment. Participants who were more confident in caring for their stoma, had adjusted better to having an ostomy.

Conclusion

In conclusion, the aims of this study were accomplished. Prevalence of specific risk factors for ostomy complications were determined, incidence and severity of early ostomy complications were described, and two newly developed instruments were developed and tested. Two clinically useful instruments were developed based on a systematic approach and guidelines established by DeVellis (2003). These instruments were carefully evaluated by an experienced panel of experts and content validity was established. Psychometric properties of the ORFI and OCSI were examined and both instruments demonstrated acceptable content validity, inter-rater reliability and construct validity. Although total ORFI scores and total OCSI scores were not correlated, the ORFI can be used at the item level to identify risk factors and the potential for ostomy complications.

The findings of this study provide valuable information regarding risk factors for the development of ostomy complications. This study generated new knowledge about the incidence and severity of ostomy complications in the early post-operative period. This study also generated two new instruments that with revision could be used by busy clinicians to reliably identify and measure important risk factors and outcomes (complications) that affect care of the patient with an ostomy.

CHAPTER FIVE

DISCUSSION

This chapter presents a summary of this study followed by a discussion of the major findings. In addition, limitations of the study, implications for future research, and conclusions will be discussed.

Summary of the Study

There are more than 800,000 individuals who currently live with an ostomy in North America and more than 120,000 new ostomies are created annually (Kelman & Minkler, 1989; Turnbull, 2003). Complications following the surgical creation of an ostomy are a common and significant problem for many individuals. Ostomy complications often have both physiological and psychosocial aspects. Physiologic ostomy complications involve changes of the stoma and peri-stoma skin (Cottam et al., 2007). Psychosocial ostomy complications involve the challenges individuals face in adjusting to living with an ostomy (Carlsson et al., 2001).

Risk factors that contribute to the development of ostomy complications have not been well established in the literature. Study design differences, inconsistent definitions and terminology, and timing of measurements make it difficult to accurately compare findings about ostomy risk factors across studies. In addition, there are few valid and reliable instruments available to measure risk factors, incidence, and severity of ostomy complications. The purposes of this study were to : 1) identify the most common risk factors that contribute to the development of fecal ostomy complications; and 2) describe the incidence and severity of early fecal ostomy complications 30 to 60 days post-operatively. A secondary objective of this research was to examine the reliability and validity of two instruments that will: 1) identify the risk factors for fecal ostomy complications, and 2) identify the incidence and severity of fecal ostomy complications. Findings of this study provide new knowledge about the prevalence of risk factors, the incidence and severity of ostomy complications, and the psychometric properties of two newly-developed instruments.

This prospective, longitudinal study used a convenience sample of 71 hospitalized adult patients who had undergone surgery to create a new fecal ostomy during their hospitalization, either colostomy or ileostomy. The participants were recruited from three sites within a large healthcare system. Data were collected at two points in time; baseline (five to seven days post-operatively) and follow-up (30 to 60 days post-operatively). At each data collection time point, participants completed two self-administered questionnaires (Baseline, patient survey and stoma care self efficacy; Follow-up, Ostomy Adjustment Inventory and Stoma care self efficacy). In addition, direct observation and physical assessment of the participant's stoma were performed and instruments were completed by the investigator (Baseline, Ostomy Risk Factor Index (ORFI), and Follow-up, Ostomy Complications Severity Index (OCSI)). Thirteen (18%) subjects were lost to follow-up and did not provide follow-up data. Two participants did not show up for follow-up appointments, two participants expired, and nine participants did not return multiple phone calls to schedule the follow-up visit.

The sample consisted of primarily white (96%) participants. There were nearly equal numbers of men (52%) and women (48%) and more than half (55%) were married or partnered. More than half the participants had a college education, 30% were employed, and more than 25% did not have enough finances to make ends meet. Results showed that 84% of participants had at least one ostomy complication present 30 to 60 days after surgery. Almost 60% of participants experienced leakage of their pouching system and 50% had peristomal irritant dermatitis. Thirty-seven percent of participants had stomal pain and 30% had stomal or peristomal bleeding. For 37% of participants, their stoma had retracted to skin level or below. Thirteen percent of participants had mucocutaneous separation, 2% had stomal necrosis, 5% had stomal stenosis, and 5% had hyperplasia. Forty-six percent of the participants scored below the mean (55.2) on the Ostomy Adjustment Index-23 (lower scores indicate poorer adjustment).

One strength of this study was the development and use of the Ostomy Complication Conceptual Model as a guiding framework to examine relationships among risk factors, ostomy

complications, self-efficacy, and ostomy adjustment. Because there has been limited use of theoretical models in ostomy research, there are wide variations in study design, inconsistent conceptual definitions of constructs, and few valid and reliable measures to examine outcomes. Comparing research findings across studies becomes very difficult. The Ostomy Complication Conceptual Model was developed by the investigator based on a comprehensive review of literature and extensive clinical experience. The Ostomy Complication Conceptual Model illustrates the relationship among demographic risk factors (age, gender, income, education, employment, partner status), environmental risk factors (pre-operative education, post-operative education, stoma care proficiency, stoma site marking by WOC nurse, and ADL functioning), clinical/physiological variables (type of effluent, stoma/abdomen characteristics, nutrition, BMI, smoking status, diagnosis, ostomy type, timing of surgery, and comorbidities), stoma care self-efficacy, early ostomy complications, and ostomy adjustment.

Two clinically useful instruments were developed to measure ostomy risk factors and ostomy complications using a systematic approach and guidelines established by DeVellis (2003). Psychometric properties of the ORFI and OCSI were examined and both instruments demonstrated acceptable content validity (CVI= .90). Inter-rater reliability of the ORFI individual categorical items was tested using Cohen's coefficient kappa and ranged 0.40 to 1.0. ORFI total scores demonstrated acceptable inter-rater reliability with Pearson coefficient correlation .999. OCSI individual item Cohen's coefficient kappa ranged 0.71 to 1.0. and OCSI total score Pearson coefficient correlation of .999 demonstrating acceptable inter-rater reliability. Acceptable internal consistency reliability for the OCSI was demonstrated with Cronbach's alpha of .68.

Discussion of Important Findings

This study provides new knowledge regarding relationships between risk factors and ostomy complications. Major contributions of this study include information regarding incidence and severity of ostomy complications and important evidence of reliability and validity of two new instruments to measure risk factors and incidence and severity of ostomy complications. In

addition, important relationships among stoma care self-efficacy, ostomy complications, and ostomy adjustment were found. A discussion of these major contributions are presented in this section.

Relationships Between Risk Factors and Ostomy Complications

One of the aims of this study was to establish the relationship between ostomy risk factors and the development of ostomy complications. It was hypothesized that the total ORFI scores would predict total OCSI scores. Although this hypothesis was not confirmed, relationships among important individual risk factors and ostomy complications were supported by the findings. Risk factors were measured using the ORFI or collected from the medical record. The ORFI consists of 15 risk factor items (age, diagnosis, timing of surgery, ostomy type, type of effluent, stoma/abdomen characteristics, stoma care proficiency, ADL function, pre-operative education given by WOC nurse, stoma site marking by WOC nurse, NPO status, serum albumin, BMI, smoking status, and post-operative education given by WOC nurse). Scores on each item range from 1-4 with 1 representing lowest risk and 4 representing highest risk. Potentially, the higher the score the more at risk the patient is for the development of ostomy complications. Ostomy type, stoma/abdomen characteristics, BMI, ADL function, stoma site marking by the WOC nurse, and nutritional status are important risk factors that were found to be associated with ostomy complications.

There is overwhelming evidence in the literature that having an ileostomy, versus a colostomy, is associated with higher rate of complications (Cottam, 2005; Cottam et al., 2007; Del Pino et al., 1997; Lefort et al., 1995; Leong et al., 1994; Park et al., 1999; Pittman et al., 2008). In this study, ostomy type was categorized on the ORFI in order from lowest to highest risk where: 1= sigmoid colostomy, 2= transverse colostomy, 3= ascending colostomy, or 4= ileostomy). Type of ostomy was significantly related to leakage (r= .31, p= .05) and peristomal irritant dermatitis (r= .26, p= .05). Those participants with a higher score, having either ascending colostomy or ileostomy, were found to have more leakage and peristomal irritant dermatitis.

These findings are consistent with other research studies in the literature (Caricato, 2006; Cottam, 2005; Courtney, 2009; Del Pino et al., 1997; Lefort et al., 1995; Leong et al., 1994; Park et al., 1999; Pittman et al., 2008).

Stoma/abdominal characteristics were defined by the shape and height of the stoma in relation to the abdominal surface and skin. Abdominal characteristics refer to the presence of skin folds and creases at the stoma site. The ORFI elicits a categorical response corresponding to the level of the stoma in relation to skin and alteration in the abdominal pouching surface. In this study, stoma/abdomen characteristics was significantly correlated with pain (r= .30, p= .05), bleeding (r= .28, p= .05), stomal necrosis (r= .28, p= .05), retraction (r= .57, p= .01), mucocutaneous separation (r= .30, p= .05), and overall OCSI total score (r= .43, p= .01). These findings indicated that participants with a flatter stoma and with more problematic skin folds and creases around the stoma had higher rates of pain, bleeding, stomal necrosis, and retraction.

It makes sense that stoma/abdomen characteristics would be more problematic in patients with a higher BMI as the thickness of the abdominal adipose layer is greater. Higher BMI can impact both the height of the stoma and can cause more problematic skin folds around the stoma. Evidence in the literature indicates that abdominal contours and BMI influence the development of ostomy complications (Arumugam, 2003; Cottam, 2005; Duchesne et al., 2002; Leenen & Kuypers, 1989; Mahjoubi et al., 2005; Richbourg et al., 2007). In this study, BMI was calculated from height and weight data obtained from the medical record. BMI was categorized on the ORFI in order of increasing risk for complications: 1= BMI 18.5-24.9; 2= BMI 24.9- 29.9; 3= BMI 30-35; or 4= BMI less than 18.5 or greater than 35. The categorical response for BMI on the ORFI is not linear, therefore, analysis was performed using Spearman's correlation coefficient. BMI as an item on the ORFI was positively correlated with leakage (r= .44, p= .01), peristomal irritant dermatitis (r= .29, p= .01), and overall OCSI total score (r= .36, p= .01). Using BMI data as a continuous variable, it was also found to be positively correlated with retraction (r= .28, p= .05), mucocutaneous separation (r=26, p= .05), in addition to leakage (r=36, p= .01), and ostomy

complication total score (r= 32, p= .05). These findings contribute to and are consistent with the evidence that higher BMI is a risk factor associated with ostomy complications, specifically leakage, peristomal irritant dermatitis, retraction, mucocutaneous separation.

The findings in this study demonstrate that stoma/abdominal characteristics and BMI contribute to the development of several ostomy complications, specifically leakage, peristomal irritant dermatitis, pain, bleeding, stomal necrosis, retraction, and mucocutaneous separation. Furthermore, regression analysis demonstrated that stoma/abdominal characteristics (p= .003) and BMI (p= .007) were significant predictors of ostomy complications total scores. These findings indicate that using the ORFI as a risk assessment tool, higher scores on the stoma/abdominal item predict higher ostomy complication and severity total scores. Also, higher scores on the BMI item predict higher ostomy complication total scores.

Another important finding indicated that greater independence in activities of daily living (ADL) function was associated with ostomy complications. ADL is defined as functions that are normally performed by the participant in daily living including bathing, dressing, toileting, transferring, continence (bladder), and feeding (Katz et al., 1963). The number of ADL functions participants needed assistance with were tallied by the investigator and a categorical response was identified using the ORFI. Higher ADL scores indicated greater assistance was needed with activities of daily living. In this study, ADL function was inversely correlated with pain (r= -.32, p= .05) and bleeding (r= -.25, p= .05), and positively correlated with stomal stenosis (r= .29, p= .05). Higher ADL scores were associated with lower pain and bleeding scores and higher stomal stenosis scores. These findings are difficult to interpret but one explanation may be that participants needing more assistance with ADL's were not performing their own ostomy care and had a skilled caregiver performing ostomy care. Alternatively, those individuals with lower ADL scores (are more independent) were more active thus incurring more complications? Nevertheless, the meaning of these relationships is unclear and requires further study.

Three major risk factors examined in this study that provide opportunities for WOC nursing intervention include stoma site marking, pre-operative education, and post-operative education. Of these WOC nursing interventions, only not having their stoma site marked was associated with greater number and severity and ostomy complications, specifically stomal retraction ($r = .32$, $p = .01$) and mucocutaneous separation ($r = .30$, $p = .05$). This results indicate that participants who did not have their stoma site marked pre-operatively by a WOC nurse had higher incidence and severity of stomal retraction and mucocutaneous separation. These findings are consistent with those of studies where having the stoma site marked by the WOC nurse and fewer ostomy complications was observed (Bass et al., 1997; Gulbiniene et al., 2004; Park et al., 1999; Pittman et al., 2008). The Wound, Ostomy and Continence Society recently published best practice guidelines recommending stoma site marking pre-operatively to reduce the incidence of complications and improve self-care (Goldberg, 2010). In addition, a joint position statement was developed and published by the American Society of Colorectal Surgeons and the Wound, Ostomy and Continence Society (2007) recommending every patient undergoing ostomy surgery have their stoma site marked by a colorectal surgeon or ostomy nurse (American Society of Colon and Rectal Surgeons Committee Members & Wound Ostomy and Continence Nurses Society Committee Members, 2007). The results of this study support the need for these recommendations.

Finally, in this study, nutrition status was another risk factor that was associated with ostomy complications although in directions that were not expected. Malnutrition has been found to increase post-operative morbidity, mortality, and duration and cost of hospital stay (Chiang, 2007). Although there is no single, effective laboratory indicator for nutritional status, in order to measure this important factor, nutrition was examined by collecting data regarding serum albumin level and number of days restricted from eating (NPO). Unfortunately, only 27 patients had serum albumin levels documented in their medical record. Therefore, this measure was omitted from the ORFI total score and was not examined. However, NPO status was shown to be

significantly associated with a number of ostomy complications. NPO status was collected by review of the physician's dietary orders for the patient and identifying the specific number of days the patient was restricted from eating (NPO). The number of days that the patient was restricted from eating was categorized using the ORFI. Higher NPO scores indicated more days restricted from eating. In this study, NPO status was negatively correlated with bleeding (r= -.35, p= .01) and overall OCSI total score (r= -.25, p=.05). The negative correlation indicates that the longer the patient was NPO, the lower their incidence and severity of bleeding and the lower their total ostomy complication score. These findings are not consistent with current evidence regarding nutritional status and the link to post-operative complications such as mortality, morbidity, wound healing, and sepsis (Dempsey et al., 1988; Duncan et al., 2006; Keele et al., 1997). The findings in our study regarding nutrition may be indicative of the lack of an accurate nutrition marker to measure this important risk factor. The findings also indicate a need for revision of the ORFI subscales regarding nutrition (albumin and NPO status). Regardless, further research is warranted regarding nutrition and the development of ostomy complications.

An interesting finding in this study were the differences in NPO status found among study sites. Significant differences in nutritional status were observed across sites (p= .000). Eleven of 17 participants (65%) at site 1 were NPO for more than five days post surgery compared to only four of 42 (10%) at site 2 and four of 11 (36%) at site 3. There was no significant difference in the incidence or severity of ostomy complications across study sites although rates of stomal retraction were approaching significance (p=.052).

Finally, while gender has been examined in a limited number of studies, but these studies have found no significant relationships between gender and ostomy complications (Duchesne et al., 2002; Helman, 1990; Pittman et al., 2008). Only one recent retrospective study in Korea added new evidence about the relationship between gender and ostomy complications. In the study of 1,170 subjects in Korea with an end colostomy, female subjects had higher incidence of peristomal hernias (OR 1.5), flush stomas (OR 0.4), and retracted stomas (OR 0.3). Men were

found to have a higher incidence of hyperplasia (OR 1.9) (Sung, Kwon, & Park, 2010). Our study adds new evidence regarding relationships among gender and ostomy complications where gender was associated with specific ostomy complications, including leakage (r= .324, p= .05), and pain (r= .269, p= .05) as well as ostomy complication total scores (r= .320, p= .05). When comparing ostomy complications total scores between males and females, females had significantly higher mean ostomy complication scores (p= .02).

