THE IMPACT OF STANDARDIZED, HEALTH LITERATE EDUCATION MATERIALS FOR POSTOPERATIVE PATIENTS WITH A NEW OSTOMY

by

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ABSTRACT

KIMBERLY A. PATE. The impact of standardized, health literate education materials for postoperative patients with a new ostomy. (Under the direction of DR. KELLY POWERS)

Patients undergoing surgery for a new ostomy require an extensive amount of education due to the complexity of the tasks required for self-care. By starting education earlier in the preoperative setting and providing written health literate materials for review, autonomy and confidence are supported by allowing sufficient time for education. The purpose of this project was to determine if supplementing the current education process with standardized, health literate written education materials improves patient self-efficacy for management of their new ostomy, with a secondary aim of decreasing post-surgical complication rates. A one-group, repeated measures, quasi-experimental design was utilized with a sample of 25 surgical patients. By adding the written materials and initiating patient education preoperatively, a statistically significant improvement in self-efficacy was demonstrated. Mean self-efficacy scores increased from 27.32 (SD = 12.15, CI = 22.30, 32.34) pre-education in the clinic to 39.56 (SD = 9.26, CI = 35.74, 43.38) post-education in the clinic ($p = 0.000$), and further increased to 47.20 (SD = 7.38, CI = 44.14, 50.25) at discharge from the hospital post-surgery ($p = 0.0004$). The quarterly complications O/E decreased from 0.99 pre-intervention to 0.88 post-intervention, indicating that the project facility performed better than the reference population. Initiating education preoperatively and supplementing it with standardized, health literate written education materials is recommended to improve patients' stoma self-efficacy. By increasing self-efficacy, patients may be more effective in self-

management of their ostomy and better prepared to care for themselves upon discharge from the hospital to prevent complications.

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LIST OF ABBREVIATIONS

DNP	Doctor of Nursing Practice
HLA	Health Literacy Advisor
IRB	Institutional Review Board
LOS	Length of stay
O/E	Observed-to-expected ratio
PAM	Patient Activation Measure
REDCap	Research Electronic Data Capture
RM-ANOVA	Repeated measures analysis of variance
SCT	Social Cognitive Theory
SMOG	Simple Measure of Gobbledygook
SPSS	Statistical Package for Social Sciences
WOC	Wound ostomy continence

CHAPTER 1: INTRODUCTION

1.1 Background

Postoperative patients with a new ostomy require extensive education prior to discharge from the hospital. Patients and family caregivers report a need for more help with ostomy care than any other medical or nursing task due to the complexity of this type of care (Kirkland-Kyhn, Martin, Zaratkiewicz, Whitmore, & Young, 2018). Unfortunately, many patients experience stoma-related complications due to a lack of self-care knowledge and skill (Kirkland-Kyhn et al., 2018). Consistent, structured education related to ostomy and peristomal skin care, the products utilized, bathing practices, activity restrictions, dietary and fluid considerations, and when to contact a healthcare professional is vital to ensure a successful discharge. During the perioperative time period, patients receive much of this information verbally. Written instructions can provide an additional source for reference upon discharge (Kirkland-Kyhn et al., 2018). When developing written education materials, it is imperative to ensure an appropriate reading level, and this is accomplished by using short sentences, plain language, and illustrations that will enhance understanding (Plain Language Action and Information Network, n.d.).

Health literacy is the ability to understand basic health information, and only 12% of Americans have proficient health literacy (U.S. Department of Health and Human Services, n.d.). In fact, more than 90 million individuals have limited health literacy, and this results in difficulty with common health-related tasks. Higher rates of limited health literacy are demonstrated by older adults and minorities, as well as individuals with lower education levels and chronic diseases (Foster, Idossa, Mau, & Murphy, 2016). Yet, many

current written health materials read at a college level, with no formalized process for review. Further, variations in the verbal information provided to the patients can exist dependent on the experience and comfort level of the nurse providing education. Therefore, there is a need for standardized, health literate education materials to help improve self-efficacy and promote positive patient outcomes. Self-efficacy is defined as belief in one's ability to succeed in certain situations or accomplish a task (Bandura, 1977), and research shows that patient education on ostomy care can significantly increase self-efficacy to result in lower incidence of ostomy complications (Mohamed, Salem, & Mohamed, 2017).

1.2 Significance

Approximately 800,000 individuals are currently living with an ostomy, and about 120,000 new ostomies are created annually in the United States and Canada (Colwell, Pittman, Raizman, & Salvadalena, 2018). In 2017, there were 808 colorectal surgeries performed at the project facility, a large 874 bed medical center in Charlotte, NC. Of this number, 184 patients had a new ostomy placed, with 115 new stomas placed by the facility's four main colorectal surgeons. The 2017 observed length of stay (LOS) for this population was 6.46 days, and the expected LOS was 6.12. If a facility's observed-to-expected ratio (O/E) is less than 1, then the facility performs better than the reference population for that indicator (Agency for Healthcare Research and Quality, n.d.). In this instance, the LOS O/E was 1.05, leaving little room for improvement. Similarly, the observed readmission rate was 11.70%, and the expected rate was 12.40% with an O/E of 0.94. Finally, the observed complication rate was 23.89%, and the expected complication rate was 26.26% (complication O/E was 0.91). Although this complication O/E is less

than 1, it still signifies that approximately 1 in 4 patients experienced a complication. Improving the patient education process for these patients may promote improved self-efficacy to result in better self-care ability and less complications. Additionally, the project facility's postoperative clinic reports receiving a large volume of calls with postoperative ostomy concerns and complications. Common reasons for clinic calls after discharge include general management concerns and complications such as a leaking ostomy pouch, irritation of peristomal skin, and dehydration (J. Moore, personal communication, September 13, 2018). Therefore, interventions to help prevent complications are vital to ensuring positive patient outcomes following ostomy surgery.

1.3 Problem Statement

To address common patient concerns and complications, new ostomates require thorough preparation, education, and support to ensure adequate ability to self-manage their new chronic condition. Due to their emotional state with a new diagnosis and surgery, a variety of educational methods are needed to support the new ostomate (Kirkland-Kyhn et al., 2018). Currently, patients at the project facility are educated via one-on-one didactic presentations and demonstrations, followed by immediate return demonstrations. Educational handouts created by a company that produces stoma care products are also provided; however, patients and nurses report that these materials are sub-optimal because the materials consist of a number of loose information sheets that are not compiled in a logical order for easy reference. Using Health Literacy Advisor, these materials were assessed for readability level, and it was found that they read at a college level. The materials utilized many three syllable words and sentences greater than 15 words. This demonstrates the need for health literate education materials to

supplement patient learning and provide a resource that will support them when performing complex care tasks without the support of healthcare professionals at home.

1.4 Purpose of the Project

The purpose of this Doctor of Nursing Practice (DNP) scholarly project was to evaluate if supplementing the current education process for new ostomates with standardized, health literate written education materials improves patient self-efficacy for management of their new ostomy. A secondary aim was to determine if the rate of postoperative complications decreases among this patient population after the supplemental education materials were integrated into patient care.

1.5 Clinical Question

In postoperative patients with a new ostomy, does the implementation of standardized, health literate written education materials improve patient self-efficacy and decrease postoperative complication rates?

1.6 Project Objectives

The objectives of this DNP scholarly project were to: (1) Develop comprehensive, health literate written education materials at a 6th grade reading level for patients with a new ostomy; (2) Provide written education materials to supplement the current education process for new ostomates prior to hospitalization, followed by thorough review prior to postoperative discharge from hospital; (3) Evaluate for changes in patients' ostomy self-efficacy with measurements occurring at three timepoints: pre-education in outpatient clinic, post-education in outpatient clinic, and post-education while in hospital following surgery; (4) Assess for changes in complication rates among

new ostomates at the project facility, comparing the rate of complications after the start of the intervention to the rate of complications prior to the start of the intervention.

CHAPTER 2: LITERATURE REVIEW

2.1 Search Terms

A literature review was conducted using the databases: Cochrane Library, CINAHL, PubMed, and ProQuest Nursing & Allied Health. The key words used in the search were stoma, colostomy, ileostomy, education, patient education, therapeutic education, health education, self-care, self-efficacy, self-management, empowerment, behavior therapy, and health literacy. Inclusion criteria were research studies and literature reviews, published in peer-reviewed journals, and published from 2012 to 2020. Results were further narrowed by including only English language articles and studies focused on adults. Duplicates and non-peer reviewed sources were excluded. Reference lists in key articles were also reviewed for pertinent literature. Each selected article was reviewed using a Rapid Critical Appraisal Checklist for validity, reliability, and generalizability. Strengths and limitations were weighed against the value for future clinical practice, and studies were weighted on the level of evidence (Fineout-Overholt, Melynk, Stillwell, & Williamson, 2010).

2.2 Studies Related to Self-Efficacy and Patient Education in General

Patient education resulting in improved self-efficacy has been linked to better self-management for many chronic conditions including hypertension, chronic kidney disease, end-stage renal disease requiring hemodialysis, obstructive sleep apnea, acute coronary syndrome, type 2 diabetes, chronic obstructive pulmonary disease, epilepsy, rheumatoid arthritis, osteoporosis, multiple sclerosis, human immunodeficiency virus, and cirrhosis. Studies also show that poor self-efficacy is linked to limited knowledge and sub-optimal compliance with self-management routines. Furthermore, a correlation

between poor self-efficacy and higher rates of complications has been noted (Daniali, Shahnazi, Kazemi, & Marzbani, 2016; Dowse, Barford, & Browne, 2014; Ha, Hu, Petrini, & McCoy, 2014; Hixson et al., 2015; Jalilian, Motlagh, Solhi, & Gharibnavaz, 2014; Kauric-Klein, Peters, & Yarandi, 2017; Kim, 2018; Liu, Wu, Willis, & Shi, 2018; Mansouri, Ghadami, Najafi, & Yektatalab, 2017; Maslakpak & Raiesi, 2014; Ndosi et al., 2016; Tülüce & Kutlutürkan, 2018; Wu, Hsieh, Lin, & Tsai, 2016). Similar findings have been noted for postoperative urostomy patients. An education initiative to prepare patients to care for their permanent urostomy resulted in enhanced knowledge, self-care ability, and self-efficacy (Mahdy, Ameen, & Mousa, 2018). Self-efficacy was noted to aid adaptation, which reduces the rate of complications. Results of this study also demonstrated that pain, medications, and psychological stress limit education effectiveness postoperatively (Mahdy et al., 2018), indicating a need to educate patients at additional time periods rather than exclusively educating in the postoperative period.

2.3 Studies Related to Self-Efficacy and Patient Education for New Ostomies

Several recent studies were found to have evaluated patient education and self-efficacy for ostomy care. Study designs included a systematic review, randomized control trials, a quasi-experimental study, case control studies, a mixed method design, and a qualitative study. Sample size ranged from 30 to 50 individuals, and participants in all studies were adults with a stoma. Most had a colostomy or ileostomy, but some participants did have a urostomy. While the majority of these patients had colorectal cancer, some studies also included genitourinary cancer, diverticulitis, and other gastrointestinal diagnoses. The length, content, method of delivery, source of delivery, and timing of patient education was variable in each study. Education interventions

included didactic presentations, group discussions, telephone follow-ups, and written materials. The length of the interventions ranged from 45 minutes to 6 weeks. Self-efficacy was measured utilizing the Generalized Self-Efficacy Scale, the Stoma Self-Efficacy Scale, or the Self-Efficacy for Ostomy Management Tool. Patient self-efficacy was measured pre-intervention and up to 6 months post-intervention. In addition to self-efficacy, studies also examined stoma knowledge, quality of life, self-management, length of stay, readmissions, and complications (Danielson & Rosenberg, 2014; Cheng, Xu, Xiao-dong, & Yang, 2012; Faury, Kolek, Foucaud, M'Bailara, & Quintard, 2017; Krouse et al., 2016; Mohamed et al., 2017; Pouresmail, Nabavi, Abdollahi, Shakeri, & Saki, 2019; Seo, 2019; Wen et al., 2019; Xu et al., 2018; Zhang et al., 2013; Zhang et al., 2014; Zhou et al., 2019).

Xu et al. (2018) demonstrated statistically significant improvement in self-efficacy in new ostomates through implementation of a 3-month education program based on self-efficacy theory. Content included self-care education and psychological support. Self-efficacy was measured using the Stoma Self-Efficacy Scale, and a statistically significant improvement was found at one ($p = 0.047$) and three months after education ($p = 0.000$) (Xu et al., 2018). Bekkers, Van Knippenberg, Van Den Borne, and Van Berge-Henegouwen (1996) created the 13-question Stoma Self-Efficacy Scale that has a reported Cronbach alpha of 0.94. It has been used in multiple studies and translated into many languages. It measures self-efficacy for ostomy skills, including preparation of the pouch, application and removal of the old pouch, and cleaning stoma and surrounding skin, with self-efficacy rated on a scale of 1 (not confident at all) to 5 (extremely confident) (Bekkers et al., 1996).

Additional research has shown that patient education can improve self-efficacy and management for a new stoma. In a quasi-experimental study, researchers found increased knowledge, a reduction in complications including peristomal skin irritation, and a statistically significant increase in self-efficacy ($p = 0.000$) immediately following participation in a self-care management program and 1-month after education. The incidence of severe peristomal skin complications decreased from 66.7% to 60% after the program (Mohamed et al., 2017). Krouse et al. (2016) implemented a five-session ostomy self-care curriculum based on the Chronic Care Model. Self-efficacy for ostomy management was significantly improved at patients' 6-month follow-up visit ($p = 0.008$). Patients also demonstrated significantly higher Patient Activation Measure (PAM) scores ($p = 0.001$), which indicate better overall health with less visits to the doctor's office and emergency department (Krouse, 2016).

In fact, all of the studies that evaluated patient education and self-efficacy for ostomy care that were located as part of this review had proposed that patients with higher self-efficacy would be more effective in the self-management of their ostomy, and all resulted in improvements in self-efficacy scores. Thus, it is imperative to design education programs to improve the self-efficacy of new ostomates. It was recommended that comprehensive, structured patient education requires a multidisciplinary team approach in the pre- and postoperative periods, and that education content should include stoma care, as well as a focus on psychosocial considerations (Danielson & Rosenberg, 2014; Faury et al., 2017; Krouse et al., 2016; Mohamed et al., 2017; Xu et al., 2018; Zhang et al., 2013).

In addition to quantitative research, qualitative findings also support the need for patient education on new stomas. In a recent qualitative study, participants reported not being well prepared to manage their stomas during hospitalization which impacted their ability to care for their stoma upon discharge (Lim, Chan, & He, 2015). In this study, participants reported that they would have preferred having more information on how a stoma looks, the different types of stoma bags, and care of the stoma before their surgical procedure. Participants reported feeling overwhelmed when all of this information was provided after surgery. It was therefore recommended that early preparation in the preoperative period can lessen the psychological impact of having a new stoma. Further, the addition of an education booklet was recommended to ensure comprehensiveness of education (Lim et al., 2015).

Thorpe, McArthur, and Richardson (2014) had similar findings. This existential phenomenological study found that patients did not feel confident in making independent choices and accepting responsibility for their ostomy prior to discharge from the hospital after surgery. Patients reported feelings of guilt due to admonishment from nurses, loss of control when the pouch was leaking, and disempowerment due to their lack of control. Accelerated discharges from the hospital were identified as a barrier to adequately preparing patients to care for their new ostomy. It was suggested that autonomy and confidence are supported by allowing sufficient time for education and starting this education earlier while patients are in the preoperative setting (Thorpe et al., 2014). Together, these qualitative findings reveal pre-surgical education is imperative and written materials should be provided to serve as a patient reference.