Often it is important to note what was not found when evaluating study findings. In this study, no significant relationships were found among ostomy complications scores and age, partner status, income, employment or education. The lack of a relationship between age and ostomy complications is especially interesting.

The average age of participants in this study was 57 years old ranging from 22 to 86 years, in contrast to the average age reported in the literature of 67 years or older. In several studies, older age has been consistently associated with the development of ostomy complications (Caricato, 2006; Harris et al., 2005; Helman, 1990; Mahjoubi et al., 2005; Park et al., 1999; Pittman et al., 2008; Sung et al., 2010). Six of these studies reported age was positively associated with increased risk of ostomy complications (Caricato, 2006; Harris et al., 2005; Helman, 1990; Mahjoubi et al., 2005; Park et al., 1999; Sung et al., 2010). Only one of these studies found that age was inversely related to the severity of skin irritation (p= 0.022), leakage (p= 0.007), and difficulty adjusting to an ostomy (p= $\leq$ 0.001). Younger subjects were more likely to report increased severity of all three of these complications (Pittman et al., 2008). However, in a recent study of 679 participants, age was not associated with the development of ostomy complications (Liu et al., 2010). Although the findings in our study did not indicate a significant association between age and ostomy complications, age did approach significance as a predictor of ostomy complications (p= .053).

Ostomy Complications Incidence and Severity

This study contributes valuable information regarding the incidence and severity of early fecal complications. Fifty-two (84%) participants developed at least one ostomy complication 30 to 60 days post-operatively. Ostomy complications have been reported to be common in the patient with an ostomy and our findings are consistent with this (Ratliff et al., 2005). Leakage was one of the most commonly occurring complication with almost 60% of the participants experiencing this problem. Peristomal irritant dermatitis was the next most commonly occurring complication with 50% of the participants experiencing it. This is consistent with other research that has reported peristomal irritant dermatitis rates of 55% (Colwell, et al., 2001).

Stomal pain (42%), retraction (39%), and stomal bleeding (32%) were the next most common complications found in our study. Finally, the least commonly occurring complications were mucocutaneous separation (14%), stoma stenosis (5%), hyperplasia (5%), and stomal necrosis (2%) respectively. Again, these findings are consistent with other research reported in the literature (Colwell, et al., 2001; Salvadalena, 2008).

The issue of timing of complications may be important as we consider the low incidence of a few of the ostomy complications (stomal stenosis, hyperplasia, and stomal necrosis) that occurred in this study. The low incidence may demonstrate that these complications occur later than 30- 60 days post operatively. The OCSI may provide improved measurement of early complications if the complications with the lowest incidence were omitted. Alternatively, with revision to include parastomal hernia and prolapse, the OCSI may provide a more complete measurement of both early and late ostomy complications.

An important and unique element in this study was the measurement of both the incidence and severity of ostomy complications. This important information is not found elsewhere in the literature. For example, 11% of the participants in this study had leakage more than once a day and 20% had moderate to severe peristomal irritant dermatitis. In practical terms, this means 20% of the participants had not only a rash and irritation around their stoma but also

loss of epithelial tissue similar to a second degree burn. Almost 10% of study participants rated their stomal pain as 7 or greater. Thirty nine percent had a stoma that was at skin level or below which often leads to leakage and peristomal irritant dermatitis. The majority of those with stomal bleeding had superficial stomal bleeding, but 2% had stomal bleeding that required medical intervention (sutures or transfusion). No other studies were found that reported ostomy complication severity in the detail provided by using the OCSI.

Instruments to Measure Risk Factors and Ostomy Complications

Psychometric properties of two newly developed instruments were tested in this study; the Ostomy Risk Factor Index (ORFI) and the Ostomy Complication Severity Index (OSCI). The ORFI demonstrated acceptable content validity (CVI= 0.9). Expert ratings also provided evidence of content validity for clarity, comprehensiveness, and appropriateness. The ORFI demonstrated acceptable inter-rater reliability for 10 of the 14 items (k=1.0) and an excellent correlation of total scores between raters (r= .999, p= .035).

The OSCI demonstrated acceptable content validity (CVI= 0.9). Expert ratings also provided evidence of content validity for clarity, comprehensiveness, and appropriateness. The OCSI demonstrated acceptable inter-rater reliability for all of the items (k= .71- 1.0) and excellent correlation of total scores between raters (r= .999, p= .000). Internal consistency reliability for the OCSI was supported by a Cronbach alpha of .68 (n= 9).

There are few valid and reliable instruments in the literature for ostomy research and those that are available measure the psychosocial aspects of having an ostomy rather than physiological outcomes. Recently, an instrument was developed to measure peristomal skin lesions (McCann, 2010). However, this instrument was limited to measuring skin injury around the stoma and did not address complications involving the stoma such as mucocutaneous separation, retraction, stomal stenosis, stomal necrosis, pain, or bleeding. Content validity for this instrument was demonstrated with a CVI of .94 (Beitz et al., 2010). There was no report of reliability testing or other psychometric properties for this instrument.

Recently, another method for diagnosing and selecting treatment options for ostomy complications was reported. Investigators developed an algorithm to facilitate a uniform approach to diagnose and treat ostomy complications. However, this algorithm has yet to be validated (Kalashnikova, Achkasov, Fadeeva, & Vorobiev, 2011).

Our study findings provide evidence of reliability and validity of two new clinically useful instruments to measure risk factors and severity of ostomy complications. Each instrument is brief, easy to use, and clinically practical. In spite of the finding that the total ORFI scores and the total OCSI scores did not correlate as expected, the ORFI and OCSI provide additional resources for the researcher and busy practitioner to document and measure ostomy risk factors and complications for patients with an ostomy.

Relationships among Stoma-care Self Efficacy, Ostomy Complications, and Ostomy Adjustment

Other major contributions of this study are the relationships found among several other variables included in the Ostomy Complications Conceptual Model; stoma care self-efficacy, ostomy complications, and ostomy adjustment. Self-efficacy, or the “strength of one’s convictions in his/her own effectiveness" explains a wide range of coping and behaviors when studying the adjustment of patients to multiple demands of illness or disease (Bandura, 1977). Task-specific self-efficacy is defined as the expectation regarding one’s ability to perform a specific task or behavior (Bekkers et al., 1995). Self-efficacy is especially pertinent when considering the technical aspects of ostomy management and pouching procedures.

Ostomy adjustment has been described as the overall impact of the stoma on psychological, social and sexual functioning, as perceived by the patient (Simmons et al., 2007). In a study examining ostomy adjustment and its relationship with stoma acceptance and social interaction, the investigators found that ostomy adjustment was associated with stoma care self-efficacy ($p = .0001$) (Simmons et al., 2007).

In this study, we examined the relationships among stoma care self-efficacy, ostomy complications, and ostomy adjustment. We measured stoma care self-efficacy at two time points; at baseline and at follow-up. Stoma Care Self-Efficacy scores at baseline did not predict Ostomy Complication Severity Index total scores at 30-60 days. However, Stoma Care Self-Efficacy scores at follow-up were negatively associated with Ostomy Complication Severity scores (r= -300, p=.05). This indicates that participants with lower stoma care self-efficacy scores had higher ostomy complication scores, meaning the less confident the participant was in their stoma care, the more ostomy complications that they had. These findings could also be interpreted as those participants with more ostomy complications had less confidence in their ability to care for their stoma. These findings lead us to question, which comes first, ostomy complications or confidence in caring for the stoma? This is an important finding indicating that stoma care self-efficacy and the factors that influence it is an area that warrants further study.

Ostomy adjustment has been defined as "the overall impact of the stoma on psychological, social, and sexual functioning as perceived by patients" (Simmons et al., 2007). Psychosocial ostomy complications involve the challenges individuals face living with and adjusting to the ostomy (Carlsson et al., 2001; Cottam et al., 2007). Some of these challenges involve body image concerns, intimacy concerns, return to recreational and social activities, while living with an ostomy and is often a significant challenge to the post-operative adjustment of having an ostomy. Successful psychosocial adjustment is often the key to full recovery and return to pre-surgery level of functioning (Olbrisch, 1983).

In addition to the relationship between stoma care self-efficacy and ostomy complications, we also examined the relationship between ostomy complications and ostomy adjustment. In this study, Ostomy Complication Severity Index total scores were inversely related to Ostomy Adjustment scores (r= -.265, p= .05). Participants who had more difficulty adjusting to having an ostomy, had higher incidence or more severe ostomy complications. To summarize, incidence and severity of ostomy complications was associated with the participants adjustment

to their ostomy and their confidence in caring for their ostomy. This is another finding that leads us to question, which comes first, ostomy complications or the ability to adjust to having an ostomy? Does the presence of complications lead to poorer adjustment? Does better adjustment to having an ostomy lead to fewer complications? These are important questions and these findings indicate that ostomy adjustment and the factors that influence it is an area that warrants further study.

In our literature search, no studies were found that specifically examined relationships between ostomy adjustment and ostomy complications. However, one study did report that the technical difficulty of managing an ostomy was the most frequently encountered problem area (84%) and was negatively correlated with psychosocial adjustment (Follick et al., 1984). Technical difficulties are commonly encountered when ostomy complications (leakage, irritant dermatitis, etc.) occur and a complicated pouching procedure is necessary. The findings of our current study provide important new knowledge regarding the inverse relationship between ostomy complications and ostomy adjustment. These findings are consistent with the relationships of variables depicted in the Ostomy Complications Conceptual Model.

In order to better understand the relationship among stoma care self-efficacy, ostomy complications, and ostomy adjustment, we also examined the relationship between stoma care self-efficacy at follow-up and ostomy adjustment. While baseline self-efficacy scores did not predict later adjustment, we observed that Stoma Care Self-Efficacy scores at follow-up (30 to 60 days post-operatively) were positively associated with Ostomy Adjustment scores (r= .599, p= .01), indicating that the more confident participants were in caring for their ostomy at follow-up, the better they adjusted to having an ostomy. These are important findings when considered in light of the study of 239 veterans by Pittman and colleagues (2008). This study found that difficulty adjusting to an ostomy predicted Health Related Quality Of Life (HRQOL) (p= < .001) (Pittman et al., 2008). Participants who adjusted well to having an ostomy, had better quality of life. Stoma care self-efficacy may be an important concept to examine and target as an outcome

when developing interventions to improve ostomy adjustment. Stoma care self-efficacy, ostomy complications, and ostomy adjustment are important concepts when considering the care of a patient with a new ostomy and this study provides valuable evidence related to the associations between these variables.

In summary, this study provides new knowledge regarding risk factors associated with the development of ostomy complications. In addition, two risk factors were found to predict ostomy complications; stoma/abdomen characteristics ($p = .007$) and BMI ($p = .002$). As the momentum for evidence-based practice accelerates, the need for standardized language and validated tools for ostomy care becomes compelling (Beitz et al., 2010). This study's findings provide evidence of reliability and validity of two new instruments to measure risk factors and incidence and severity of ostomy complications. In addition, stoma care self-efficacy and ostomy adjustment were found to be associated with incidence and severity of ostomy complications and are important concepts that should be considered in the care of the patient with a new ostomy.

Limitations

Several limitations should be noted when interpreting the results of this study. One important limitation was the use of two newly established instruments, the Ostomy Risk Factor Index (ORFI) and the Ostomy Complications Severity Index (OCSI). Because no other appropriate instruments were identified to measure ostomy complications and their severity or ostomy risk factors, it was necessary to develop two new instruments for this study.

Another limitation of this study was the small sample size used to examine inter-rater reliability. Due to unforeseen circumstances only a small number of subjects were included in these analyses and further reliability testing is recommended. Notwithstanding, it should be noted that the ORFI demonstrated acceptable content validity and inter-rater reliability and the OCSI demonstrated acceptable content validity, inter-rater reliability, and internal consistency reliability.

Another limitation relates to the presence of experienced, expert WOC nurses at each study site. In this study, expert WOC nurses provided pre-operative education, stoma site marking pre-

operatively, post-operative education, and ongoing ostomy management during the patients' hospital stay. Therefore, generalizability of results may be limited to those healthcare settings with WOC nurses. There is limited data regarding the actual numbers of expert WOC nurses employed in acute care settings but we know they are not always available in every acute healthcare facility and many smaller systems do not offer this advanced level of nursing care. These settings may provide a different level of care and have different ostomy outcomes including complication rates. Complication rates between settings have not been extensively studied and differences may be difficult to evaluate due to the potential number of confounding factors (patient acuity, number/type of surgeries, provider/clinician expertise, WOC nurse presence, etc.).

Finally, the potential for selection bias may be another limitation of this study. This sample may not represent the average population undergoing ostomy surgery. In this study, the majority of subjects were recruited from two large urban healthcare hospitals. One facility was an academic teaching hospital setting and the other a large Level 1 Trauma Center. The population within these two sites were critically ill or had multiple comorbidities and high acuity. Fortunately, this study was able to enroll a small number of subjects from a smaller community acute care facility that may be more representative of smaller healthcare settings. The addition of the smaller community hospital setting increased the generalizability of the study findings.

Implications for the Future

This study has important implications for the future in two major areas; research and clinical practice. One major strength of this study was the use of the Ostomy Complication Conceptual Model as a guiding framework for identifying specific risk factors, ostomy complications, self-efficacy, and ostomy adjustment. Because the use of theoretical models in ostomy research has been limited, there are variations in study design, inconsistent definitions and terminology, and few valid and reliable measures for data collection. Comparing research findings becomes very difficult. The use of a conceptual model when developing a research study is helpful as it contains the concepts and organization that lead to development of the variables

and the testable hypotheses. The conceptual model guides the choice of empirical indicators (Fawcett, 2005). This study design and use of a theoretical model specific to ostomy issues provided a structured and systematic approach for examining ostomy complications and the factors that may influence them.

Another major contribution of this study is the development and testing of two new instruments to measure risk factors and ostomy complications for the researcher. In an area where there are limited instruments available, these instruments, with revision, provide reliable and valid methods for measuring ostomy risk factors and ostomy complications.

The findings of this study have important implications to the clinical practice of healthcare providers who care for these patients, including surgeons, WOC nurses, and bedside nurses. The findings provide valuable contributions to the existing evidence regarding the outcomes of this common surgical procedure. Results from our study also provide new knowledge that may guide the development of interventions to avoid or decrease the severity of ostomy complications.

The ORFI and the OCSI are instruments that have great potential to be easily translated into clinical practice. They provide an objective method for examining potential risk factors and a method to measure the presence and severity of ostomy complications. The format and brevity of both instruments make them easy to use and applicable to the clinical setting. For example, the ORFI could be used in the immediate post-operative period to identify individual risk factors prior to discharge in order to target appropriate discharge plans. The OCSI could be used to objectively measure the severity of early ostomy complications and subsequent improvement or worsening of those complications.

These instruments have great potential for use by both the researcher and the clinician but there is an opportunity for improvement with appropriate revision and testing. For example, the findings of this study indicate that revising the nutrition items (albumin and NPO status), merging ostomy type into three categories (sigmoid colostomy, ascending and transverse colostomy, and

ileostomy), and examining ADL categories of the ORFI may be beneficial. Findings also indicate that with the addition of late-occurring complications (prolapse and parastomal hernia, the OCSI could be used to measure the incidence and severity of both early and late ostomy complications.

Finally, the findings regarding stoma care self efficacy, ostomy complications and ostomy adjustment have important implications. The literature demonstrates that ostomy complications occur frequently and that adjustment can be difficult for individuals living with an ostomy. Not only does the individual have to cope with a serious and often life-threatening diagnosis but the placement of an ostomy requires significant changes to one's lifestyle. Individuals with an ostomy face difficulty adjusting to and coping with their new ostomy, social isolation, occupational changes and challenges in daily living. Ostomy complications make adjustment even more difficult because they often require complex ostomy management techniques causing interruption of daily, occupational, social, and physical activities. Despite the many improvements that have occurred in the management of an ostomy, including advanced surgical techniques/procedures and innovative new ostomy equipment, ostomy complications continue to commonly occur. This study generated important new knowledge for both the researcher and the clinician regarding potential areas for intervention development. Stoma care self-efficacy, ostomy adjustment, and risk factors contributing to ostomy complications are important areas of investigation for future research.