2.4 Studies Related to Specialized Nurses Providing Education

Patients with ostomies report that bedside nurses demonstrate a lack of confidence and skill related to ostomy care. Lower levels of bedside nurse confidence are associated with less years of experience, lack of ostomy training, and lower frequency of providing ostomy care (Cross, Roe, & Wang, 2014). Due to time constraints and excess workload, stoma care and patient education are not often viewed as a priority by bedside nurses. In contrast, specialized nurses, titled wound ostomy continence (WOC) nurses, exhibit higher levels of clinical expertise (Lapkin et al., 2018). In a quasi-experimental study, patients experienced improvements in quality of life when cared for by a nurse specializing in ostomy care ($p < 0.05$). Self-management also differed when a specialized nurse was available. Participants reported feeling more secure in cleaning their stoma ($p = 0.005$), changing their ostomy ($p < 0.01$), obtaining ostomy supplies ($p < 0.001$), and accessing someone to provide expert advice about problems with their ostomy ($p < 0.001$) (Coca, Larrinoa, Serrano, & Garcia-Llana, 2015). With their unique knowledge, skills, and experience, WOC nurses are ideal for providing structured, consistent education to new ostomates and ensuring adequate understanding. The abilities of the WOC nurse make them an ideal candidate to present the health literate written materials to augment the face-to-face instruction they provide.

2.5 Studies Related to Readability and Suitability of Patient Education Materials

Smith et al. (2014) evaluated 125 patient education materials designed for patients undergoing colorectal cancer surgery using a validated suitability and comprehensibility assessment tool. Findings revealed that 13.6% were rated not suitable, 76.8% were suitable, and 9.6% were superior. Almost one-third (29%) of materials were found to be

difficult to comprehend. Additionally, patient focus groups identified that materials did not meet the needs of patients in the following areas: general and personal care, personal implications, support from family and significant others, usability, trustworthiness, and support groups (Smith et al., 2014).

Studies assessing other chronic conditions also demonstrate that patient education materials are often difficult to comprehend. In a study assessing 69 patient education materials for chronic kidney disease from 19 different facilities, nearly one-half (43%) of the patient education materials demonstrated a reading level higher than that of a 6th grade student. Considering that the average American reads at an 8th grade level, this would significantly impact the suitability of the materials and limit effectiveness (Tuot, Davis, Velasquez, Banerjee, & Powe, 2013). Similar results were found in a review of 22 written health education materials for patients with heart disease and chronic lung conditions, which revealed one-half (50%) of the materials were written at a reading level greater than 6th grade (Jacob, Davis, Mansfield, & Logsdon, 2016). Further, when reviewing the education materials for cardiac patients, only 38% were found to be of good quality (Ghisi, Abdallah, Grace, Thomas, & Oh, 2014). These findings, demonstrating that patient education materials are often not written at an appropriate reading level and are often of poorer quality, suggest that there is a need for review and improvement of written patient education materials. As patients with new ostomies report a need for more help with ostomy care due to its complexity, effective written materials are a key resource to help ensure a successful discharge and recovery period (Kirkland-Kyhn et al., 2018).

2.6 Conceptual/Theoretical Framework

In Albert Bandura's Social Cognitive Theory (SCT), self-efficacy plays a pivotal role in modifying health behaviors and the ability to handle life events (Bandura, 1977). Strong self-efficacy is developed through repeated success, and the negative impact of occasional failure is reduced. Thus, occasional failure can be overcome by persistence if the individual finds that even challenging tasks or obstacles can be mastered. Individuals who consider themselves to have a high level of self-efficacy attribute their failures to insufficient effort. If they face a setback, they will increase or continue their efforts. Individuals can also be persuaded verbally that they have the ability to master specific activities and will use greater effort if they have self-doubts and dwell on personal shortcomings when problems arise (Bandura, 1977).

According to SCT, strengthening the current education process for patients with new ostomies through development of standardized, health literate written education materials to reinforce didactic education and return demonstration, knowledge, and skill in caring for an ostomy will improve self-care practices. Self-efficacy will increase through repeated positive experiences while in the hospital and better prepare the patient to care for themselves upon discharge. Ostomates with high self-efficacy would then be able to handle their stressors with higher confidence and perform the necessary behaviors to manage their new chronic condition, leading to decreased rates of postoperative complications.

CHAPTER 3: METHODS

3.1 Project Design

This quality improvement project utilized a one-group, repeated measures, quasi-experimental design to evaluate the effectiveness of supplementing the current education process for new ostomates with standardized, health literate written education materials. Outcomes measures included stoma care self-efficacy level and rates of postoperative complications.

3.2 Sample

Convenience sampling was used, and patients were recruited during their initial pre-surgery appointment for stoma placement site marking at two of the project facility's outpatient clinics. At this appointment, the project lead explained the intervention to patients, including the project purpose and data collection procedures. They were also informed that their participation in the surveys for data collection was voluntary, and the supplemental education would be provided regardless of whether or not they chose to participate in data collection. A handout outlining the project was provided by the project lead (Appendix A). Ongoing recruitment occurred over six months in 2019.

Patients were invited to participate if their age was 18 years or greater, they were able to speak and read in English, and they were scheduled for colorectal surgery to result in ostomy placement through the two surgical clinics at the project facility. Patients were excluded if age was less than 18 years, unable to speak or read in English, or an unplanned or emergent ostomy occurred. Patients who received an unplanned or emergent ostomy were excluded because they were admitted directly to the hospital without the ability to provide patient education at the outpatient clinics. Excluded

individuals, with the exception of those unable to speak or read English, still received education, but they were not invited to participate in the surveys for data collection. Unfortunately, the new written ostomy education materials created for this project were not yet available in languages other than English. Individuals who could not speak English received the same written education materials (available in multiple languages) that were previously used at the project facility. Following project completion, findings will be used to demonstrate the importance of investing in translation services and ongoing product printing costs at the project facility.

3.3 Setting

The education intervention was initiated in two identified outpatient surgery clinics at the project facility and continued during the postoperative stay in the hospital through the time of discharge. The project facility's two clinics and hospital are located in Charlotte, NC. The hospital is an 874 bed, level 1 trauma and academic medical center.

3.4 Intervention

Comprehensive, health literate written education materials were developed by the project lead for patients scheduled to receive a new ostomy at the project facility. To ensure all needed components were included, collaboration occurred with inpatient bedside nurses, outpatient clinic nurses, surgeons, and WOC nurses. Content was created based on current literature, the facility's supporting data, and clinical observations (Appendix B). Health Literacy Advisor (HLA) was utilized to ensure the materials read at a 6th grade reading level. HLA is a software tool with a variety of readability formulas including the Fry-Based Electronic Readability Formula and Precise Simple Measure of

Gobbledygook (SMOG) that assists with the implementation of plain language (Health Literacy Innovations, n.d.). Approval of the written education materials was obtained from the project facility's Health Literacy Committee (Appendix C), as well as the marketing department to ensure appropriate branding.

During the project design and planning stages, administrative support was solicited due to the need for buy-in, cost of printing the educational booklets, and time needed from the WOC nurses to implement the education intervention. Prior to the start of the project, training was provided to the WOC nurses by the project lead to ensure all patients received the same ostomy education using the new written educational materials. In addition to review of the materials, this WOC nurse training also included discussion of health literacy principles as well as health literacy statistics and average reading levels to ensure adequate understanding and establish buy-in during the transition from use of the current education materials. The training was necessary to standardize the process of educating patients because two WOC nurses provided the education.

The outpatient clinic nurses alerted the WOC nurses when a patient was scheduled for their preoperative stoma site marking. During this appointment, the health literate written education materials were provided and reviewed by one of the WOC nurses to supplement the current one-on-one didactic education process prior to hospitalization. Data on self-efficacy was collected by the project lead immediately prior to and after this education in the outpatient clinic. Patients then had the written materials to take home, allowing time for review prior to the stress of hospitalization. Then, when patients were in the hospital following their surgery, return demonstration with a thorough review of the materials by the WOC nurses occurred, with repeated data

collection by the project lead on self-efficacy prior to postoperative discharge from hospital.

3.5 Measurement Tools

Demographic data was collected using a 9-item survey created by the project lead. Information collected included age, gender, reason for ostomy, type of stoma, prior surgical experience, comfort using medical terms, presence of additional chronic illnesses, family support, and previous family history of an ostomy (Appendix D). This data was only collected at the first timepoint, prior to the initial education in the outpatient clinic.

To measure the impact of patient education on self-efficacy, permission was received to utilize the Stoma Self-Efficacy Scale developed by Bekkers et al. (1996) (Appendix E). It has a reported Cronbach alpha of 0.94 (Bekkers et al., 1996) and has been used in multiple studies. This scale has 13 items to measure stoma care self-efficacy for skills such as applying the stoma collection materials, preventing leakage, avoiding skin problems, and following nutrition instructions. The format is a 5-point Likert scale, with response options ranging from 1 (not confident at all) to 5 (extremely confident) (Appendix F). To evaluate total self-efficacy, scores for the items are summed, with higher total scores corresponding to higher levels of self-efficacy (Bekkers et al., 1996). Self-efficacy data collection occurred at all three timepoints: pre- and post-education in the outpatient clinic and post-education following surgery in the hospital. In addition, patient feedback was requested by asking participants to respond to an open-ended question post-education in the outpatient clinic and post-education following surgery in the hospital. Participants were asked “Do you have any comments or feedback

about your ostomy education that you would like to share?" Following surgery in the hospital, participants were also asked "How many minutes did you spend reviewing the written education materials between your outpatient clinic visit and your admission to the hospital?" and "How many minutes did you spend reviewing the written education materials while you were in the hospital?"

Finally, postoperative complication rates were monitored to compare the rate of complications for the two quarters after the start of the intervention in 2019 to the rate of complications for the two quarters prior to the start of the intervention in 2019. This data is routinely collected by the Quality Department at the project facility and reported each quarter to the project lead. Complications can include infections, bleeding from the surgical site, pressure injuries, peristomal skin irritation, and dehydration. The rate of complications is reported as the percentage of patients who had a complication out of all patients within 30 days of colorectal surgery.

3.6 Data Collection Procedure

Data collection occurred after hospital approval for quality improvement projects and university institutional review board (IRB) approval were obtained (Appendix G). Pre-education and immediate post-education data collection occurred in the outpatient clinics. Upon coming to the clinic, patients were approached by the project lead who explained the project and offered participation as previously outlined. For those who volunteered to participate, the demographic survey and Stoma Self-Efficacy Scale were then completed. Next, didactic education supported by the created health literate, written patient education booklet was provided by one of the two WOC nurses. After this education was complete, participants again completed the Stoma Self-Efficacy Scale

which ended with the open-ended question to gather feedback regarding the education provided. Participants were then encouraged to completely review the written patient education materials prior to surgery.

The data collection post-education following surgery occurred in the hospital. Upon admission to the hospital and after surgery, participants were approached daily by one of the two WOC nurses who used the written education materials to educate participants to ensure successful completion of return demonstrations of ostomy self-care. Immediately prior to discharge, participants again completed the Stoma Self-Efficacy Scale and the open-ended question to gather feedback regarding the education provided. Participants also reported the number of minutes spent reviewing the written education materials: a) between the outpatient clinic visit and admission to hospital and b) during hospitalization. See Figure 1 for schematic outline of the data collection procedures.

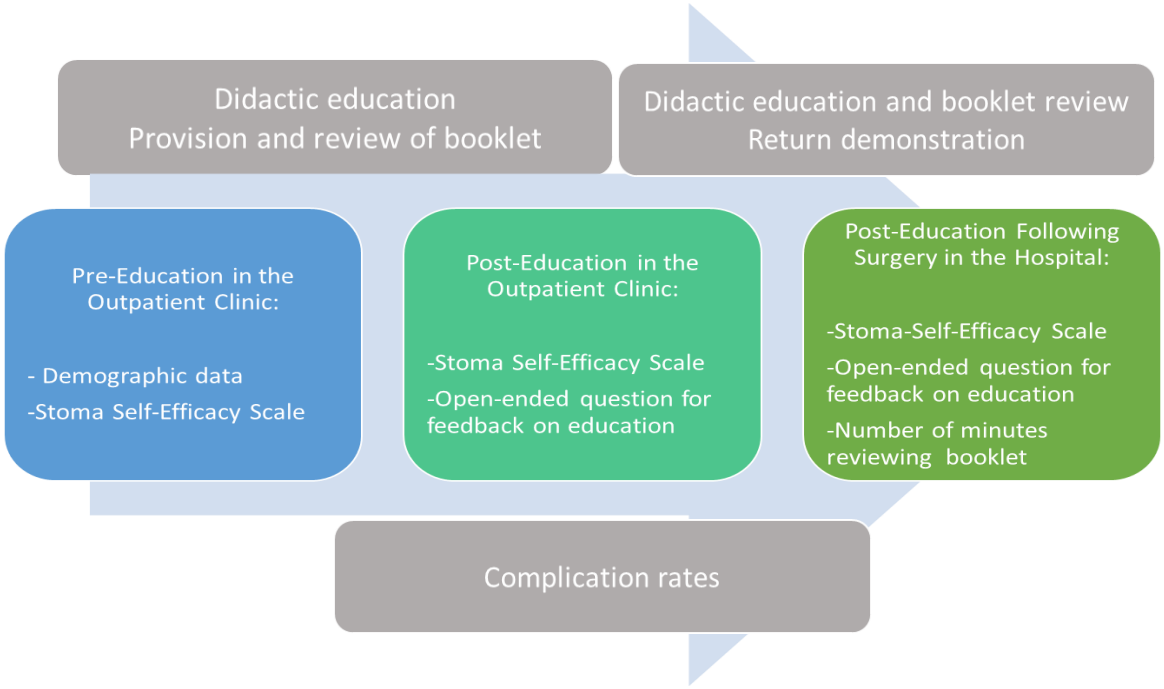

Figure 1. Data collection procedures

At all of the data collection timepoints, the project lead collected the survey data, and the trained WOC nurses implemented the educational intervention. Participant recruitment, the intervention, and self-efficacy data collection occurred over a six-month period from May to October 2019. Surveys were administered via paper and pencil format, and all survey data was manually entered and stored in the Research Electronic Data Capture (REDCap) database, which is a secure, web-based application (Vanderbilt University, n.d.). Data on complication rates is routinely collected at the project facility. The project lead was provided with a quarterly report on complication rates. Complication rate data was collected for the entire year of 2019 and is inclusive of all patients undergoing colorectal surgery. For the purposes of this project, Quarters 1 and 2 (January to March and April to June) represented pre-intervention rates. Quarters 3 and 4 (July to September and October to December) represented post-intervention rates. As the pre-surgery outpatient clinic appointment occurred about 1-month prior to surgery, patients recruited in May 2019 would have had surgery in June 2019, and 30-day complication rates would be part of the Quarter 3 report of data. Patients recruited in September 2019 would have had surgery in October 2019, and 30-day complication rates would be part of the Quarter 4 report of data. It is important to note that although recruitment and self-efficacy data collection ended in October 2019, the new education materials continue to be used at the project facility; thus, Quarter 4 data continues to represent patient complications after use of the new education materials. See Table 1 for the timeline of project events.

Table 1. Timeline of project events

Dates	Project Components
January 2019-March 2019	Pre-Intervention Quarter 1 Complication Rates Collected
April 2019-June 2019	Pre-Intervention Quarter 2 Complication Rates Collected
May 2019	Participant Recruitment and Self-Efficacy Data Collection Began
May 2019-September 2019	Ongoing Participant Recruitment and Self-Efficacy Data Collection
July 2019-September 2019	Post-Intervention Quarter 3 Complication Rates Collected
October 2019	Self-Efficacy Data Collection Ended for Patients Recruited in September (Outpatient clinic in September = Hospital in October)
October 2019-December 2019	Post-Intervention Quarter 4 Complication Rates Collected

3.7 Data Analysis

Data was analyzed using the Statistical Package for Social Sciences (SPSS) version 23. Data was transferred from REDCap into SPSS for analysis. Descriptive statistics were utilized to evaluate participants' demographic data and the number of minutes spent reviewing the written education materials prior to and during hospitalization. Descriptive statistics were also used to present mean scores for each item

of the Stoma Self-Efficacy Scale as well as means for total summed scores at all three timepoints. Repeated-Measures Analysis of Variance (RM-ANOVA) and paired t-tests were used to detect statistically significant changes, with significance set at $p < 0.05$. Written comments to provide feedback on the education were analyzed by the project lead to identify themes. Complication rates for each quarter of 2019 were presented using descriptive statistics. Descriptive statistics were also used to present pre-intervention complication rates (averages for Quarters 1 and 2) and post-intervention complication rates (averages for Quarters 3 and 4).