Conclusion

Research has shown that ostomy complications negatively affect the quality of life for individuals living with an ostomy, and often result in physical and psychosocial limitations for these individuals and their families (Pittman et al., 2008). Not only does the person with an ostomy have to cope with a serious and often life-threatening diagnosis, but the placement of an ostomy requires significant changes to one's lifestyle. The findings of this study provide important information regarding risk factors specific to the development of ostomy complications. This study findings also confirm the available evidence that ostomy complications

are a common problem following ostomy surgery (Smith, 1992). This study used a prospective longitudinal design, consistent definitions and terminology, and well-defined timing of measurements. In addition, this study provided evidence of reliability and validity for two new instruments to measure risk factors and severity of ostomy complications. These instruments, with revision, may provide additional resources for the WOC nurse and other healthcare providers when providing care to those individuals with new ostomies.

This study makes important contributions to the evidence related to ostomy complications and risk factors. Studying the incidence and severity of ostomy complications and the factors that lead to the development of such complications contributes new scientific knowledge and provides a foundation upon which to build future research. This new information may potentially lead to the development of interventions that will improve care and quality of life for individuals living with an ostomy.

APPENDICES

Appendix A: Pittman Ostomy Risk Factor Index (ORFI)

Pittman Ostomy Risk Factor Index Time **Baseline: 5-7 Days Post surgery _____** Subject ID:_____					
For each item assign the score above the corresponding description and document in the Total column on the right. Then total all risk factors for total score.					
Risk Factor	**1 ▼**	**2 ▼**	**3 ▼**	**4 ▼**	**Total**
Age	18-49	50-59	60-69	70+	
Diagnosis	Colon Cancer	Rectal Cancer	IBD (Chrohn's, UC)	Other Diagnosis (diverticulitis, trauma, other)	
Timing of Surgery	Planned/scheduled	xxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxx	Emergent	
Ostomy Type	Sigmoid Colostomy	Transverse Colostomy	Ascending Colostomy	Ileostomy	
Type of Effluent	Solid	Formed, Soft	Thick liquid	Liquid	
Stoma/Abd Characteristics	Above skin level, round, flat pouching surface	Above skin level, oval, Minor alterations in peri-stoma abd surface	Skin level, round or oval, peri stoma skin folds/creases problematic	Below skin level, oval, deep peri-stoma skin folds/creases	
Stoma Care Proficiency (Patient or Caregiver)	Independent/Competent= 0 cues	Requires minimal assist= 1-2 verbal cues	Requires moderate assist= ≥3 verbal cues	Unable/incompetent= unable without hands-on WOC assistance	
ADL Function	Independent in all 6 ADL functions	Minimal= dependent in 1-2 ADL functions	Moderate= dependent in 3-4 ADL functions	Total assistance= dependent in 5-6 ADL functions	
Pre-operative Education By WOC Nurse	All components received	2 components received	1 component received	No preop education received	
Stoma Site Marked by WOC Nurse	YES	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxx	NO	
NPO Status	NPO < 24 hours	NPO 1-2 days	NPO 3-4	NPO ≥5 days	

Serum Albumin	>3.0 g/dl	2-2.9 g/dl	1.0-1.9 g/dl	<1.0 g/dl	
BMI	Normal- 18.5-24.9	Overweight- 24.9-29.9	Severe Obesity-30-35	Underweight- <18.5 Morbid Obesity- 35+	
Smoking status	Nonsmoker	Past ex-smoker (> 2 mo)	Recent ex-smoker (< 2 mo)	Current smoker	
Post-operative Education	All items	3-4 items	1-2 items	No post education received	
Total →					

Pittman Ostomy Risk Factor Index (ORFI)

Instructions for Use

Complete the ORFI 5-7 days post surgery or prior to discharge. For each item write the *number (1 to 4) that corresponds to the appropriate category and mark in the Total column* on the right.

1. Age: (medical record or patient survey). Score 1= age 18-49, 2= age 50-59, 3= age 60-69, or 4= age 70 or greater.
2. Diagnosis: (medical record). Mark the corresponding score for the primary diagnosis related to the creation of the ostomy. Score 1= colon cancer, 2= rectal cancer, 3= IBD (Crohn's or Ulcerative Colitis), or 4= other diagnosis (diverticulitis, trauma, or other).
3. Timing of surgery: (medical record). Mark 1= planned or scheduled surgery or 4= for emergent surgery.
4. Ostomy Type: (medical record). Mark 1= sigmoid colostomy, 2= transverse colostomy, 3= ascending colostomy, or 4= ileostomy.
5. Type of Effluent: (observation). Mark the appropriate score for the consistency of the effluent or stool in the pouch. Mark 1= solid stool in the pouch, 2= formed but soft stool, 3= thick liquid (not formed) stool, or 4= liquid stool.
6. Stoma/Abdomen Characteristics: (observation). Mark 1= stoma that is above skin level, stoma is round, and surrounded by flat abdominal pouching surface, 2= stoma that is above skin level, is oval, and surrounded by minor alterations in abdominal pouching surface, 3= stoma that is skin level, is round or oval, and surrounded by abdomen that has skin folds/creases that are problematic, or 4= stoma that is below skin level, oval, and surrounded by deep abdominal skin folds/creases that are problematic.
7. Stoma Care Proficiency: (observation). Mark the appropriate score that describes the patient or caregiver's proficiency. Mark 1= the patient or caregiver that is independent and competent in completing the pouch change; 2= the patient or caregiver that requires less than 3 verbal cues to complete the task; 3= the patient or caregiver that requires 3 or more verbal cues to complete the task; or 4= the patient or caregiver that is unable to complete the task without hands-on assistance from the WOC nurse.
8. ADL Function: (patient survey). ADL Functions include bathing, dressing, toileting, transferring, continence (bladder), and feeding. Mark 1= the patient that is independent in all 6 ADL functions; 2= dependent in 1 or 2 ADL functions; 3= dependent in 3-4 of the ADL functions; 4= dependent in 5-6 ADL functions.
9. Pre-operative Education: (patient interview). Ask the patient, Did the Ostomy (WOC) nurse explain: 1) how your intestines or bowels work? (yes/no); 2) what kind of surgery, or operation, you will have (yes/no); and 3) what you can expect after your surgery (yes/no)" Tally the "yes" responses and Mark 1= 3 items, 2= 2 items, 1= 1 items, or 4= No items.
10. Stoma Site Marked by WOC Nurse: (patient interview and medical record). Ask the patient "Did you have the stoma site marked before surgery by the WOC nurse?". The information may also be collected from review of the medical record. Mark 1= YES and 2= NO.
11. NPO Status: (medical record). Mark 1= NPO less than 24 hours; 2= NPO 1-2 days; 3= NPO 2-4 days; 4= NPO greater than 5 days.
12. Serum Albumin Level: (medical record**).** Mark 1= albumen level of greater than 3.0, 2= albumen 2-2.9. 3= albumen of 1.0-1.9, 4= albumen less than 1.0
13. BMI: (Obtain height and weight from medical record). Divide weight in kilograms by height in meters squared. Mark 1= BMI 18.5-24.9; 2= BMI 24.9- 29.9; 3= BMI 30-35; or 4= BMI less than 18.5 or greater than 35.

14. Smoking status: (patient survey). Mark 1= nonsmoker and has never smoked; 2= quit smoking greater than 2 months ago; 3= quit smoking less than 2 months ago; or 4= current smoker.
15. Post-operative Education: (patient interview). Ask the patient, "Did the ostomy (WOC) nurse explain: 1) the ostomy surgical procedure (yes/no), 2) how to obtain your ostomy supplies (yes/no), 3) how to empty the pouch (yes/no), 4) how to change the pouch (yes/no), and 5) your diet with an ostomy (yes/no)?". Tally the "yes" responses and mark 1= all items; 2= 3-4 items; 3= 1-2 items; or 4= No items).

Appendix B: Medical Record Review **Time 1: 5- 7 Days Post Surgery _____**

Subject ID: _____
Date: _____

Investigator Initials: _____

Diagnosis:
1 ____ Colon Cancer
2 ____ Rectal Cancer
3 ____ IBD
4 ____ Other (Diverticulitis, Trauma, other)

Timing of surgery:
1 ____ Planned
2 ____ Emergent

Ostomy type:
1 ____ Sigmoid Colostomy
2 ____ Transverse Colostomy
3 ____ Ascending Colostomy
4 ____ Ileostomy

Stoma site marked pre-operatively:
1 ____ Yes
2 ____ No

Most Recent Serum Albumin: _____

NPO status: _____ (No. of days)
1 ____ < 24 hours
2 ____ 1-2 days
3 ____ 3-4 days
4 ____ 5 days or more

BMI: _____

Height: _____

Weight: ___

Appendix C: Patient Survey
5-7 days Post Surgery _____ **Subject ID: _____**

This group of questions will provide us with important information about you. Please answer the following questions by completing or checking the appropriate space.

1. What is your age? _____ years

2. What is your gender?

    1._____ Male
    2._____ Female

3. Are you currently….

    1._____ Married or living with a partner
    2._____ Single, never married
    3._____ Widowed, divorced, separated

4. Who will be primarily responsible for caring for your stoma?

    1._____ Self
    2._____ Spouse/partner
    3._____ Other, Specify: _____

5. Are you of Hispanic or Latin origin, such as Cuban, Mexican American, Puerto Rican, South or Central American?

    1._____ Yes
    2._____ No
    3._____ Unknown

6. What is your race?

    1. _____ African American or Black
    2. _____ White
    3. _____ American Indiana or Alaska Native
    4. _____ Asian
    5. _____ Native Hawaiian or other Pacific Islander
    6. _____ Unknown or Other: Please specify: _____

7. What is the highest grade or year of school that you have completed?

    1. _____ Less than High School
    2. _____ High school, Diploma or GED
    3. _____ Vocational school (e.g. Technical/secretarial/business)
    4. _____ Some college
    5. _____ Graduated from college with 4 year degree
    6. _____ At least some graduate work
    7. _____ Completed graduate degree

8. Considering your household income from all sources (today), would you say you are:

    1. _____ Comfortable
    2. _____ Just have enough to make ends meet
    3. _____ Do NOT have enough to make ends meet

9. What is your current employment status?

    1. _____ Employed full-time
    2. _____ Employed part-time
    3. _____ Not currently employed
    4. _____ Other: Please specify: _____

10. Has your doctor ever told you that you have: (Check all that apply)

    1. _____ Heart problems
    2. _____ High blood pressure
    3. _____ Diabetes or high sugar
    4. _____ Cancer
    5. _____ Rheumatoid Arthritis
    6. _____ Osteoarthritis or Degenerative Arthritis
    7. _____ Lung problems
    8. _____ Kidney disease
    9. _____ Ulcer or Stomach problems
    10. _____ Liver problems
    11. _____ Anemia or blood disease
    12. _____ Back pain or back problems
    13. _____ Depression
    14. _____ Other
        Please specify _____

11. Do you need assistance in:

    Bathing
        1. _____ Yes
        2. _____ No

    Dressing
        1. _____ Yes
        2. _____ No

    Toileting (going to the bathroom)
        1. _____ Yes
        2. _____ No

    Transferring from bed to chair
        1. _____ Yes
        2. _____ No

    Continence (controlling your bladder)
        1. _____ Yes

2. _____ No

Feeding yourself
1. _____ Yes
2. _____ No

12. Are you currently a smoker (check one)?

1. _____ No, I have never smoked
2. _____ No, I quit more than 2 months ago
3. _____ No, I quit less than 2 months ago
4. _____ Yes, I currently smoke

Thank you for taking the time to answer these questions. The information you have given is appreciated.

Please return the survey to the Ostomy Study Team.

Appendix D: Stoma-Care Self-Efficacy Scale (SCSES)
5-7 days post surgery____ 30-60 Days post surgery _____Subject ID: _____

STOMA-CARE SELF-EFFICACY SCALE
(Bekkers, 1996)

Circle who is completing: 1.-Patient, 2.-Caregiver

Mark an X in the column that indicates how confident you feel in response to each item.	**1 Not confident**	**2 Slightly confident**	**3 Fairly confident**	**4 Highly confident**	**5 Extremely confident**
1. Apply the stoma collection materials before leakages appear?					
2. Prevent having leakages?					
3. Take care of the stoma in the right way at home?					
4. Prevent having skin problems?					
5. Prevent having stoma bleeding and damage?					
6. Apply the stoma collection materials in the way you learned to do?					
7. Prevent having obstruction?					
8. Follow the WOC nurse's instructions for handling the stoma?					
9. Follow the doctor's advice for taking care of your stoma and nutrition					

pattern?					
10. Take care of the stoma in the right way outdoors?					
11. Take care of the stoma when you are ill?					
12. Wear most of the clothes you like?					
13. Carry out light duties in and around the house (for instance washing up and gardening)?					
TOTAL					

Appendix E: Ostomy Adjustment Index-23 (OAI-23)
30- 60 Days Post Surgery _____ Subject ID: _____

The statements below relate to how you feel about your stoma. For each statement please insert a √ in one of the boxes, "Strongly Agree" to Strongly Disagree" to indicate your agreement with the statement. Please try to answer all of the questions.

	Strongly Agree	Agree	Unsure	Disagree	Strongly Disagree
1. I feel that I have recovered from my stoma operation.					
2. I don't like to touch or see my stoma.**					
3. I have a meaningful life even with a stoma.					
4. I enjoy food and drinks as much as I did before my stoma.					
5. My stoma inhibits me from having a proper bath or shower.**					
6. I sleep well without worrying about my stoma.					
7. Because of my stoma I feel I am no longer in control of my life.**					
8. I am reluctant to mix socially since having my stoma.**					
9. I have now accepted my stoma as part of my body.					
10. I cannot get over the shock of having a stoma.**					
11. Because of my stoma I limit my range of activities.**					
12. Because of my stoma I feel that I will always be a patient.**					
13. I am always conscious that my stoma may leak, smell or be					

noisy.**					
Continued next page.... **14. I have accepted the changes in my appearance which were caused by the stoma.**					
15. I am grateful that the stoma has given me a new lease of life.					
16. Caring for my stoma is difficult.					
17. I feel that I am less sexually attractive because of my stoma.**					
18. I feel angry about having a stoma.**					
19. Despite my stoma I feel I have a rewarding life.					
20. I will be able to manage my stoma in the future.					
21. I am always anxious about my stoma.**					
22. With my stoma I feel that my life-threatening experience has passed.					
23. I can engage in a variety of activities despite having a stoma.					

****Reverse Scored**

Stoma PAIN:

Please choose (*circle*) a number from 0 to 10 that best describes your stoma pain:
0 1 2 3 4 5 6 7 8 9 10

Appendix F: Pittman Ostomy Complication Severity Index (OCSI) **Time 2: 30-60 Days post surgery _____**

Subject ID: _____

PITTMAN OSTOMY COMPLICATION SEVERITY INDEX					
For each item mark the score that corresponds to the description and mark in the Total column on the right. Then total all items for total score.					
Complication:	0 ▼	1 ▼	2 ▼	3 ▼	**Total**
Leakage	None	Approx. 1-2x/mo	Approx. 1-2x/wk	Approx. 1-2x/day	
Peristomal Irritant Dermatitis	None	Mild- erythema or rash but no skin loss. Skin intact	Moderate- Rash with skin loss <50% peri-stoma	Severe- Skin loss >50% peri-stoma	
Pain	0 	1, 2, 3 	4, 5, 6 	7, 8, 9, 10 	
Bleeding-stoma or peristoma	None	Superficial; Stopped easily	Moderate-persistent bleeding requiring prolonged pressure ≥10 min, AgNO3, cauterization, or hemostatic agent	Severe-requiring advanced medical intervention (sutures, transfusion)	
Stomal Necrosis	None	Stoma dusky	Stoma black ≤ 50 % or greater	Stoma black/dry > 50%	
Stomal Stenosis	None	Stoma Os <5th digit diameter, No pain or discomfort, Output normal	Stoma Os < 5th digit diameter, Ribbon-like output, Occasional discomfort.	Unable to insert any digit into stoma os, No output x ≥6 hrs, Abd pain and distention.	
Retraction	Stoma above skin level	Stoma level with skin	Stoma below level of skin	Unable to see stoma Or Stoma >2cm below skin	
Mucocutaneous Separation	None	1%- 49%	50%-74%	75 %- 100%	
Hyperplasia	None	1%-49%	50%-74%	75%-100%	
Total ——————————▶					

Pittman Ostomy Complication Severity Index (OCSI)

Instructions for Use

Complete the OCSI 30 days post surgery. For each item mark the number (0 to 3) that corresponds to the appropriate category and mark in the Total column on the right. The total all items for a Total score.

1. Leakage: (patient interview & observation). Ask the patient or caregiver, "Have you had any leakage of ostomy drainage that interfered with the seal of the skin barrier in the past 30 days?". If yes, ask how often, "approximately 1-2 times in past 30 days, or approximately 1-2 times per week, or approximately 1-2 times per day?". Mark 0= no leakage; 1= leakage that occurred approximately 1-2 times in past 30 days; 2= leakage that occurred approximately 1-2 times per week; or 3= leakage that occurred approximately 1-2 times per day.

2. Peristomal Irritant Dermatitis: (patient interview & observation). Ask the patient or caregiver, " Have you had any skin irritation around the stoma in the past week?" If yes, ask how much, "redness, or rash but no skin loss and skin is intact, or redness, or rash with skin loss that is less than 50% around the stoma, or redness, or rash with skin loss that is greater than 50% around the stoma?". Mark 0= no peristomal irritation; 1= peristomal erythema, redness, or rash but no skin loss and skin is intact; 2= peristomal erythema, redness, or rash with loss that is less than 50% of peristoma skin; 3= peristomal erythema, redness, or rash with loss that is greater than 50% of peristoma skin.

3. Pain: (patient interview). Ask the patient to rate their present stoma pain using the scale on the OCSI. Mark 0= no stoma pain; 1= stoma pain 1, 2, or 3; 2= stoma pain 4, 5, 6; 3= stoma pain 7, 8, 9, or 10.

4. Bleeding: (patient interview & observation). Observe the stoma for present bleeding. If there is no present bleeding, ask the patient or caregiver, "Have you had any bleeding from the stoma or around the stoma in the past week?" If yes, ask how much, 1) superficial and stopped easily, 2) Moderate and stopped after 10 minutes of pressure, or 3) Severe and did not stop and had to see a doctor. Mark 0= no stoma or peristoma bleeding; 1= stoma or peristomal bleeding that is superficial and stopped quickly; 2= stoma or peristomal bleeding that is persistent and requires either prolonged pressure ≥10 minutes, AgNO3 cauterization or hemostasis agent; 3= stoma or peristomal bleeding that requires advanced medical intervention (sutures or transfusion).

5. Stomal Necrosis: (observation). Mark 0= no stomal necrosis, stoma is pink and moist; 1= dusky stoma; 2= stoma that is less than or equal to 50% black; 3= stoma that is greater than 50% black.

6. Stomal Stenosis: (observation). Mark 0= stoma os that has no stenosis or narrowing; 1= stoma os that is less than 5^{th} digit diameter, with no pain or discomfort and output is normal; 2= stoma os that is less than 5^{th} digit in diameter, has ribbon-like output, and with occasional abdominal discomfort; 3= stoma os that is unable to accommodate the 5^{th} digit, no output x 6 hours or greater, and with abdominal pain and distention.

7. Retraction: (observation). Mark 0= stoma is above skin level; 1= stoma is level with the skin; 2= stoma is below skin level; 3= stoma is greater than 2 centimeters below skin level or is unable to be visualized.

8. Mucocutaneous Separation. (observation). Mark 0= no separation of the stoma from the mucocutaneous junction; 1= 1-49% separation of the stoma from the mucocutaneous junction; 2= 50-74% separation of the stoma from the mucocutaneous junction; 3= 75-100% separation of the stoma from the mucocutaneous junction.

9. Hyperplasia: (observation). Mark 0= no hyperplasia around the stoma; 1= hyperplasia that is 1-49% around stoma; 2= hyperplasia that is 49-74% around stoma; 3= hyperplasia that is 75-100% around stoma.

Appendix G: Literature Review Table

Source	Sample and Design	Variables/Instruments	Findings and Comments
Arumugam PJ, Bevan L, Macdonald L, Watkins AJ, Margan AR, Beynon J, Carr ND Colorectal Diseases	Prospective descriptive design. n= 97 patients over 1 yr		BMI, diabetes and emergency surgery were significant risk factors. Pre-operative siting by stoma nurses and the grade of operating surgeon did not affect the outcome.
Baldwin, C., Grant, M., Wendel, C., Rawl, S., Schmidt, M., Ko, C., Krouse, R.; 2008	Mixed method. n= 120 Purpose- to examine the spiritual QOL of veterans with intestinal stomas	Comparing male veterans with spiritual total QOL scores in the upper (n=59) and lower (n=61) quartiles of the COHQOL-Ostomy survey	The higher spiritual scoring group was more likely to be married, older, report more years since surgery.
Barr, J.	Overview of stoma complications and states a conceptual framework	None presented	General information.
Barrera, R., Shi, W., Amar, D., Thaler, H., Gabovich, N., Bains, M., White, D. (2005).	Prospective study. n= 300 pts with lung CA	None discussed	Smoking and timing of cessation. Risk of pneumonia was lower in nonsmokers thatn smokers.
Bass EM, Del Pino A, Tan A, Pearl RK, Orsay CP, Abcarian H Diseases of the Colon and Rectum	Descriptive retrospective comparison design. N=593 patients who underwent elective stoma surgery.	Group I- (n= 292) elective stoma surgery with pre-operative stoma site marking by ET nurse Group II- (n= 301) elective stoma surgery without pre-operative stoma site marking by ET nurse.	Comparison of number of total, early and late complications in the 2 groups. The difference in total number of complications between groups and early complications (necrosis, retraction, parastomal infection, skin problems) between groups was significant, with those subjects marked having fewer. Pre-op evaluation, marking and education reduced adverse outcomes.

Source	Sample and Design	Variables/Instruments	Findings and Comments
Beitz, J.; 1999	Qualitative phenomenogical design n= 10, purposive sample, using face-to-face interviews, audiotaped and transcribed	Interviews, audiotaped and transcribed lived experiences of individuals with an ileoanal reservoir	Multiple theme clusters were: restricted life world, living with uncertainty and fear, seeking control, vicious cycles: crisis and normalcy, seeking and giving support, alienation from the body, living with bodily alterations, the gift of time, role and relationship changes, and end of the tunnel but relative results.
Beitz, J., Gerlach, M., Ginsburg, P., Ho, M., McCann, E., Schafer, V., Scott, V., Stallings, B., Turnbull, G. (2010).	Content validation of a standardized algorithm for ostomy care.	Variables- ostomy complications	Content validity analyses presented.
Bekkers, M., Van Knippenberg, F., Van Den Borne, H., Van Berge-Henegouwen, G.; 1996	Descriptive, prospective longitudinal design. n= 59 patients Data collected at 3 time points- 1 wk, 4 mo, and 1 year	1) Stoma Self-efficacy Scale- 29 items, 2 factors- social functioning-related self-efficacy factor and stoma care-related SE factor. 2) Psychoscoial Adjustment to Illness Scale (PAIS-SR).	Stronger feelings of self efficacy shortly after surgery predicted fewer psychosocial problems in the first post-operative year. Stoma-care related self efficacy appears important in the first phase after surgery.
Bosio, G., Pisani, F., Lucibello, L., et al. 2007; Italy	Prospective observational design over 24 weeks. Group 1 (<1yr since surgery) N=656 Group 2 (>1 yr since surgery) N=339 Skin lesions examined at week 0, 4, 12, 24. Photos taken.	Age 25-91 62% male Content validation was conducted using an expert panel to validate the classification system of the complications observed by photos of the injuries, consensus conference, and questionnaire to 4 different experts.	Attempt at developing a universal classification instrument for peristomal skin irritation. No reliability or validity analysis was described except for the strength of agreement was rated “very good” (*K* value = 0.91). No description of the peristomal complications, items, or definitions was given.

Source	Sample and Design	Variables/Instruments	Findings and Comments
Caricato M, Ausania F, Ripetti V, Bartolozzi F, Compoli G, Coppola R. Colorectal Disease.	Retrospective study of patients with a stoma—included only those followed for 3 months by ET N=132	60 % complication rate Complications included dermatitis, parastomal hernia, leakage, stenosis	Younger patients and those with end colostomies have lower incidence of complications.
Carlsson, E., Berglund, B., Nordgren, S.; 2001	Qualitative design n= 6 with Crohn's disease	Semi structured interviews with a questionnaire, to describe the practical aspects of daily life of 5 areas: nutrition and excretion, ostomy problems, associated medical and surgical problems, socioeconomic situation, and social and leisure activities.	Most significant observation was the limited ability to act spontaneously, 3 said they had never accepted the ostomy, others would not return to pre-stoma lifestyle, limitations in social life reported
Castillo, R., Bosse, M., MacKenzie, E., Patterson, B., LEAP Study Group. (2005).	Impact of smoking on fracture healing and risk of complications in limb-threatening open tibia fractures.		
Chao, H., Tsai, T., Livneh, H., Lee, H., Hsieh, P.	Cross-sectional descriptive design; n= 110	Variables- acceptance of disability; Instrument- Acceptance of Disability Scale.	Those patients with shorter disease duration, stoma, lower education level, or Duke C1 stage or above reported lower levels of acceptance.
Chaudri, S., Brown, L., Hassan, I., Horgn, A.; 2004	RCT comparing pre-operative intensive, community-based education with conventional post-operative stoma education after elective colorectal surgery N= 42 randomized into 2 groups.	Intervention group included 2 preop visits, goal-directed post-operative education was standardized for both groups. Protocol for education given. Both groups were seen using the standardized education protocol post-operatively. This included post op visits at least 3 times (0-6 wks).	All outcomes (time to proficiency, hospital stay, and unplanned stoma-related community interventions per pt) were improved in the treatment group. Average cost savings per pt in tx group was $2,104. Hospital stay 8 days vs 10 days.

Source	Sample and Design	Variables/Instruments	Findings and Comments
Cheung, MT; 1995; Australia/New Zealand (Abstract)	Descriptive retrospective design. n= 316 patients with 322 stomas		End colostomies 48.5% Urological ileal conduits 38.2% Complications 66.8% Hernia-31.1%, stenosis- 10.2%, and prolapse 6.8%. Complications occurred earlier in colostomies than urostomies. (Does not state time frame).
Chiang, S., Gerten, K., Miller, K. (2007)	Opimizing outcomes of surgery in advanced age-perioperative factors to consider.		
Cingi, A., Cakir, T., Sever, A., Aktan, A.; 2006; Turkey	Descriptive prospective design using convenience sampling. Participants had stoma surgery over a 5-yr period (1/2000-1/2005) n= 46; 23 still had stoma, 23 had been repaired.		12 of the 23 had a hernia (52%) upon physical exam, 21 of the 23 (78%) were found to have hernia by CT (2 refused CT). Midline incisional hernias were found in 4 of the 21. In those with closed stomas- 6 of the 23 had incisional hernias and 5 had hernias at closed stoma site (by CT). Age, surgical site infection, BMI, ostomy site, post-operative chemotherapy, and radiotherapy did not contribute to incisional hernia formation.
Colwell J., Beitz J; 2007 JWOCN	Descriptive, mixed method design; mailed survey with 10 open-ended questions n= 686	RN's who include ostomy care in their professional practice were surveyed by mail to quantify the degree of validity of the stated stomal and peristomal definitions and interventions	Definitions and interventions were rated as valid. Survey validity index was .91, with definitions scoring higher than interventions. Qualitative analysis identified 10 themes

Source	Sample and Design	Variables/Instruments	Findings and Comments
Colwell, J., Gray, M.; 2007	Systematic review of the literature; 3 studies identified related to #1 3 studies identified related to #2	1) Does pre-operative teaching impact surgical outcomes in patients undergoing ostomy surgery? 2) Does preop stoma site marking impact surgical outcomes in patients undergoing ostomy surgery?	1) Limited evidence supports the conclusion that preop education by WOC nurse improves outcomes. 2) Sparce evidence supports that preop stoma site marking may reduce ostomy complications.
Coons, S., Chongpison, Y., Wendel, C., Grant, M., Krouse, R.; 2007	Descriptive; Secondary analysis of larger study. Cross-sectional. Quantitative data analysis of the ostomy group n= 239 veterans with a fecal ostomy	Outcomes- QOL & difficulty paying for ostomy supplies. Instrument- City of Hope Quality of Life Ostomy Questionnaire- 1 item "How good is your overall quality of life?"0 (poor)-10 excellent)	Those with reported difficulty paying for supplies had a lower QOL. Note: This study used a single item to measure QOL and correlated it to difficulty paying.
Cottam, J. 2005	Descriptive study across 9 centers in the UK, of 50 consecutive stomas over one year N=434 stomas	Outcome- problematic stoma. Instrument-	Problematic= needs one or more accessories to keep pt clean/dry for 24 hours. 134 or 30% were problematic. 59% of the problematic stomas had colorectal cancer. Loop Ileostomy had the most problems. 3 major problems were retraction (51%), mucocutaneous separation(20%), and necrosis (15%).

Source	Sample and Design	Variables/Instruments	Findings and Comments
Cottam, J., Richards, K., Halstad, A., Blackman, A. 2007	Descriptive design using a prospective audit of 50 stomas over 1 year for problematic stoma within 3 weeks of surgery. 93 hospital-based stoma services reported. N=3970. 1329 were problematic	Outcome- early problematic stoma. Complications defined as retraction, necrosis, mucocutaneous separation, A printed proforma was used to collect data	Problematic- needs one or more accessories to keep pt clean/dry x 24 hrs. that occurred within 3 wks of surgery. 34% stomas were problematic. Increased age, decrease problems; stoma height, gender, stoma type, increase BMI, loop ileostomies diagnosis, emergent surgery were significant risk factors; Most common problem- retraction, mc separation.
Del Pino, A.; 1997	Descriptive retrospective design over a 19-year period (1976-1995) n= 1758 stomas, 1044 (59%) were emergent,	Outcome- Complications of skin problems, parastomal problems (infection, separation), retraction, stenosis, necrosis, prolapse, and herniation. Instrument- none	35% of emergent stomas with complications, 55% with skin problems, 12% parastomal problems, 11% retractions, 4% stenosis, 12% necrosis, 3% prolapses, 3% herniated. 37% of nonemergent stomas had complications. Emergent stomas are NOT at greater risk for complications
Delgado-Rodriguez, M., Medina-Cuadros, M., Matinez-Gallego, G., Gomez-Ortega, A., Mariscal-Ortiz, M. Palma-Perez, S., Sillero-Arenas, M. (2003).	.Prospective cohort study design; n= 2,989	Variables- nosocomial infection, admission to ICU, in-hospital death, and length of stay.	A prospective study of tobacco smoking as a predictor of complications in general surgery
Dempsey, D., ; Mullen, J.; Buzby, G. (1988)	The link between nutritional status and clinical outcome: can nutritional intervention modify it?		
Duchesne JC, Wang YZ, Weintraub SL,	Descriptive retrospective design using the Charity	Outcome- complications and risk factors of procedures resulting in an	25% had complications, 39% occurred within 1 month of surgery. Complications