3.8 Ethical Considerations

This project was submitted for ethical approval at the project facility, and it was determined that the project did not meet the definition of human subjects research. Approval to proceed with the project as quality improvement was obtained from the project facility. Approval was also obtained from the IRB at the University of North Carolina at Charlotte. Participant recruitment and data collection began after IRB approval was obtained. The purpose of the project was explained to each patient (verbally and in writing), and completion of surveys was voluntary. Verbal consent was obtained with no formal signature required as the project did not meet the definition of human subjects research. In addition, voluntary completion of project surveys, after review of the study's purpose and procedures, conveyed consent to participate. All patients were informed they would receive the education intervention even if they choose not to complete the surveys.

Ethical practices were ensured throughout the project implementation. Confidentiality was maintained by not collecting personal information (such as name,

date of birth, etc.) from participants in any of the surveys. In order to link survey results across data collection timepoints, participants only reported the last five digits of their telephone number on the surveys. All data was maintained securely by the project lead in a REDCap database. Printed surveys were stored in a secure, locked cabinet after data was entered by the project lead into REDCap. All surveys and stored data will be securely stored for a period of 3 years after the project is completed and then will be destroyed. In all manuscripts and presentations resulting from this project, survey responses will be reported in aggregate form, and individual participant survey responses will not be reported.

CHAPTER 4: RESULTS

4.1 Characteristics of Sample

A total of 25 patients participated in this project. Demographic data showed 36% were greater than 60 years old, 36% were 50 to 59 years old, 24% were 40 to 49 years old, and 4% were 30 to 39 years old. In regard to gender, 56% were male, and 44% were female. The primary reason for surgery to create an ostomy was cancer (88%), and most patients had a colostomy placed (72%). Of the 25 participants, 14 (56%) reported that this was their first surgery. In addition, participants reported a variety of chronic illnesses with 28% of participants having high blood pressure. Other reported conditions included arthritis, obstructive sleep apnea, chronic obstructive pulmonary disease, thyroid disease, obesity, anxiety, and endometriosis. A small number (8%) reported having a family member who previously underwent ostomy surgery. Comfort with understanding medical terminology was also explored, with 12% reporting not comfortable, 20% slightly comfortable, 48% fairly comfortable, 16% highly comfortable, and 4% extremely comfortable. Favorable amounts of self-reported confidence for family support in caring for their new stoma were noted, with 48% reporting themselves as being extremely confident and 40% highly confident. See Table 2 for demographic results and Table 3 for patient comfort with medical terminology and confidence in family support.

Table 2. Participant demographics

		Number of participants	Percentage (%)
Age range			
	20-29 years	0	0%
	30-39 years	1	4%
	40-49 years	6	24%
	50-59 years	9	36%
	>60 years	9	36%
Gender			
	Male	14	56%
	Female	11	44%
Reason for ostomy			
	Cancer	22	88%
	Crohn's disease	0	0%
	Ulcerative colitis	1	4%
	Diverticulitis	1	4%
	Other	1	4%
Type of stoma			
	Colostomy	18	72%
	Ileostomy	6	24%
	Don't know	1	4%
First surgery			
	Yes	11	44%
	No	14	56%
Other chronic illnesses			
	Diabetes	3	12%
	High blood pressure	7	28%
	Kidney disease	1	4%
	Asthma	1	4%
	Other	20	80%
Family history of ostomy			
	Yes	2	8%
	No	22	88%
	Unknown	1	4%

Table 3. Patient comfort with medical terminology and confidence in family support

		Number of participants	Percentage (%)
Comfort with medical terminology			
	Not comfortable	3	12%
	Slightly comfortable	5	20%
	Fairly comfortable	12	48%
	Highly comfortable	16	16%
	Extremely comfortable	4	4%
Confidence in family support			
	Not confident at all	0	0%
	Slightly confident	1	4%
	Fairly confident	2	8%
	Highly confident	10	40%
	Extremely confident	12	48%

4.2 Self-Efficacy Results

Analysis of individual Stoma Self-Efficacy Scale item results (range of responses and mean scores) showed that participants demonstrated an increase in self-efficacy with each additional step in the education process (i.e. at each data collection timepoint). Pre-education in the clinic, a large number of participants reported no confidence in avoiding leakage, preventing skin problems, preventing stoma bleeding and damage, and taking care of their stoma when ill. However, confidence improved in each category after receiving education in the clinic and then increased further after inpatient education prior to discharge from the hospital. At the time of discharge from the hospital, participants reported the least confidence in preventing obstructions and caring for their stoma when ill. The greatest comfort was demonstrated for the items: following the provider's advice for taking care of the stoma and nutrition pattern, as well as following instructions for handling the stoma. See Table 4 and Table 5 for frequency of responses, then Table 6 for self-efficacy mean scores at each point of data collection.

Table 4. Individual Stoma Self-Efficacy Scale item frequency of scores at 3 data collection points

		Pre-education in the clinic	Post-education in the clinic	Discharge from the hospital
		(number of participants/percentage)		
Apply the stoma collection materials before leakages appear				
	Not confident at all	7 (28%)	0 (0%)	0 (0%)
	Slightly confident	12 (48%)	6 (24%)	0 (0%)
	Fairly confident	5 (20%)	12 (48%)	12 (48%)
	Highly confident	0 (0%)	6 (24%)	11 (44%)
	Extremely confident	1 (4%)	1 (4%)	2 (8%)
Prevent having leakages				
	Not confident at all	11 (44%)	0 (0%)	0 (0%)
	Slightly confident	9 (36%)	8 (32%)	0 (0%)
	Fairly confident	3 (12%)	11 (44%)	13 (52%)
	Highly confident	1 (4%)	5 (20%)	10 (40%)
	Extremely confident	1 (4%)	1 (4%)	2 (8%)
Take care of the stoma in the right way at home				
	Not confident at all	8 (32%)	0 (0%)	0 (0%)
	Slightly confident	11 (44%)	6 (24%)	0 (0%)
	Fairly confident	3 (12%)	12 (48%)	11 (44%)
	Highly confident	2 (8%)	6 (24%)	12 (48%)
	Extremely confident	1 (4%)	1 (4%)	2 (8%)
Prevent having skin problems				
	Not confident at all	11 (44%)	0 (0%)	0 (0%)
	Slightly confident	8 (32%)	8 (32%)	1 (4%)
	Fairly confident	5 (20%)	12 (48%)	11 (44%)
	Highly confident	0 (0%)	4 (16%)	11 (44%)
	Extremely confident	1 (4%)	1 (4%)	2 (8%)
Prevent having stoma bleeding and damage				
	Not confident at all	11 (44%)	0 (0%)	0 (0%)
	Slightly confident	9 (36%)	10 (40%)	1 (4%)
	Fairly confident	3 (12%)	13 (52%)	13 (52%)
	Highly confident	1 (4%)	1 (4%)	9 (36%)
	Extremely confident	1 (4%)	1 (4%)	2 (8%)
Apply the stoma collection materials in the way you are taught				
	Not confident at all	5 (20%)	0 (0%)	0 (0%)
	Slightly confident	12 (48%)	2 (8%)	0 (0%)
	Fairly confident	4 (16%)	15 (60%)	7 (28%)
	Highly confident	3 (12%)	7 (28%)	16 (64%)
	Extremely confident	1 (4%)	1 (4%)	2 (8%)

Table 5. Individual Stoma Self-Efficacy Scale item frequency of scores at 3 data collection points, continued