Source	Sample and Design	Variables/Instruments	Findings and Comments
Boyle M, Hunt JP Am Surg.	Hospital (New Orleans) database n=164	ostomy. Instrument- standardized collection form	included prolapse (22%), necrosis (22%), stenosis (17%), irritation (17%) infection (15%), bleeding (5%), retraction (5%). Complications were not related to location or type but to obesity and IBD. ET may be instrumental in preventing complications
Duncan, D., Beck, S., Hood, K., Johansen, A. (2006)	RCT comparing conventional nursing care with additional nutritional support; N=38	Variables- post-operative mortality rate in the acute care setting, at 4 mos post-operatively, length of stay, energy intake, and nutritional status.	Experiemtnal group were less likely to die in the acute care unit, and at 4 mo¸better mean energy intake, small reduction in mid-arm circumference.
Edlund, B.; 1981	Descriptive design with static group comparison of 3 units n= 15 Unit I- Ostomy care guide and resource ostomy nurses Unit II- No ostomy care guide, but did use ostomy resource nurses Unit III- No ostomy care guide, no resource ostomy nurses.	Outcomes- 1) Documentation of care 2) Comprehensiveness of care 3) patient self-care Using Chart audit form, nursing audit form, subject questionnaire, subject follow-up interview	Outcomes not clearly defined. Documentation of care was poor, 7/15 charted discharge information taught but not specifics, nursing audits indicated that nurses performed more activities than documented, subjects on Unit I were aware of step-by-step process and more return demonstration opportunities; Unit III subjects had more problems managing their ostomies, Nurses felt ostomy care guide was valuable in assisting them in teaching strategies but did require more paperwork.
Edwards, D., Leppington-Clarke, A., Sexton, R., Heald, R., Moran, B.; 2001	RCT comparing outcomes of loop ileostomy and loop colostomy n= 70; temporary ileostomy (n=34), colostomy (n=31) from the UK, age 32-90, 70% male	Outcomes- ostomy complications Instrument/Measure- none described	Hernia: 0 ileostomy, 6% colostomy; prolapse- 0 ileostomy, 6% colostomy; high output- 3% ileostomy, obstruction- 3% colostomy; fistula- 3% colostomy, wound infection- 3% ileostomy, 6% colostomy; DVT, PE included as complications. Colostomy group had significantly more

Source	Sample and Design	Variables/Instruments	Findings and Comments
			complications
Follick, M., Smith, T., Turk, D.; 1984	Descriptive study using mailed questionnaire. n= 131 ostomy patients, 59 males	Outcome- Ostomy adjustment difficulties Questionnaire has 6 clusters of items: technical management, emotional adjustment, social adjustment, family/marital adjustment, sexual adjustment, and occupational adjustment; plus items r/t received adequacy of information provided about procedure, and about social support availability. 66 items.	Technical difficulties were associated with impaired emotional, social, and marital/family functioning; emotional difficulties were associated with problematic social, marital/family adjustment, and impaired sexual functioning; technical, emotional, and social problems were associated with perception of inadequate preparatory information.
Garcia-Botello, S.A., Garcia-Armengol, J., Garcia-Granero, E.; 2004	Descriptive study at a hospital in Spain over a 10-y period n= 127 convenience sample, 57% male	Outcomes- ostomy complications of ileostomy Instruments- None described	Overall rate- 39.4% Dermatitis- 12.6%, erythema-7.1%, stoma mucositis 6.3%, flush stoma-4.7%, retraction- 3.9%, fistula-3.9%, prolapse-3.1%, hernia- 3.1%, ischemia- 0.8%, dehydration- 0.8%
Gulbuiniene, J., Markelis, R., Tamelis, A., Saladzinskas, Z.; 2004; Lithuania (abstract)	RCT study in at 2 university hospitals. n= ? Patients divided into 3 groups (?), 1 control group	Outcome- QOL Questionnaires used EORTC QLQ-C30, EORTC QLQ-CR38, 10 supplementary questions administered day before surgery, and 2 mo after surgery	Difficult to evaluate due to only access to abstract and limited information Conclusions- Those that received adequate education and stoma siting had better emotional functioning and less gastrointestinal problems. Preop and post op education helped gain better experience in self stoma care.
Harris, D., Egbeare, D., Jones, S., Benjamin, H., Woodward, A., Foster, M.; 2005	Retrospective, descriptive design n= 345 stomas over 8 years	Outcomes- complications following stoma formation	Stoma creation increased over the period but complications decreased. Complications occurred more often in emergent surgery. Age, urgency of surgery, and diagnosis were associated with high

Source	Sample and Design	Variables/Instruments	Findings and Comments
			levels of mortality and morbidity
Haugen, V., Bliss, D., Savik, K.; 2006	Descriptive cross sectional design. n= 147	Outcomes- ostomy adjustment and perioperative factors. Instruments- 1) Survey of perioperative factors of ostomy adjustment (self-report), 2) Ostomy Adjustment Scale, 3) Demographic form	Most common reasons for pouch leakage was abdominal contours (33%), overfilling of the pouch (24%), and height of the stoma and skin condition were least common. 43% reported negative effect on sex life. Distress about obtaining supplies was associated with lower OAS scores. OAS scores were higher when preop education by a WOC nurse was helpful. Condition of the skin, and emotional problems were associated with lower OAS scores.
Hellman, J., Lago, C.; 1990; NY; (abstract)	Descriptive, retrospective and telephone survey design n= 93, 58 ileostomy, 35 colostomy.	Outcome- peristomal skin complications Measures- Chart review and Telephone survey	Direct relationship between age and peristomal skin problems, gender is not a risk factor.
Herlufsen, P., Olsen, A., Carlsen, B., Nybaek, H., Karlsmark,T., Jemec, G.; 2006	Descriptive, 2 consecutive phases. n= 202 subjects with ostomies,	1st phase-mailed questionnaire received from 338 subjects This reports the 2nd phase-cross-sectional of returned surveys, via clinical examination by 3 stoma care nurses and 2 dermatologists Measures- questionnaire and clinical examinations.	45% had peristomal skin disorder, only 38% of the subjects agreed, 80% with skin disorder did not seek help
Herlufsen, P., Olsen, A., Carlsen, B., Nybaek, H., Karlsmark,T., Jemec, G.; 2006	Descriptive, 2 consecutive phases. n= 202 stoma subjects in a Danish community	1st phase-mailed questionnaire 2nd phase-cross-sectional of returned surveys, Measures- questionnaire and clinical examinations	See above. Feces-induced erosion was most common cause of skin irritation, 56% reported leakage under adhesive plate within past 14 days, No correlation of incorrect placement of plate with skin problems.

Source	Sample and Design	Variables/Instruments	Findings and Comments
Herlufsen, P., Olsen, A., Carlsen, B., Nybaek, H., Karlsmark,T., Laursen, T., Jemec, G.; 2006	Descriptive, 2 consecutive phases. n= 202 stoma subjects in a Danish community,	Outcome-Peristoma skin disorders Measures- 1st phase-mailed questionnaire 2nd phase-cross-sectional of returned surveys, Measures- questionnaire and clinical examinations.	Peristoma skin disorders higher in ileostomies (57%), urostomies (48%), than colostomies (35%). But only 38% agreed they had a skin disorder.
Jain, S., McGory, M., Ko, C., Sverdlik, A., Tomlinson, J., Wendel, C., Coons, S., Rawl, S., Schmidt, M., Grant, M., McCorkle, R., Mohler, J., Baldwin, C., Krouse, R.; 2007	Descriptive Retrospective comparison of patient with an ostomy (cases) and those without (controls). n= 237 ostomates n= 268 control;	Outcome- QOL and comorbidities Instruments- SF-36V Charlson-Deyo Comorbidity Index	Mean age 69, 64% colostomies, 36% ileostomies. 29% had high level of comorbidities. High comorbidity predicted low HR-QOL in 6 subscales of the SF 36v, having an ostomy was a predictor in 4
Kalashnikova, I., Achkasov,S., Fadeeva, S., Vorobiev, G. (2011). OWM	Descriptive design; N= 1427 over 2005-2007 Moscow, Russia	Variables: Stoma complications and peristoma complications. Investigator developed algorithm, no instruments mentioned	The development and use of algorithms for diagnosing and choosing treatment of ostomy complications: Results of a prospective evaluation. 38.8% had ostomy complications. 89% of those with complications were contact dermatitis., 25% had parastomal hernia, 18.6% mucocutaneous separation, 16.8% prolapse, 14.2% retraction.
Kairaluoma, M., Rissanen, H., Kultti, V., Mecklin, J., Kellokumpu, I.; 2002;	Descriptive Prospective design n= 141 temporary colostomy/ileostomy pts	Outcomes- temporary ostomy complications	Overall complication rate 12%. Categorized as post-operative and stoma-related. Hernia 1%, prolapse 4%, necrosis 4%, stenosis 1%, retraction 1%

Source	Sample and Design	Variables/Instruments	Findings and Comments
Finland.			
Karadag, A., Bulent, M., Sultan, A.; 2005; Turkey	Descriptive, prospective comparison design n= 35 n=25 irrigating n= 10 nonirrigating	Outcome- QOL Instruments- Digestive disease QOL questionnaire-15 (DDQ-15) and the SF-36	Colostomy irrigation was found to be effective for achieving fecal continence with no complications or significant side effects. DDQ-15 scores were higher in the irrigating group, improvements in role limitation due to physical and emotional problems, social functioning, general mental health, vitality, and bodily pain were higher.
Keele, A., Bray, M., Emery, P., Duncan, H., Silk, D.; 1997, UK	RCT; n= 100 admitted for elective moderate or major GI surgery	Outcome- nutritional intake, weight, height, mid arm circumference, BMI, hand grip strength, self-report fatigue, various lab values Instrument- Daily food record, weight scale, well-being index for surgical patients (WISP).	Supplement group resulted in significant clinical benefit while in the hospital but did not confirm after discharge. Skeletal muscle conserved in supplement group, lesser reports of fatigue in supplement group, and reduced incidence of post-operative complications in the treatment group (4 vs.12)
Kelman, G., Minkler, P.; 1989	Descriptive, prospective design. n= 50 individuals with an ostomy in NY from the UOA registry;	Outcomes- QOL and self-esteem. Demographic variables-management routine, cost of supplies, reimbursement for supplies, and utilization pattern. Instrument- QOL Index (Grant.Padilla), Rosenberg's self-esteem scale; instruments described	Description of population given in detail. 38% were seen postop by ET nurse, 48% from RN. Limited results section. Self-esteem (low score means higher self-esteem) and QOL (0-100) correlation was r= -0.5370. Author does not discuss this except to say that there is a relationship between self-esteem and QOL.
Krouse, R., Grant, M., Ferrell, B., Dean, G., Nelson, R., Chu, D.; 2007	Descriptive, mailed survey to 2455 California UOA members n= 1457 (59%) respondents,	Outcome- QOL Instrument- COHQOL –Ostomy questionnaire	Common QOL problems included sexual problems, gas, constipation, travel difficulties, and dissatisfaction with appearance. Overall- cancer patients had

Source	Sample and Design	Variables/Instruments	Findings and Comments
	599 with a colostomy.		less difficulty adjusting to their colostomies.
Krouse, R., Grant, M., Wendel, C., Mohler, J., Rawl, S., Baldwin, C., Coons, S., McCorkle, R., Ko, C., Schmidt, M.; 2007	Descriptive, case-control survey design from 3 VA sites- Tucson, Los Angeles, and Indianapolis n= 511/1063 , response rate 48%. n= 239 ostomy, n= 272 control	Outcome- QOL Instruments- COHQOL-Ostomy questionnaire, SF 36v	Ostomy pts reported lower scores on scales/domains reflecting psychological and social functioning and well-being. Ostomy pts reported lower scores on the SF 36 v reflecting physical functioning. Greatest differences between groups was in the psychological and social functioning domains.
Krouse, R., Mohler, J., Wendel, C., Grant, M., Baldwin, C., Rawl, S., McCorkle, R., Rosenfeld, K., Ko, C., Schmidt, M., Coons, S.; 2007	Mixed method, Descriptive, case-control survey design from 3 VA sites- Tucson, Los Angeles, and Indianapolis. n= 300 ostomates (goal)	Outcome- QOL Instruments- COHQOL-Ostomy questionnaire, SF-36v, focus groups at each site	Reported recruitment, reliability of surveys, and demographic characteristics of the sample. Cronbach's alpha for domains scales ranged 0.71-0.96. Focus groups had 2-6 subjects per group.
Law, w., Chu, K., Choi, H.; 2002; Hong Kong	RCT n= 80 adults in Hong Kong hospital, Loop ileostomy= 42 Loop colostomy=38, 61% male.	Outcomes- ostomy complications Instrument- none	Ileostomy-Hernia 3%, dermatitis 10%, high output 3%, obstruction 7%, ileus 10%. Colostomy-dermatitis 18%, prolapse 8%, ileus 3%. Stoma-related complications no significant difference between groups.
Leenen, L., Kuypers,J. (1989).	Some factors influencing the outcome of stoma surgery.		
Lefort, M., Closset, J., Sperduto, J., Houben, J.; 1995	Descriptive study of fecal ostomies complications in Belgium hospital. n= 50 over 1 year, followed	Outcome- complications, treatment (local treatment, medical attention by surgeon and ET) Instrument- None	Dermatitis- 43% ileo, 17% colo; mc separation- 30% colo; granuloma- 9%; QOL is improved by information and attention by the surgeon and ETN.

Source	Sample and Design	Variables/Instruments	Findings and Comments
	by ET nurse		
Leong, A., Londono-Schimmer, E., Phillips, R.; 1994	Retrospective, descriptive design using a life-table actuarial analysis of stomas constructed over a 10-yr period n=150 permanent end colostomies.	Outcome- stomal complications Instrument-standard pro forma from St. Mark's Hospital	By 20 years, complications incidence approached 76% for those with UC and 59% for those with Crohn's. The 4 most common were skin problems (34%), obstruction (23%), retraction (17%), and herniation (16%).Herniation was not reduced by siting through the rectus.
Liu, L., Herrinton, L., Hornbrook, M., Wendel, C., Grant, M., Coons, J., Mohler, M.J., Bladwin, C., Matayoshi, E., Green, S., Krouse, R. (2010)	Descriptive prospective design examining early and late complications. n= 679 (284 with ostomies, 395 with anastomosis	QOL measured via mailed survey questionnaires. Instrument-mCOH-QOL-Ostomy	Early and late complications among long-term colorectal cancer survivors with ostomy or anastomsis. Complications not clearly defined (stomal vs peristomal vs other). 19% of ostomy survivors and 10% of anastomosis survivors experienced complications, bleeding and post-operative infection were common early complications.
Lucanova, L, Mistuna, D.; 2003; Martin, Slovakia	Descriptive study using a mailed questionnaire (no psychometrics) n= 34 stoma patients from Slovakia, members of stoma organization.	Outcome- QOL Instrument- mailed questionnaire (researcher created), 31 items.	No age or gender differences, 57% did not return to jobs, Sexual life altered 57%, social life altered 78%, 6% do not travel anymore; 32% had no serious health troubles
Lynch, B., Hawkes, A., Steginga, S., Leggett, B., Aitken, J.; 2008; Australia	Secondary analysis of a larger study. Descriptive prospective design. n=1966 colorectal cancer patients, 322 of which had an ostomy. of	Outcomes- Patient concerns Instrument/Measures- Computer assisted telephone interviews that consisted of items r/t side effects/worries, 7 aspects of cancer care, preop information provision, diet, activity, and follow-up care. Data was collected via telephone interviews at 5,12, and 24 mo	The most common ostomy difficulties (@ 3 time points)were peristomal skin irritation (40.1%, 32.5%, 20%), odor (40.7%, 43.1%, 31.2%), noise (87.7%, 80.6%, 72.0%), need to empty pouch frequently (46.1%, 31.9%, 28%); most distressing were leakage (29.8%, 25.6%, 23.2%), fear of running out of supplies (16.9%, 12.5%, 8%), and disposing of full

Source	Sample and Design	Variables/Instruments	Findings and Comments
		following diagnosis	pouch when away from home (2.4%, 1.9%, 3.2%).
Ma, N., Harvey, J., Stewart, J., Andrews, L., Hill, A.	Descriptive design, n= 49	Variables- QOL using the SF-36 v2, measured pre-operatively, 6 mo, and 12 mo	Younger patients continued to improve in QOL to 12 mo, older patients started out higher but then improvement over time was small, older patients reached maximum QOL by 6mo, younger continued to improve.
Mahjoubi, B., Moghimi, A., Mirzaei, R., Bijari, A.; 2005	Descriptive study of the prevalence of complications and factors related n= 330	Outcomes- recent/early complications Instrument/Measures- physical examination	Early complications (during 1st month after surgery) included stoma site pain, early dermal irritation, stomal retraction, and psychosocial complications. Late complications were peristoma hernia, stoma stenosis, later dermal irritation, stoma retraction, stomal necrosis, and others (perforation, fistula). 30.6% had no complications (69.4% had complications); increase age (>40) associated with psychosocial problems, mucosal hemorrhage, and early dermal irritation. BMI>25 associated with peristomal hernia and early dermal irritation.
Marquis, P., Marrel, A., Jambon, B.; 2003; France	Descriptive study of the QOL of Europeans (16 countries) with a stoma n= 4,739	Outcomes- QOL Instrument- Stoma Quality of Life Index (SQLI) recruited by 618 stoma nurses, completed the Stoma Care QOL Index at hospital discharge, 3, 6, and 12 mo. Cronbach's alpha 0.92%, correlation of the French and British groups was 0.40	Mean age- 61.6, 53.7% male, 66.5% colostomy, consistent scores in all pts immediately after surgery and improved steadily over time, with the only difference between post-op and 3mo. Scores were higher in those who were satisfied with care than those who were not. Those who had a good relationship with their stoma nurse and felt confident with changing had higher scores than those who did not.

Source	Sample and Design	Variables/Instruments	Findings and Comments
			Conclusions- QOL changes over time and access to specialist ostomy nurse is important.
Martinsson, E., Josefsson, M., Ek, A.; 1991	Descriptive study using a telephone survey interview. n= 53 ileostomy, UC and Crohn's	Outcomes- Early complications- occur during hospitalization Late- occur after hospitalization Instrument/Measure- telephone survey. No instrument reliability or validity information reported	Early complications arose in 57% of UC. ileostomy patients and in 50% of those with Crohn's; 84% of UC patients and 87% of those with Crohn's had late complications. Work capacity unchanged in 41/53. QOL reported in subset.
Millan, M., Tegido, M., Biondo, S., Garcia-Granero, E. (2010).	Descriptive design of care received by ostomy patients. n= 270 in Spain	Two survey questionnaires- no information reported regarding validity or reliability.	Pre-operative stoma siting and education by stomatherapists of colorectal cancer patients: a descriptive study in twelve Spanish colorectal surgical units. Early skin irritation ocurred in 36.4% of emergent stomas vs 8.2% of planned stomas.
Mitchell, K., Rawl, S., Schmidt, M., Grant, M., Ko, C., Baldwin, C., Wendel, C., Krouse, R.; 2007	Secondary analysis of a mixed method design study. Descriptive, cross-sectional, correlation design. n= 239 veterans with a fecal ostomy, 92% male.	Outcomes- demographic (age, sex, race, education, income, partnered), clinical (type of ostomy, permanence of ostomy, ostomy nurse helped teach, reason for ostomy) and QOL variables related to embarrassment. Instrument- mCOHQOL-Ostomy questionnaire and 1 open-ended question. Cronbach's alpha 0.95 with acceptable subscale alpha's.	High embarrassment was associated with poorer total QOL, and physical, psychological, social, and spiritual subscales. Younger and unpartnered had higher embarrassment. High embarrassment was associated with higher anxiety, depression, and difficulty w/intimacy, more isolation.
Mohler, M., Coons, S., Hornbrook, M., Herrinton, L., Wendel, C., Grant, M., Krouse, M.; 2008	Descriptive, cross-sectional mixed methods design using a mailed survey and focus groups. n= 679/1308 and 34	Outcomes- QOL and ostomy-related obstacles and adjustments. Instruments- SV-36v2 and the mCOH-QOL-Ostomy questionnaire.	This study reported the methods, design, and psychometric properties of the instruments used. Survey response 52% (284 cases, 395 controls), Internal consistency for both questionnaires were

Source	Sample and Design	Variables/Instruments	Findings and Comments
	subjects in focus groups		acceptable; mCOH-QOL-O Cases 0.94, control 0.93; sf-36 v2 subscales ranged 0.85-0.95.
Monfrecola, G., Riccio, G., Sacarese, C., Posterarao, G., Procaccini, E. (1998).	Descriptive design; n= 20	Variables- cutaneous blood flow Instrument-Laser Doppler flowmeter	The acute effect of smoking on cutaneous microcirculation blood flow in habitual smokers and nonsmokers was decreased 38% in smokers and 28% in nonsmokers.
Nichols, T., Riemer, M.; 2008	Descriptive cross-sectional design. n= 1,495 with 37% colostomy, 50% ileostomy or 10% urostomy, 47.4% male,	Outcome- stabilizing lifestyle forces (occupation, spousal/life partner relationships, and family life) following ostomy surgery and life satisfaction Instrument/Measures- Ostomy Comprehensive Health and Life Assessment Survey data (Hollister). 113 items combining the Rand Medical Outcomes Study Measure of QOL SF-36, the Medical Outcomes Study Measures of Life Social Support Survey, and Hawthorne's Index of Social Isolation. Crohnbach's alpha 0.84.	Occupational stability influences overall recovery. Spouse/partner relationship stability also influences successful rehabilitation. Both of these variables profoundly and positively influenced life satisfaction. Stability of spouse/partner predicted positive life satisfaction.
Notter, J., Burnard, P.; 2005; UK	Qualitative secondary study of a larger study: The QOL of women following restorative protocolectomy. Design: Descriptive phenomenology to explore lived experience n= 50 women	Outcome- Lived experience and perceptions of women undergoing restorative proctocolectomy. Instrument/Measures- Semi-structured interviews, purposive sampling, audio recording and transcribed.	Surgery was pivotal in their lives and reminded them that the dream of full recovery was gone. Memories were dominated by issues of pain, body image changes, loss of feminity, problems with the ileostomy. Role of the specialist stoma nurse was limited and often sparse

Source	Sample and Design	Variables/Instruments	Findings and Comments
Nybaek, H., Knudsen, D., Laursen, T., Karlsmark, T., Jemec, G.	Descriptive comparative design; n= 141	Variables- QOL SF-36, Dermatologic Life Quality Index, Ostomy Adjustment Scale	Negative impact on QOL scores in those patients with skin problems.
Olbrisch, M.; 1983	Descriptive design of the development and psychometric properties of the OAS n= 53 initial respondents/31 retest	Outcomes- Ostomy adjustment Instrument- 1) Demographic information, information about the surgery, and information of the doctor-patient relationship 3) Texas Social Behavior Inventory, 4) Marlowe- Crowne Social Desirability Scale, 5) Self-Consciousness Scale, 6) Ostomy Adjustment Scale.	OAS is a 34-item scale found to demonstrate reliability with Cronbach's alpha .85, test-retest .72. Discriminate validity discussed. Sample too small to permit any clear statements about the adjustment process itself although there was a relationship between adjustment and time since surgery.
Padubidri, A., Yetman, R., Browne, E., Lucas, A., Papay, F., Larive, B., Zins, J. (2001).	Complications of postmastectomy breast reconstruction in smokers, ex-smokers, and nonsmokers.		
Park JJ, Del Pino A, Orsay CP, Nelson RL, Pearl RK, Contron JR, Abcarian H Dis Colon Rectum	Descriptive retrospective design. n=1616	Outcomes- stoma complications, early, late, total. Instrument/Measures- Analysis of data cards complied by ET over 19 yr period (1976-1995)	Complications are common. 34% had complications 28 % early (within 1mo of surgery- skin irritation, pain, partial necrosis) 6% late (greater than 1 mo after surgery- skin irritation, prolapsed, necrosis. Pre-operative marking especially in older patients and avoiding the ileostomy particularly in the loop configuration can help minimize complications. Predictors of early complications but not late was increasing age. Ileostomy had more total

Source	Sample and Design	Variables/Instruments	Findings and Comments
			complications as did loop configurations. ET visit decreased the incidence of stoma complications. No significance found in emergent stomas, BMI, gender, operating service.
Persson, E., Gustavsson, B., Hellstrom, A., Lappas, G., Hulten, L.; 2005; Sweden	Descriptive cross sectional postal survey design. n=42 ileostomy and 49 colostomy patients	Outcome- patients' perspective of their quality of care. Instrument/Measure- Identify-oriented dimension of the Quality of care from the Patients' Perspective questionnaire (no psychometric properties reported)	1/3 of the colostomy pts and ½ of the ileostomy pts were dissatisfied with information received about the results of medical exams and lab tests, most participants were dissatisfied with their opportunities to participate in decision-making process or to discuss sexual matters. Stoma complications (skin problems, granuloma, necrosis, stenosis, retraction, leakage, hernia, prolapse) occurred in 71% had no impact on the results.
Pittman, J., Rawl, S., Schmidt, M., Grant, M., Ko, C., Wendel, C., Krouse, R.; 2008	Secondary analysis of a mixed method cross-sectional design. Quantitative data used in this study. n= 239 veterans	Outcomes- Ostomy complications and QOL, Instrument-COHQOL-Ostomy questionnaire	Skin irritation, leakage, and adjustment difficulty were related to demographic, clinical and QOL domains. Age, income, employment, preop care (stoma-site marking and education), having a partner, ostomy type, reason for ostomy, time since surgery, total QOL scores and each subscale were related to each complication (skin irritation, leakage, and adjustment)
Piwonka, M.A., Merino, J.; 1999; Chile	Cross-sectional design n= 60 participants	Outcomes- factors contributing to the post-operative adjustment of patients who had undergone permanent colostomy surgery; Instrument/Measures- structured interview, demographic	Factors found to predict adaptation to a colostomy include education for ostomy self-care, psychological support, and social support from family/significant other. Ostomy self-care was the most important variable predicting positive adjustment to

Source	Sample and Design	Variables/Instruments	Findings and Comments
		questionnaire, and Olbrisch Ostomy Adjustment Scale	the ostomy
Porter, J., Salvati, E., Rubin, R., Eisenstat, T.; 1988	Descriptive prospective design. n= 126 with 130 stomas followed for 35 months	Outcome- Complications Instrument/Measure- chart review	44% had complications; Complications included skin excoriation 13.5%, hernia 9.3%, stricture 8.7%, small-bowel obstruction 7.2%, wound infection 7.2%, prolapse 3.2%, poor location 1.6%, abscess 1.6%, peristomal fistula 0.8%. Complications were not associated with stoma site, disease, urgency of procedure, or segment of colon used. Wound infection was associated with urgently created stomas; Incidence of hernias was equivalent in stomas brought out thru incision or at separate site.
Pringle, W., Swan, E., 2001	Descriptive design; n= 112, at 1 wk, 1 mo, 6 mo, and 1 y after surgery Multicentered in UK, convenience, 62% male, mean age 68,	Outcome- complications of pts with permanent colostomy for CR CA. Instrument/Measures-	Hernia 20% by time 4, ulceration <5%, prolapse 10% by time 4, retraction 10% by time 4, stenosis <10% by time 4. Complications shown as bar graph, percentages not clear.
Ratliff, C.	Prospective descriptive design.	Variables- peristomal skin complications with first 2 months of surgery. Investigator-developed peristomal complication form. Inter-rater reliability described.	47% of patients had peristomal complications. Brief descriptive analyses was completed, no comparisons, or correlations.
Ratliff C, Donovan AM Ostomy Wound Management, 2001	Descriptive prospective design. n=161 New ostomy patients at a major medical center evaluated 2 months post-op.	Outcome- peristomal complications Instrument/Measure- peristomal skin complication tool	Peristomal complications rate of 6%. All had retracted stomas resulting in skin damage. Suggests that those with ileal conduits and retracted stomas require more frequent follow-up visits for monitoring.

Source	Sample and Design	Variables/Instruments	Findings and Comments
Ratliff CR, Scarano KA, Donovan AM JWOCN, 2005	n=220	Outcome- peristomal complications Instrument/Measure- a tool developed by the investigators at 2 mo after surgery	Complication rate of 16% included irritant dermatitis, mechanical injury and candidiasis. Related factors included flush stomas, hernia, improper sizing and mechanical injury. Follow up is necessary for additional education Also need universal definitions for complications.
Richbourg, L., Fellows, J., Arroyave, W.; 2008	Descriptive exploratory design n=551	Outcomes- demographic information, medical history, and ostomy wear time Instrument/Measure- mailed surveys	Mean wear time is 4.8 days, urostomies 5.02 days, ileostomies 5.01 days, colostomies 4.55 days.
Richbourg, L., Thorpe, J., Rapp, C.; 2007	Descriptive cross-sectional design study n= 34 , 14 male	Outcomes- demographic and anthropometric data, stoma complications, self-evaluation of emotional state, and support contact. Instrument/Measures- mailed survey	20% received preop visit from ostomy nurse, 65% were independent in stoma care. 76% reported skin problems, 62% leakage, 59% odor, 35% pain around stoma, 35% sleep problems, 26% sexual problems, 53% depression, 21% retraction, 53% bulge around stoma, 14% prolapse, 11% stenosis, 48% coping fair to poor. Data reported on wear time, support.
Robertson I, Leung E, Hughes D, Spiers M, Donnelly L, Mackenzie I, Macdonald A Colorectal Diseases; 2005	Descriptive Prospective design n=408	Outcomes- complication rates at different time-points during the post-operative follow up period. Instrument/Measures-not specified	Proportion of patients who had post-op complications did not improve with time. Rate of hernias increased with time. Night time emptying in the ileostomy group was worse with time. Ileostomy patients had a higher incidence of skin excoriation, leakage, soiling and night time emptying and should receive additional support. Similar complication rates between elective and emergent procedures
Roed-Peterson, K.,	RCT;	Outcomes-Morbidity, complications	57% male, ages 36-89

Source	Sample and Design	Variables/Instruments	Findings and Comments
Anderson, B., Baden, H., Burcharth, F.; 1992; Denmark	n= 100 pts with colostomies during post-operative period	Instrument/Measures- not specified	Retraction 0.5%, necrosis 0.5%, One person in each group sustained a stoma complications (no difference between groups)
Salvadalena, G.; 2008	Systematic review	Outcomes- ostomy complications incidence and definitions Instrument/Measures-	13 descriptive, 13 clinical trials.
Simmons, K., Smith, J., Bobb, K., Liles, L.; 2007	Descriptive exploratory design. n= 51 completed questionnaires	Outcomes- adjustment, stoma acceptance, social interaction, and stoma care self-efficacy. Instrument/Measure- Ostomy Adjustment Scale- short form 2 (Olbrisch), Acceptance of Illness Scale (Felton), Stoma Self-efficacy scale (Bekkers), Inventory of Interpersonal Problems-Sociable subscale (Horowitz).	Stoma care self-efficacy (57.5%), stoma acceptance, interpersonal relationship (both 13%), and location of stoma (4.6%), and gender (1.9%) were strongly associated with adjustment.
Simmons, K., Smith, J., Wroe, A., Rimmer-Gray, M., Ilett, H., Tyte, S.; 2008	Descriptive exploratory design for the development of the OAI-23. n= 570 British ostomates	Outcome- ostomy adjustment and psychometric properties of the OAI-23. Instrument/Measure- Ostomy Adjustment Inventory- 23; a self-report multidimensional scale to assess psychosocial adjustment in patients with a stoma.	Reliability- Cronbach's alpha= .93, split-half= .91, test-retest= .83, and validity- corresponding positively with Feltman's Acceptance of Illness Scale, Four factors which accounted for 55.4% of the total variance
Sinclair, L.	Qualitative design; narrative inquiry; n=7.	Exploring the experience of young adults with an ileostomy.	Common themes were disease processes, hospitalization, and social and personal adjustments.