Prevent having obstruction				
	Not confident at all	11 (44%)	0 (0%)	1 (4%)
	Slightly confident	8 (32%)	9 (36%)	3 (12%)
	Fairly confident	5 (20%)	13 (52%)	13 (52%)
	Highly confident	0 (0%)	2 (8%)	6 (24%)
	Extremely confident	1 (4%)	1 (4%)	2 (8%)
Follow the stoma therapist's instructions for handling the stoma				
	Not confident at all	3 (12%)	0 (0%)	0 (0%)
	Slightly confident	11 (44%)	2 (8%)	0 (0%)
	Fairly confident	5 (20%)	13 (52%)	6 (24%)
	Highly confident	5 (20%)	8 (32%)	16 (64%)
	Extremely confident	1 (4%)	2(8%)	3 (12%)
Follow the doctor's advice for taking care of your stoma and nutrition pattern				
	Not confident at all	4 (16%)	0 (0%)	0 (0%)
	Slightly confident	10 (40%)	4 (16%)	0 (0%)
	Fairly confident	5 (20%)	10 (40%)	6 (24%)
	Highly confident	5 (20%)	9 (36%)	16 (64%)
	Extremely confident	1 (4%)	2 (8%)	3 (12%)
Take care of the stoma the right way outdoors				
	Not confident at all	10 (40%)	0 (0%)	0 (0%)
	Slightly confident	10 (40%)	8 (32%)	1 (4%)
	Fairly confident	1 (4%)	13 (52%)	12 (48%)
	Highly confident	3 (12%)	3 (12%)	9 (36%)
	Extremely confident	1 (4%)	1 (4%)	3 (12%)
Take care of the stoma when you are ill				
	Not confident at all	11 (44%)	0 (0%)	0 (0%)
	Slightly confident	7 (28%)	8 (32%)	2 (8%)
	Fairly confident	3 (12%)	12 (48%)	13 (52%)
	Highly confident	3 (12%)	4 (16%)	7 (28%)
	Extremely confident	1 (4%)	1 (4%)	3 (12%)
Wear most of the clothes you like				
	Not confident at all	9 (36%)	0 (0%)	0 (0%)
	Slightly confident	11 (44%)	4 (16%)	1 (4%)
	Fairly confident	2 (8%)	14 (56%)	6 (24%)
	Highly confident	2 (8%)	6 (24%)	12 (48%)
	Extremely confident	1 (4%)	1 (4%)	6 (24%)
Carry out light duties in and around the house				
	Not confident at all	9 (36%)	0 (0%)	0 (0%)
	Slightly confident	7 (28%)	6 (24%)	0 (0%)
	Fairly confident	7 (28%)	15 (60%)	10 (40%)
	Highly confident	0 (0%)	2 (8%)	13 (52%)
	Extremely confident	2 (8%)	2 (8%)	2 (8%)

Table 6. Individual Stoma Self-Efficacy Scale item expressed mean scores at 3 data collection points

	Pre-education in the clinic mean score	Post-education in the clinic mean score	Discharge from the hospital mean score
Apply the stoma collection materials before leakages appear	2.04	3.08	3.60
Prevent having leakages	1.88	2.96	3.56
Take care of the stoma in the right way at home	2.08	3.08	3.64
Prevent having skin problems	1.88	2.92	3.56
Prevent having stoma bleeding and damage	1.88	2.72	3.48
Apply the stoma collection materials in the way you are taught	2.32	3.28	3.80
Prevent having obstruction	1.88	2.80	3.20
Follow the stoma therapist's instructions for handling the stoma	2.60	3.40	3.88
Follow the doctor's advice for taking care of your stoma and nutrition pattern	2.56	3.36	3.88
Take care of the stoma the right way outdoors	2.00	2.88	3.56
Take care of the stoma when you are ill	2.04	2.92	3.44
Wear most of the clothes you like	2.00	3.16	3.92
Carry out light duties in and around the house	2.16	3.00	3.68

The Stoma Self-Efficacy Scale scores for each participant were summed, and the highest possible score for the 13-items was 65.00. The mean of the total summed scores demonstrated a consistent increase over the three data collection points. Mean summed scores were 27.32 (SD = 12.15, CI = 22.30, 32.34) pre-education in the clinic, 39.56 (SD = 9.26, CI = 35.74, 43.38) post-education in the clinic, and 47.20 (SD = 7.38, CI = 44.14, 50.25) at discharge from the hospital post-surgery. See Table 7 for mean (with standard deviation), median, minimum, and maximum total summed scores and Figure 2 for a visual representation of the total summed scores. A RM-ANOVA test demonstrated a

statistically significant difference in the mean total summed scores (F (2,48), $p = 0.000$). Using paired t-tests, statistical significance was identified between the pre-education in the clinic timepoint and post-education in the clinic timepoint ($p = 0.000$), between the pre-education timepoint in the clinic and discharge from the hospital timepoint ($p = 0.000$), and between the post-education timepoint in the clinic and discharge from the hospital timepoint ($p = 0.0004$).

Table 7. Stoma Self-Efficacy Scale total score measures of central tendency

	n	Mean	Standard deviation	Median	Minimum	Max
Pre-Education in Clinic Total Score	25	27.32	12.15	26	13	61
Post-Education in Clinic Total Score	25	39.56	9.26	39	26	64
Discharge from Hospital Total Score	25	47.20	7.38	49	37	65

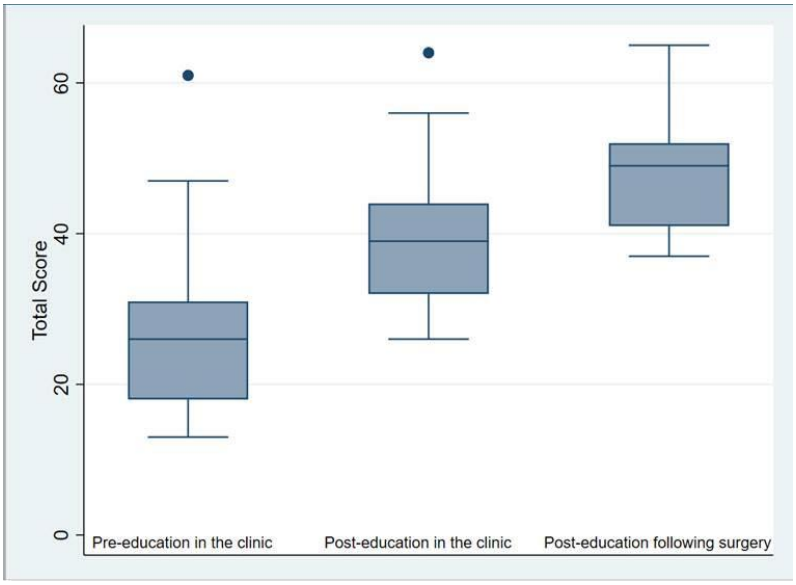

Figure 2. Stoma Self-Efficacy Scale total scores at 3 data collection points

4.3 Time Spent Reviewing Materials

After their clinic visit but prior to admission to the hospital, 36% of participants spent greater than 30 minutes reviewing the written education materials, 32% reviewed them for 21 to 30 minutes, 28% for 11 to 20 minutes, and 4% for 5 to 10 minutes. During hospitalization, 16% of participants spent greater than 30 minutes reviewing the written education materials, 24% reviewed them for 21 to 30 minutes, 36% for 11 to 20 minutes, 12% for 5 to 10 minutes, and 12% for less than 5 minutes.

4.4 Participant Feedback

Eight individual comments were received at the two identified points in time. Participant feedback from the open-ended questions in the surveys was limited but demonstrated appreciation of the WOC nurses, the quality of the information provided, and the comprehensive nature of the written materials. Individual comments included "[WOC nurse] was a wonderful teacher, very informed and thoroughly answered all questions," "Everything has been well-covered," and "Good information; it's a lot, but I needed to hear it."

4.5 Rates of Complications

When comparing the quarterly rate of postoperative complications for all patients undergoing colorectal surgery in 2019, rates ranged from 23.5% in Quarter 1 to 29.61% in Quarter 2 (pre-intervention data) and then ranged from 23.18% in Quarter 3 to 22.17% in Quarter 4 (post-intervention data), which is similar to the baseline of 23.89% in 2017. The quarterly 2019 O/E ratios were 0.9, 1.07, 0.85, and 0.90, respectively, with O/E in the Quarters 3 and 4, lower than the O/E of 0.91 in 2017. The O/E is the ratio of observed to expected complications. If a facility's O/E is less than 1, then the facility

performs better than the reference population for that indicator (Agency for Healthcare Research and Quality, n.d.). See Table 8 for quarterly complication rates data for 2019. The quarterly complication rates were averaged and the 2019 pre-intervention (Quarters 1 and 2) rate was 26.56%, which decreased to a rate of 22.68% for 2019 post-intervention (Quarters 3 and 4). In addition, the complications O/E decreased from 0.99 for 2019 pre-intervention (Quarters 1 and 2) to 0.88 for 2019 post-intervention (Quarters 3 and 4). See Table 9 for the average complication rates for 2017 baseline and 2019 pre- and post-intervention.