Source	Sample and Design	Variables/Instruments	Findings and Comments
Speirs, M., Leung, E., Hughes, D., et al. 2006	RCT, Loop ileostomies in UK, n=602 groups: With rod (n=29); Without (n= 28)	Outcomes- Complications Instrument/Measures-Evaluated by stoma nurse over 3 mo period, day 3,7,10, and 3 mo.	Stoma retraction rate 7.1% with rod, 6.8% without. One participant with rod developed stoma laceration.
Stott, C., Graaf, L., Morgan, P., Fairbrother, G.; 2002	Descriptive, prospective design; convenience sample characteristics,. n= 122 (colo, ileo, urostomy) in Australia	Outcome- complications, and outcomes over 2 y period, Instrument/Measure- not specified	60% male, mean age 64-91. Multiple regression of pt descriptors predicted coping at 3 mo. Hernia 1%, dermatitis 15%, mc separation 3%, retraction 3%, other, leak, lifting poor dexterity, high output, anxiety. Complications categorized as surgical, stoma, or psychological.
Sung, Y., Kwon, I., Park, S. (2010).	Retrospective descriptive design; n= 1,170	Variables- ostomy related complications- stomal vs peristomal. Investigator-designed data collection form.	Factors affecting ostomy-related complications in Korea. Flat stoma was the most common stomal complication (8.5%), Irritant contact dermatitis was most common peristomal complications (15.5%).
Symms, M., Rawl, S., Grant, M., Wendel, C., Coons, S., Hickey, S, Baldwin, C., Krouse, R.; 2008	Secondary analysis of a mixed method cross sectional design. n= 481 male veterans, n=224 ostomies n= 257 controls	Outcome- QOL, sexual health (sexual function or activity, sexual satisfaction, and erectile function) Instrument- COHQOL-Ostomy questionnaire	Erectile dysfunction higher in ostomates than controls, sexual resumption lower in the ostomy group, Presence of an ostomy was associated with lower rates of sexual activity and higher erectile dysfunction. Both of these were related to social and psychological domains of HR-QOL among men with ostomies.
Tappe, A., McKenzie, F., Sheldon, J., Smith, A., Colton, B., Woolley, D.; 2005.	Descriptive exploratory design n= 252 participants from 7 countries	Outcome- demographics and incidence of stoma complications. Instrument/Measure- new instrument.	Skin problems at 0-2wk 25%; 40% at 3-6 wk; 20% at 7-12 wks, 20% at 3-6 mo, and 15% at 6-12 mo
Wade, B.; 1990	Descriptive, prospective	Outcome- psychological and	Mean age 63.4, 55% male Retraction or

Source	Sample and Design	Variables/Instruments	Findings and Comments
	design n= 215 with colostomy in UK, stratified, random sample, n= 215 at 10 wks, n= 85 at 1 yr	physical problems to evaluate the benefits of specialist nursing care	prolapse 13% at 12 wks, 15% at 1 y; depression and anxiety 25% at 10 wk. Depression and anxiety were more prevalent at 10 wk in the group without stoma nursing care.
Wu, H., Chau, J., Twinn, S.; 2007	Cross- sectional, descriptive, correlation design n= 96 stoma patients from 2 hospitals in Hong Kong	Outcome- self-efficacy and QOL Instrument/Measure- Stoma self-efficacy scale, SF-36	Positive correlation found between the Chinese Stoma Self-efficacy scale and SF 36 (r= 0.21, p=.039), 2 SE subscales and all 8 of SF36. Age was negatively correlated with the SE Scale and social SE Scale, older patients had a lower level of SE; higher income had higher levels of SE; gender (Male scored higher SE), care provider were also associated with level of SE.

Appendix H: Patient Brochure

Tri-fold, page 1

How do I take part ?

If you are interested in joining the study, simply tell us when we contact you. We will answer any questions you may have.

Or…

Tell your physician or Ostomy nurse that you would like to join the study.

Project Team

Principal Investigator:

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Indiana University School of Nursing & Clarian Health

Adjusting to an Ostomy

A doctoral nursing research study
Indiana School of Nursing
Center for Research and Scholarship

For information call:
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Appendix H: Patient Brochure

Tri-fold, page 2

What is this study about?

We are interested in finding out more about adjustment to an ostomy. You can help us by providing information about yourself as you recover from surgery.

Who can participate in this Study?

You can take part if you :

- Are 18 years old or older
- Plan to or have just had ostomy surgery
- Are able to speak and read English
- Willing and able to return for 30 day postop visit.
- Will be responsible for caring for your ostomy

What does being a part of the Study mean?

If you are asked to join the study, you will be asked to:

1. Answer questions about yourself and health.
2. Allow the Ostomy Study nurses to examine your ostomy.
1. Return for a visit 30 days after your surgery.
2. Complete 2 surveys, 1 week after surgery and again at 30 days after surgery.

Will this affect my medical care?

NO. You may decide to take part or not to take part in the study. Either way, it will not affect your medical care.

Who will see my answers?

Your answers will not be shared with anyone outside this study.

Will I have to go anywhere?

All contact will be while you are in the hospital and when you return for a visit 30 days after surgery.

What if I do not want to finish the study?

You are free to stop at any time.

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Dear Expert Reviewer,

Thank you very much for agreeing to review two newly developed instruments related to ostomies for content validity. Your expertise will be invaluable in helping me determine the content validity of these instruments.

As a PhD student at Indiana University School of Nursing, I have developed two (2) instruments that I am planning to use in my dissertation research. The focus of my study will be to determine the contributions of a variety of risk factors to the development of early (first 30 days) ostomy complications.

The first instrument, titled the ***Ostomy Outcome Risk Assessment Scale*** is a 14-item risk assessment for the development of ostomy complications. The second instrument, titled the ***Ostomy Outcome Classification Index*** is a 9 item ostomy complication classification index. I am asking you to review both instruments for their face validity, relevance, clarity and comprehensiveness using the tables provided (See Tables 1 and 2). I have included several documents to assist you in this endeavor:

Thank you for assisting me in the development of two valid and reliable Your knowledge and experience is greatly appreciated. If you have any questions, please do not hesitate to contact me. Please return completed Tables 1 and 2 to me via fax, or mail no later than August 16, 2008.

Sincerely,

Joy Pittman APRN- BC, CWOCN

Purpose/Aims of this Study

Purpose/Aim: The purpose of this study is to develop two reliable and valid instruments to assess risk for the development of ostomy-related complications in the 30 day post-operative period.

Aim 1: To develop the Ostomy Outcomes Risk Assessment Scale (OORAS); identifying and classifying the risk factors associated with ostomy complications.

Aim 2: To psychometrically test the OORAS instrument for reliability and validity.

Hypothesis 1: Content validity of the OORAS will be supported by expert reviewers.
Hypothesis 2: The ostomy risk factor scale will demonstrate internal consistency reliability with Cronbach's alpha of at least 0.70.
Hypothesis 3: Each individual risk factor will be significantly correlated with at least one ostomy complication at approximately 30 days post surgery.
Hypothesis 4: The total OORAS score will be significantly correlated with the total ostomy complication score at approximately 30 days post surgery

Aim 3: To develop the Ostomy Outcomes Classification Index (OOCI), identifying the incidence of ostomy complications and their severity.

Aim 4: To psychometrically test the OOCI instrument for reliability and validity.
Hypothesis 1: Content validity of the OOCI will be supported by expert reviewers.
Hypothesis 2: The OOCI will demonstrate internal consistency reliability with Cronbach's alpha of at least 0.70.
Hypothesis 3: Each individual OOCI item will be significantly correlated with at least one ostomy risk factor.
Hypothesis 4: The total OOCI score will be significantly correlated with the total OORAS score.

Conceptual Definitions

***Risk Factors for Ostomy Complications*:**

Risk factors for ostomy complications will be conceptually defined in this study as antecedents, both demographic and clinical. Demographic antecedents will include age, caregiver support, stomal care proficiency. Clinical antecedents will include diagnosis, ostomy type, type of effluent, stoma and abdominal characteristics, pre-operative education, stoma site marking, nutritional status (current and prior), body mass index, smoking, and post-operative education. Each of these risk factors will be defined and identified by the level of severity or complexity (Figure 3) and the Ostomy Outcome Risk Assessment Scale (OORAS). Demographic information will be collected using a Demographic information form. The medical record, specifically the face sheet, will be utilized to collect the demographic data.

Ostomy Complications (within 30 day post-op)

Ostomy Complications in this study will be conceptually defined as those ostomy complications that include both stomal and peristomal complications. We will also be limiting our timeframe for development of ostomy-related complications to 30 days post operative. Stomal complications will be defined as stomal necrosis, stenosis, retraction and mucocutaneous separation. Peristomal complications will be defined as leakage, peristomal irritant dermatitis, pain, bleeding, and hyperplasia.

Operational Definitions

Risk Factors for Ostomy Complications

Risk factors for ostomy complications will be operationally defined in this study with the application of the ***Ostomy Outcome Risk Assessment Scale.*** This instrument contains 14 items that have been developed through prior research endeavors, clinical practice, and literature review. The subject will be assessed for each item and assigned a score 1 through 4. The higher the assigned score, the risk for ostomy-related complication development is higher. The individual scores will be added in order to obtain a total score. The higher the total score, the higher the risk for development of ostomy complications.

Ostomy Complications (within 30 day post-op)

Ostomy complications will be operationally defined in this study with the application of the ***Ostomy Outcome Classification Index.*** This instrument contains 9 items that have been developed through prior research endeavors, clinical practice and literature review. The subject will be assessed for each item and assigned a score 1 through 4. The higher the score, the more severe the complication is. The individual scores will be added in order to obtain a total score. The higher the score, the more severe the ostomy complications are.

Instructions for Reviewers:

Content validity is the extent that a measure (instrument) adequately represents all facets of the concept. I am attaching 2 content validity surveys; one for each instrument. Please rate the item according to its relevance, clarity and comprehensiveness to ostomy risk factors or ostomy complications, respective to the instrument.

In addition, I am interested in your opinion regarding the relative importance or ***weight*** you would assign to each risk factor in terms of its contribution to the development of ostomy complications. To evaluate the relative weight of each risk factor, please rank order the risk factors from 1 to 14, with "1" being the MOST IMPORTANT risk factor and "14" being the LEAST IMPORTANT risk factor.

If you have any questions about these instructions or the process for completing this assignment, please do not hesitate to email me at joyce.pittman@comcast.net or call me at 812-498-4789. Please return completed Tables 1 and 2 to me via email, mail, or fax no later than August 16th.

THANK YOU AGAIN!!

Table 1: Content Validity Survey for the Ostomy Outcome Risk Assessment Scale

	Relevance as a Risk Factor for Ostomy-related Complications **1. Item is NOT relevant** **2. Item needs MAJOR revision to be relevant** **3. Item needs MINOR revision to be relevant** **4. Item IS relevant**	**Clarity of item** **1. Item is NOT clear** **2. Item needs MAJOR revision to be clear** **3. Item needs MINOR revision to be clear** **4. Item IS clear**	**Comprehensive-ness of item** **1. Item should be <u>deleted</u>** **2. Item should be <u>retained</u>**	**Rank in order of importance as a risk factor:** **1= MOST IMPT** **14= LEAST IMPT**	**Appropriateness of numeric rating scale for each item (Eg. Rating of smoking status: 1=nonsmoker, 2=< 1 ppd, 3=1-2 ppd, 4=> 2 packs per day)** **1. Rating scale is NOT appropriate** **2. Rating scale needs MAJOR revision to be appropriate** **3. Rating scale needs MINOR revision to be appropriate** **4. Rating scale IS appropriate**
Age	1 2 3 4	1 2 3 4	1 2		1 2 3 4
Diagnosis	1 2 3 4	1 2 3 4	1 2		1 2 3 4
Ostomy Type	1 2 3 4	1 2 3 4	1 2		1 2 3 4
Type of Effluent	1 2 3 4	1 2 3 4	1 2		1 2 3 4
Stoma/Abd characteristics	1 2 3 4	1 2 3 4	1 2		1 2 3 4
Stomal care proficiency	1 2 3 4	1 2 3 4	1 2		1 2 3 4
Caregiver Support	1 2 3 4	1 2 3 4	1 2		1 2 3 4
Pre-operative Ostomy Education	1 2 3 4	1 2 3 4	1 2		1 2 3 4
Stoma site marked	1 2 3 4	1 2 3 4	1 2		1 2 3 4

Prior Nutritional Status: (Albumin level)	1 2 3 4	1 2 3 4	1 2		1 2 3 4
Current Nutritional status: (NPO duration)	1 2 3 4	1 2 3 4	1 2		1 2 3 4
BMI	1 2 3 4	1 2 3 4	1 2		1 2 3 4
Smoker	1 2 3 4	1 2 3 4	1 2		1 2 3 4
Post-operative Ostomy Education	1 2 3 4	1 2 3 4	1 2		1 2 3 4

Table 2: Content Validity Survey for the Ostomy Outcome Classification Index (OOCI)

	Relevance as an Ostomy-related complication **1. Item is NOT relevant** **2. Item needs major revision to be relevant** **3. Item needs minor revision to be relevant** **4. Item is relevant**	**Clarity of item** **1. Item is not clear** **2. Item needs major revision to be clear** **3. Item needs minor revision to be clear** **4. Item is clear**	**Comprehensiveness of item** **1. Item should be <u>deleted</u>** **2. Item should be <u>retained</u>**	**Appropriateness of numeric rating scale for each item (Eg. Rating of leakage; 1=none, 2=approx 1-2x/mo, 3=approx 1-2x/wk, 4=approx 2-3x/day)** **1. Rating scale is NOT appropriate** **2. Rating scale needs MAJOR revision to be appropriate** **3. Rating scale needs MINOR revision to be appropriate** **4. Rating scale IS appropriate**
Leakage	1 2 3 4	1 2 3 4	1 2	1 2 3 4
Peristomal Irritant Dermatitis	1 2 3 4	1 2 3 4	1 2	1 2 3 4
Pain	1 2 3 4	1 2 3 4	1 2	1 2 3 4
Bleeding	1 2 3 4	1 2 3 4	1 2	1 2 3 4
Stomal Necrosis	1 2 3 4	1 2 3 4	1 2	1 2 3 4
Stomal Stenosis	1 2 3 4	1 2 3 4	1 2	1 2 3 4
Retraction	1 2 3 4	1 2 3 4	1 2	1 2 3 4
Mucocutaneous Separation	1 2 3 4	1 2 3 4	1 2	1 2 3 4
Hyperplasia	1 2 3 4	1 2 3 4	1 2	1 2 3 4

Figure 2: **Ostomy Outcomes Risk Assessment Scale (OORAS) Draft**

For each risk factor assign the score above the corresponding description and document in the Total column on the right. Then total all risk factors for total score.					
Risk Factor	**1 ▼**	**2 ▼**	**3 ▼**	**4 ▼**	**Total**
Age	70+	60-69	50-59	<50	
Diagnosis	Colorectal Cancer	Rectal Cancer	IBD (Chrohn's, UC)	Emergent surgery (diverticulitis, trauma, other)	
Ostomy Type	Sigmoid Colostomy	Transverse Colostomy	Ascending Colostomy	Ileostomy	
Type of Effluent	Solid	Formed, Soft	Thick liquid	Liquid	
Stoma/Abd Characteristics	Above skin level, round, flat pouching surface	Above skin level, oval, Minor alterations in peri-stoma abd surface	Skin level, round or oval, peri-stoma skin folds/creases problematic	Below skin level, oval, deep peri-stoma skin folds/creases	
Stomal Care Proficiency	Independent/ Competent	Minimal assist	Moderate assist	Unable/ incompetent	
Caregiver Support	24 hours/day	Daily contact	Weekly	None	
Pre-operative Education	WOC nurse	Physician	Non-specialty nurse	None	
Stoma Site Marked	WOC nurse Pre-hospital	WOC nurse Pre-operatively	Physician	None	
Prior Nutritional Status (Albumin)	>3.0	2-2.9	1.0-1.9	<1.0	
Current Nutritional Status (NPO Duration)	NPO < 24 hours	NPO 1-2 days	NPO 2-4	NPO >5 days	
BMI	Normal- 18.5-24.9	Overweight- 24.9-29.9	Severe Obesity-30-35	Underweight- <18.5 Morbid Obesity- 35+	
Smoker	None	<1 pk/day	1-2 pks/day	>2 packs/day	
Post-operative Education*	All 5 goals met	3-4 goals met	1-2 goals met	None	
Total →					

*Post op education goals include: 1)Description of procedure 2)Supply procurement 3)Pouch emptying procedure 4)Ostomy pouch/wafer change procedure 5)Patient returned demonstration

Figure 3: Ostomy Outcome Classification Index (OOCI)

Ostomy Outcome Classification Index (OOCI) **For each complication assign the score above the corresponding description and document in the Total column on the right.**					
Complication:	1 ▼	2 ▼	3 ▼	4 ▼	**Total**
Leakage (self report)	None	Approx. 1-2x/mo	Approx. 1-2x/wk	Approx. 2-3x/day	
Peristomal Irritant Dermatitis (WOC observation)	None	Mild- rash 25%. Skin intact	Moderate- Rash with excoriation, denudement <50% peri-stoma	Severe- Skin denuded >50% peri-stoma	
Pain (self report)	0 	1, 2, 3 	4, 5, 6, 7 	8, 9, 10 	
Bleeding* (self report or WOC observation)	None	Petechial bleeding	Mild blood loss (clinically significant)	Gross to debilitating (requires transfusion, retinal or cerebral)	
Stomal Necrosis (WOC observation)	None	Stoma dusky	Stoma black 50 % or greater	Stoma back/dry 100%	
Stomal Stenosis (WOC observation)	None	Stoma Os <5th digit diameter, No pain or discomfort, Output normal	Stoma Os < 5th digit diameter, Ribbon-like output, Occasional discomfort.	Unable to insert any digit into stoma os, No output x ≥6 hrs, Abd pain and distention.	
Retraction (WOC observation)	Stoma above skin level	Stoma level with skin	Stoma below level of skin	Unable to see stoma Or Stoma >2cm below skin	
Mucocutaneous Separation (WOC observation)	None	25%- 49%	50%-74%	75 %- 100%	
Hyperplasia (WOC observation)	None	25%-50%	50-74%	75-100%	
Total →					

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Wynd, C., Schmidt, B., & Schaefer, M. (2003). Two quantitative approaches for estimating content validity. *Western Journal of Nursing Research 25*(5), 508- 518.
Zassi. (2008). [Zassi: Medical Evolutions].