Table 8. Complication rates by quarter, 2019

	2019 Quarter 1	2019 Quarter 2	2019 Quarter 3	2019 Quarter 4
Total Cases	183	206	220	221
Complications Observed	23.50%	29.61%	23.18%	22.17%
Complications O/E	0.90	1.07	0.85	0.90

Table 9. Complication rates pre- and post-intervention, 2017 baseline and 2019

	2017 Baseline	2019 Quarters 1 and 2 Average	2019 Quarters 3 and 4 Average
Complications Observed	23.89%	26.56%	22.68%
Complications O/E	0.91	0.99	0.88

In addition, LOS and readmission rates are monitored at the project facility. Although the project objectives did not focus on reducing these rates, 2019 quarterly data was monitored. In 2019, the LOS O/E remained consistent, with a quarterly ratio of 1.00, 1.22, 1.18, and 1.10, respectively. These ratios are similar to the 2017 baseline ratio of

1.05. The readmission O/E also remained consistent, with a quarterly ratio of 0.85, 0.84, 1.08, and 0.88, respectively. This is comparable to the 2017 baseline ratio of 0.94. See Table 10 for length of stay and readmission data.

Table 10. LOS and Readmission O/E by quarter, 2017 baseline and 2019

	2017 Baseline	2019 Quarter 1	2019 Quarter 2	2019 Quarter 3	2019 Quarter 4
LOS O/E	1.05	1.00	1.22	1.18	1.10
Readmissions O/E	0.94	0.85	0.84	1.08	0.88

CHAPTER 5: DISCUSSION

5.1 Impact of the Addition of Standardized Health Literate Written Education Materials

Overall, the literature did not focus on the health literacy level of written education materials utilized in their intervention. Dowse et al. (2014) enhanced self-efficacy for HIV positive patients on antiretrovirals with patient information leaflets using simple text and pictograms. However, it has been identified that many written materials are not written in a manner that meets the needs of patients with chronic health conditions (Tuot et al., 2013; Jacob et al., 2016; Ghisi et al., 2014). The comprehensive, health literate written education materials in this project were found to be a positive addition to the current education process for patients with new ostomies, as demonstrated by the improvements in self-efficacy post-education in the clinic which further elevated prior to discharge from the hospital. Specifically, mean total summed Stoma Self-Efficacy scores increased significantly from pre- to post-education in the clinic (p = 0.000) and then from post-education in the clinic to post-education in the hospital (p = 0.0004). In fact, the mean total summed score increased from 27.32 at baseline to 47.20 at time of hospital discharge, with a maximum total score of 65.00 possible. The findings of increased self-efficacy in this project mirror prior research that has evaluated the impact of ostomy care patient education on self-efficacy (Danielson & Rosenberg, 2014; Cheng, Xu, Xiao-dong, & Yang, 2012; Faury, Kolek, Foucaud, M'Bailara, & Quintard, 2017; Krouse et al., 2016; Mohamed et al., 2017; Pouresmail, Nabavi, Abdollahi, Shakeri, & Saki, 2019; Seo, 2019; Wen et al., 2019; Xu et al., 2018; Zhang et al., 2013; Zhang et al., 2014; Zhou et al., 2019). In this project, achieving a significant increase in the self-efficacy total summed mean score is especially important when considering the

low score of 27.32 (out of 65.00) prior to education in the outpatient clinics. Overall, participants in this project had low self-efficacy in caring for their ostomy before they received education. Low self-efficacy has been linked to lower self-care ability, increased complications, and psychosocial adjustment (Mohamed et al., 2017). Mohamed et al. (2017) demonstrated similar results with pre-program self-efficacy total summed mean scores of 15.60, increasing to 25.83 post-program and 41.60 at one-month follow-up.

The positive trend in self-efficacy is particularly impactful when considering that many participants had not experienced a family member who had an ostomy previously, and only about half of the participants had a previous surgery allowing them to know what to expect. In addition, many participants were not found to be extremely or highly comfortable with medical terminology. Thus, the improvements in self-efficacy demonstrate that the written materials added to the education process were conveyed in a format that was helpful to this patient population. Providing patients with health literate education materials enhances understanding, improves self-efficacy, and promotes positive patient outcomes (Mahdy et al., 2018). An additional factor that could have contributed to the improvements in self-efficacy may have been the high levels of family support that were reported among participants in this project. Literature shows patients undergoing this surgery look to their family and loved ones for physical and emotional support as they adapt and learn to care for their new ostomy (Ayaz-Alkaya, 2019).

Although total summed Stoma Self-Efficacy mean scores significantly increased at all three timepoints, some participants displayed high scores pre- and post-education in clinic which then declined at discharge from the hospital. According to Ayaz-Alkaya

(2019), fear and anxiety could have a negative impact on the ability to engage in self-care and successfully manage a new ostomy. Therefore, the decrease of some participant scores in this project could have been linked to the fear, anxiety, and feelings of being overwhelmed with actually experiencing their ostomy post-surgery and coming to terms with their new chronic condition.

Next, complication rates were monitored due to reported concerns from the two outpatient clinics, despite positive performance as evidenced by the complication O/E data. Quarterly postoperative complications rates prior to the intervention (2019 Quarters 1 and 2) were compared to rates after the project (2019 Quarters 3 and 4). Preliminary findings showed the complication rates decreased from 26.56% (2019 Quarters 1 and 2) to 22.68% (2019 Quarters 3 and 4), with the 2017 baseline at 23.89%. In addition, the complications O/E decreased from 0.99 (Quarters 1 and 2) to 0.88 (Quarters 3 and 4), which was consistent with the 2017 O/E of 0.91 indicating that the project facility performed better than the reference population for that indicator. This may imply the quality and positive impact of the education. Current literature supports that patients exhibiting higher levels of self-efficacy are more effective in the self-management of their ostomy and experience less complications (Danielson & Rosenberg, 2014; Cheng, Xu, Xiao-dong, & Yang, 2012; Faury, Kolek, Foucaud, M'Bailara, & Quintard, 2017; Krouse et al., 2016; Mohamed et al., 2017; Pouresmail, Nabavi, Abdollahi, Shakeri, & Saki, 2019; Seo, 2019; Wen et al., 2019; Xu et al., 2018; Zhang et al., 2013; Zhang et al., 2014; Zhou et al., 2019), and this project further supports the evidence linking improved self-efficacy to lower rates of complications. In reviewing the LOS and readmissions O/E for the project facility, both remained consistent with the 2017 baseline. The

challenge in drawing correlations is that the population of this project are only a small portion of the overall sample of colorectal surgery patients represented in the complication, LOS, and readmission data.

In addition to positive feedback immediately after receiving education in the clinic, all participants reported that they continued to review the written materials prior to returning to the hospital for surgery. All participants also reported using the written materials again while in the hospital. Although it is not known how much patients reviewed the prior education materials that were used at the project facility, the amount of time spent reviewing the new health literate materials between the clinic and hospitalization is encouraging. Pain, medications, and psychological stress can impact the education effectiveness postoperatively (Mahdy et al., 2018). By initiating education preoperatively, autonomy and confidence are supported, allowing additional time for education (Thorpe et al., 2014).