CURRICULUM VITAE

JOYCE A. PITTMAN

EDUCATION:

Degree Granting Institution	Degree /Focus	Date Awarded
Palm Beach Junior College	AS	5/1978
University of South Florida	BSN	12/1979
Emory University	Wound, Ostomy, Continence	1999
Indiana University	MSN/Adult NP	2003
Northern Kentucky University	Family NP	2004
Indiana University	PhD Nursing	2011

LICENSURE/CERTIFICATIONS:

Description	State/Certifying Organization
Registered Nurse	Indiana
Nurse Practitioner	Indiana
Adult Nurse Practitioner	ANCC (expired)
Family Nurse Practitioner	ANCC
Wound, Ostomy, Continence Nurse	WOCNCB

PROFESSIONAL EXPERIENCE:

Location	Title/Position	Dates
Community Home Health Boynton Beach, FL	Staff Nurse/Coordinator/Audit Nurse	1980-1985
Frank Kucera, MD (General Surgeon) Boynton Beach, FL	RN Surgical Assist/Office Nurse	1984-1986
GranCare Home Health North Vernon, IN	Clinical Manager	1994-1997
Jennings Community Hospital	Director/Administrator	1997-1999

Home Health North Vernon, IN		
Schneck Medical Center Seymour, IN	Wound, Ostomy, Continence Nurse Adult/Family Nurse Practitioner	1999- 2006
Family Medical Center Seymour, IN	Adult/Family Nurse Practitioner	2003-2006
West Virginia University Hospital Morgantown, WV	Adult/Family Nurse Practitioner Wound, Ostomy, Continence	2006-2007
Indiana University Health Methodist Hospital Indianapolis, IN	Adult/Family Nurse Practitioner Wound, Ostomy, Continence Team Leader	2007-present
Indiana University School of Nursing Indianapolis, IN	Teaching Assistant PhD R 603: Research: Design/Methods	Spring 2010

TEACHING EXPERIENCE:

School	**Title/Position**	**Dates**
University of Indianapolis	Preceptor for NP students	2009- present
Waynesburg College	Clinical Mentor (shadow) for RN students	2006- 2007
Northern Kentucky University	Clinical Preceptor for MSN students	2003
Emory University	Clinical Preceptor for WOCN students	2002- present
Indiana University	Clinical Preceptor for BSN students	2001
Ivy Tech	Clinical Mentor (shadow) for LPN, RN students	1999-2006
Indiana University	Clinical Mentor (shadow) for LPN, RN students	1999-2006

HONORS/AWARDS:	Granted By	Dates
Charles Bryant Enterostomal Therapy Nurse Education Program Scholarship	Mideast Region WOCN Society	1997
Graduate Nurse Professional Traineeship	Indiana University School of Nursing	2003
Excellence in Writing	Mideast Region WOCN Society	2003
Aging Fellowship	Indiana University School of Medicine	2007
Dr. Sherri Smith Memorial Grant	Carrington Labs, WOCN Society	2007
WOCN Advance Practice Grant	WOCN Society	2007
Travel Grant	Indiana University School of Nursing	2007
Advanced Education Nursing Traineeship Department of Health andHuman Services (DHHS), Health Resources and Service Administration	Indiana University School of Nursing	2008, 2009
Emily Holmquist Award	Indiana University School of Nursing	2009
Graduate Student Research Award	Indiana University School of Nursing	2010

PROFESSIONAL MEMBERSHIPS/SERVICE:

Organization	Role	Dates
Wound, Ostomy, Continence Society (WOCN)	Member	1999- present
WOCN Society National Conference Planning Committee	Abstract Coordinator: Coordinate the submission, review and presentation of research, case studies, and practice innovation abstracts for poster and oral presentation at the national conference.	2005- 2008

	Wound Track Co-Chair	2009-2010
WOCN Society National Conference Planning Committee	Co-Chair	2010-2011
WOCN Society National Conference Planning Committee	Chair: Coordinates the annual national conference and oversees content processes.	2011- 2013
WOCN Clinical Center For Investigation	Board member: Co-authored the Grant Writing Toolkit. Participates in the review of grant applications and research proposals.	2006- Present
WOCN Ostomy Taskforce	Developed and co-authored Ostomy Guidelines	2009-2010
Mideast Region Wound, Ostomy, Continence Society	Member Trustee Historian	1999- present 2006- 2009 2000- 2005
Midwest Nursing Research Society	Member	2006- present
American College of Nurse Practitioners	Member	2005- present
Boy Scouts of America Medical Explorers- Jackson County	Group Leader	1999- 2005
Jennings County First Steps Council- Indiana State Department of Health, Division of Family Services	Member	1997- 2000
United Way- Jennings County	Member	1997-1999
Step Ahead Council- Indiana State Department of Health, Division of Family Services	Member	1996-1998
American Red Cross	Volunteer CPR Instructor	1996-1999

RESEARCH (nonfunded):	**Dates**
Comparative study of the use of an antimicrobial barrier film dressing in post-operative incision care. *(Principal Investigator)*	2005
The lived experience of a chronic wound: Living a life of never healing.	2005
Demographic and Clinical Factors Related to Ostomy Complications and Quality of Life in Veterans with an Ostomy.	2007
New Stoma Formation Study (*Principal Investigator)* Indiana University Health, Indianapolis, IN	2007-2009

RESEARCH (funded):

Granting Agency	**Title of Project**	**Dates**
WOCN/Center for Clinical Investigation (*Principal Investigator)* $15,000.00	An Interventional Study of Bowel Management Methods to Decrease Incontinence Associated Dermatitis	7/2008- 7/2010
Indiana University School of Nursing (*Principal Investigator)* $3,000.00	Ostomy Complications and Associated Risk Factors: Development and Testing of Two Instruments	12/2009- present
WOCN/Center for Clinical Investigation (*Principal Investigator)* $15,000.00	A Unit-Based Educational Program: Bowel Management Methods in the Critical Care Unit.	6/2010- present
WOCN/Center for Clinical Investigation *(Principal Investigator)* $5,000.00	Avoidable and unavoidable pressure ulcers	6/2011

PUBLICATIONS:

Pittman, J., The chronic wound and the family. Wound Ostomy Management, Vol: Feb, 2003. HMP Communications.

Pittman., The lived experience of a chronic wound: Living a life of never healing. (Abstract). Journal of Wound, Ostomy & Continence Nursing, 32(3S) Supplement 2:S29, May/June 2005.

Pittman, J., Tape, J., Pelecia, J., Tanner, D., Comparative study of the use of an antimicrobial barrier film dressing in post-operative incision care. (Abstract). Journal of

Wound, Ostomy & Continence Nursing, 32(3S) Supplement 2:S25-S26, May/June 2005.

Pittman., Uphold, B., Atwell, N., Theory guided evidence-based practice. Journal of Wound, Ostomy & Continence Nursing, 34(3S) Supplement:S55, May/June 2007.

Pittman, J. Effect of Aging on Wound Healing: Current Concepts. Journal of Wound, Ostomy & Continence Nursing, 34(4):412-417, July/August 2007.

Pittman, J., Rawl, S., Schmidt, C. Max, Grant, M., Ko, C., Wendel,C., Krouse, R., Demographic and Clinical Factors Related to Ostomy Complications and Quality of Life in Veterans with an Ostomy. (Abstract) Journal of Wound, Ostomy & Continence Nursing, 35(3) Supplement: S66-S67, May/June 2008.

Pittman, J., Rawl, S. Statistical and Clinical Significance: Are They One and the Same? Journal of Wound, Ostomy & Continence Nursing, 35(4):374-376, July/August 2008

Pittman, J.; Kozell, K.; Gray, M. Should WOC Nurses Measure Health-Related Quality of Life in Patients Undergoing Intestinal Ostomy Surgery? Journal of Wound, Ostomy & Continence Nursing, 36(3):254-265, May/June 2009.

Pittman, J., Rawl, S., Schmidt, C. Max, Grant, M., Ko, C., Wendel,C., Krouse, R., Demographic and Clinical Factors Related to Ostomy Complications and Quality of Life in Veterans with an Ostomy. Journal of Wound, Ostomy & Continence Nursing, 35(5):493-503, September/October 2008.

Pittman, J., Bakas, T. Measurement and Design. Journal of Wound, Ostomy & Continence Nursing, 37(6):603-607, November/December 2010.

Ostomy Guidelines Task Force; Goldberg, M.; Aukett, L..; Carmel, Jane; Fellows, J., Folkedahl, B, Pittman, J.; Scribe: Ronald Palmer, Fullerton, California. Management of the patient with a fecal Ostomy: Best practice guideline for clinicians. Journal of Wound, Ostomy & Continence Nursing, 37(6):596-598, November/December 2010

Pittman, J. Characteristics of the Patient with an Ostomy. Journal of Wound, Ostomy & Continence Nursing, June, 2011.

PRESENTATIONS:

Pittman., J. The lived experience of a chronic wound: Living a life of never healing. Presented as a poster at the 37th Annual Wound, Ostomy and Continence Conference: Las Vegas, Nevada June 12-16, 2005. (Refereed)

Pittman, J., Tape, J., Pelecia, J., Tanner, D. Comparative study of the use of an antimicrobial barrier film dressing in post-operative incision care. Presented as a poster at the 37th Annual Wound, Ostomy and Continence Conference: Las Vegas, Nevada June 12-16, 2005: Research Abstracts: Wound-Dermatological Management/Issue. (Refereed)

Pittman, J. Continence Awareness Program. Presented at the Women's Health Forum, Schneck Medical Center Foundation. November, 2005. (Invited)

Pittman., Uphold, B., Atwell, N. Theory guided evidence-based practice. Presented as a poster at the 39th Annual Wound, Ostomy and Continence Nurses Conference, Salt Lake City, Utah, June 9-13, 2007. (Refereed)

Pittman, J., Tape, J., Pelecia, J., Tanner, D. Comparative study of the use of an antimicrobial barrier film dressing in post-operative incision care. Presented at the 32nd Annual Nursing Research Conference in Indianapolis, IN., December, 2006. (Refereed)

Pittman, J., Rawl, S., Schmidt, C. Max, Grant, M., Ko, C., Wendel,C., Krouse, R. Demographic and Clinical Factors Related to Ostomy Complications and Quality of Life in Veterans with an Ostomy. Presented as a poster at the 40th Annual Wound, Ostomy and Continence Nurses Conference: Orlando, Florida: June 21-25, 2008. (Refereed)

Pittman, J., Kent, D. Implementation Strategies: We Will Reduce Pressure Ulcers! Presented at the Indiana State Department of Health Pressure Ulcer Prevention Initiative Learning Session 2, December 2008. (Invited)

Pittman, J., Rawl, S., Schmidt, C. Max, Grant, M., Ko, C., Wendel,C., Krouse, R. Risk Factors related to Ostomy Complications and Quality of Life. Presented as a poster at the MidWest Nursing Research Society Annual Conference: Minneapolis, MN 2009. (Refereed).

Pittman, J. Development of the Ostomy Outcome Risk Assessment Scale and the Ostomy Outcome Classification Index. Presented at the MidWest Nursing Research Society Annual Conference: Minneapolis, MN 2009. (Refereed)

Pittman, J. Skin Care & RT: New connections. Presented at the Respiratory Therapeutics Seminar, Clarian Health, Indianapolis, IN, Feb, 2009. (Invited)

Pittman, J. Pressure Ulcers: Present on Admission (POA) or Hospital Acquired (HA). Presented to physician at Lunch & Learn, Clarian Health, Indianapolis, IN, December and April 2009. (Invited)

Pittman, J. Nutrition for Healing. Presented at Clarian Health, Indianapolis, IN, May 2009. (Invited)

Pittman, J. Present on Admission or Hospital Acquired: The Search is ON! Presented to medical coders at Clarian Health, August 2009. (Invited)

Pittman, J. Development of the Ostomy Outcome Risk Assessment Scale and the Ostomy Outcome Classification Index. Presented as a poster at the 41ST Annual Wound, Ostomy, Continence Nurses Conference: Minneapolis, MN, 2009. (Refereed)

Pittman, J. Development of the Ostomy Outcome Risk Assessment Scale and the Ostomy Outcome Classification Index. Oral presentation at the 41ST Annual Wound, Ostomy, Continence Nurses Conference: Minneapolis, MN, 2009. (Refereed)

Pittman, J. Wound Management: Occupational Trauma. Presented to Occupational Health Nurses Society, Indianapolis, IN, September, 2009. (Invited)

Pittman, J. Developing Your Framework, Guest lecture for R603: Research Method and Design, Indiana University School of Nursing, February 2010. (Invited)

Pittman, J. Instruments: Ostomy Outcome Risk Assessment Scale & Ostomy Outcome Classification Index, Guest lecture for R603: Research Method and Design, Indiana University School of Nursing, March 2010. (Invited)

Pittman, J. Characteristics of the Patient with an Ostomy. Presented at the 42nd Annual Wound, Ostomy and Continence Nurse Conference: Phoenix, AZ, 2010. (Refereed)

Pittman, J. Fecal Containment Methods & Devices. Presented at the 42nd Annual Wound, Ostomy and Continence Nurses Conference: Phoenix, AZ, 2010. (Invited)

Pittman, J. Skin and Wound, PESI Healthcare. Presented Indianapolis, Fort Wayne, Merrillville, IN. June, 2010. (Invited)

Pittman, J. Skin and Wound, PESI Healthcare. Presented Oklahoma City, OK & Tuscon, AZ. July, 2010. (Invited)

Pittman, J. Skin Injury: Incontinence, Ostomies and Fistulas. Indiana Advanced Wound Care Symposium. Presented Indianapolis, IN. October 2010. (Invited)

Pittman, J. Integumentary System. PESI Healthcare. Presented Las Vegas, NV. April 2011. (Invited)

Pittman, J. Complex Wound Management. PESI Healthcare. Presented Las Vegas, NV. April 2011. (Invited)

Pittman, J. Developing Your Pressure Ulcer Prevention Program. PESI Healthcare. Presented Las Vegas, NV. April 2011. (Invited)

Pittman, J., Beeson, T., Kirk, L., Kessler, W. An interventional study of bowel management systems to decrease incontinence associated dermatitis. To be presented as oral presentation at the 43rd Wound, Ostomy, Continence Nurses Society National Conference, June 2011. (Refereed)