Individual patient comments indicated they appreciated this process of initiating education in the outpatient clinic setting and having the materials to access when at home. Adjustments to the prior education process did not consume additional time from the WOC nurses or increase their workload as the education materials were easily incorporated into their routine workflow. The cost related to printing the written health literate education materials was promptly approved by leadership due to the potential return on investment from ensuring timely discharge and preventing readmissions. Additional strengths impacting the success of this initiative were the engagement and interdisciplinary collaboration of the WOC nurses, clinic staff, and surgeons. All parties worked closely together in the development of the materials and the implementation of

the new education process which facilitated buy-in and ensured adherence to utilizing the written materials. Anecdotally, the bedside nursing staff also expressed a positive perspective of the new education process and having written materials as a consistent resource for patients to reference. Having written materials and the support of specially trained WOC nurses limited undue stress on bedside nurses who may not demonstrate confidence in conveying this important information.

5.2 Recommendations for Practice

Based on the project findings, the process for educating patients with new ostomies at the project facility will be modified to include the created written health literate education materials. Sustainability will be dependent on ensuring content experts (WOC nurses) are able to consistently provide the education, as well as financial support from the institution for the cost of that individual's time and for production of the new written health literate materials. The findings of this project will be utilized to secure the necessary funding and support for the translation of the written materials into additional languages to impact more patient populations.

In addition, it may be beneficial to incorporate the written materials into a video that patients could watch repeatedly while they are practicing the steps in changing the drainage pouch for their new ostomy, as well as other essential self-care skills covered in the created educational booklet. Having such technology-enhanced educational resources would help to ensure ample access to instruction when WOC nurses are not present, and in instances where the bedside nurse is not experienced in ostomy education. This may also be preferred by individuals with auditory learning styles. Having the materials readily available at all times may encourage more self-care practice to enhance patients'

self-efficacy and better prepare them to care for themselves safely and effectively when they are discharged home.

Next steps would be to utilize the project outcomes to support advancing the initiative to emergent or non-scheduled procedures and additional surgical populations. As healthcare facilities continue to work to improve outcomes (such as decrease complications) and decrease LOS and readmissions, it is imperative to identify innovative ways to bridge the continuum of care between outpatient and inpatient settings to ensure adequate education of patients. This will help to alleviate risks such as increased readmissions due to common complications. When expanding to other patient populations, the education materials will require tailoring to fit the preoperative course of treatment, as well as the self-care skills that are most important for patients to fully understand and demonstrate prior to discharge from the hospital.

5.3 Recommendations for Future Projects and Studies

It would be beneficial to expand future projects and studies to include a broader sample of surgical patients with ostomies, as the population for this project was predominantly cancer patients who had a colostomy placed during surgery. Patients undergoing additional surgical procedures such as a cystectomy, esophagectomy, or pancreaticoduodenectomy may also benefit from starting education sooner and the addition of health literate written education materials as an ongoing resource. It would have also been beneficial to repeat data collection at an additional point in time beyond discharge from the hospital. This would allow for extra time to review the written education materials, and the long-term impact on self-efficacy could be assessed, as well as rates of complications. In monitoring the patients over a period of time after discharge

from the hospital, the number and specific type of complications for this distinct patient population could be collected and evaluated to better determine the impact of implementing health literate written education materials on both colorectal surgery patients as well as other complex surgical procedures. Also, the materials were only available in English during the intervention. Looking forward, an additional opportunity would be to secure funding to translate the written education materials into other languages to reach additional patients. Assessing outcomes of diverse patients is necessary to ensure positive outcomes for those who do not speak or read English. An additional opportunity would be to explore the use of resources to better incorporate the principles of cultural competence, which would increase the applicability of the written education materials to all populations.

5.4 Limitations

Limitations include the small sample size which consisted predominantly of patients with cancer, and the intervention only occurring at one hospital with connections to 3 surgeons and 2 clinic sites. In addition, by only examining patients up until the point of discharge from the hospital, the long-term benefit of additional time to review the written health literate education materials on self-efficacy and the occurrence of complications was not explored. Evaluating the number and specific type of complications was limited by only having access to data in the aggregate form of all patients undergoing colorectal surgery. The materials were also only available in English during the intervention which prevented examination of self-efficacy and complications among patients who did not speak or read English. Additionally, participant race/ethnicity information was not

collected in the initial demographic data. Further study with a large and diverse sample is warranted.

5.5 Conclusion

Patients undergoing surgery for a new ostomy require an extensive amount of education due to the complexity of the tasks required for self-care (Kirkland-Kyhn, 2018). The addition of written health literate education materials and initiating patient education preoperatively, allowing for sustained access to the written materials prior to hospitalization, resulted in a statistically significant improvement in patients' self-efficacy for stoma care. Self-efficacy levels improved from pre- to post-education in the clinic prior to surgery, and then improved further prior to discharge from the hospital post-operatively. In addition, the rate of complications experienced decreased, and the O/E ratio trended downwards indicating that the project facility performed better than the reference population for that indicator. By improving self-efficacy, patients will be more effective in the self-management of their ostomy and better prepared to care for themselves upon discharge from the hospital.

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APPENDIX A: PARTICIPATION DISCLAIMER

Written Ostomy Patient Education & Confidence Surveys

Project Information and Participation Disclaimer

This is a description of the project and important information related to your participation:
Title of Quality Improvement Project: The Impact of Standardized, Health Literate Education Materials for Postoperative Patients with a New Ostomy
Affiliations: Project in conjunction with the University of North Carolina at Charlotte and Carolinas Medical Center.
Personnel: Project lead is Kimberly Pate, DNP Candidate. Ms. Pate can be contacted at kapate@uncc.edu or 910-995-1105 should you have any questions or concerns about participation in this project. You may also contact the student's advisor Dr. Kelly Powers at kpower15@uncc.edu or 704-687-7736 should you have questions or concerns about the project. For questions regarding the rights of participants, any complaints or comments regarding the manner in which the project is being conducted, please contact the UNC Charlotte Office of Research Compliance at 704-687-1871.
Project Purpose: The purpose of this project is to determine the impact of providing written, health literate education materials to patients who are undergoing surgery with placement of a new ostomy on their self-confidence for managing their new ostomy.
We are asking you to participate in this project because you are a patient at Carolinas Medical Center who is scheduled for colorectal surgery which will result in ostomy placement. To participate, you also must be at least 18 years old and able to speak and read in English.
Your participation is voluntary. Choosing not to participate will not affect the care that you receive in any way. You will still get the written education materials even if you choose not to answer the surveys. There are no direct benefits to participating in this project, but you may gain additional knowledge about caring for your new ostomy.
Project Procedures: We will be conducting an analysis of the education by asking you to answer a series of questions about you and your health, as well as your confidence in taking care of your new ostomy after surgery. We will ask you about your confidence at three points in time (each survey will take less than 10 minutes to complete). Your participation will involve:

- TimePoint#1: You will be asked to answer 9 questions about yourself and your health. You will then be asked to complete 13 questions about your confidence for managing your new ostomy. This will occur today during your pre-education appointment in outpatient clinic.
- TimePoint #2: You will then receive education on caring for your new ostomy, which will include a review of the new written education materials (which you can take home with you). Then, you will be asked to complete 13 questions about your confidence for managing your new ostomy and to write in comments or feedback you want to share about your education. This will occur post-education today in outpatient clinic.
- TimePoint #3: During your surgical hospital stay, you will be visited to receive education on managing your ostomy. Prior to going home from the hospital, you will be asked to complete 13 questions about your confidence for managing your new ostomy, to indicate how much time you spent reviewing the written materials provided, and to write in comments or feedback you want to share about your education. This will occur post-education while in hospital following surgery.

We will not be collecting any data that can link you to the answers you provide, and hospital/clinic registration information will not be linked in any way to information you provide during participation in this study. To link your surveys together, you will only be asked to report the last 5 digits of your telephone number. Confidentiality of your responses will be protected as much as possible. If you are uncomfortable answering any question or participating in any part of the surveys, you may choose to not answer that question or to stop your participation and have any notes, data recordings or hard copy answers destroyed. To further protect the confidentiality of your responses, we will not be collecting a signed consent form but will instead consider your participation in the study as consent permitting us to collect the data you provide.

APPENDIX B: CONTENT OF WRITTEN EDUCATION MATERIALS

Table of Contents
What is an ostomy
Caring for my pouch – Emptying and changing my one- or two-piece pouch
Taking care of me – Skin care, taking a bath, foods to eat, odor and gas, medicine, constipation, diarrhea, dehydration
Caring for my ostomy – Sex and personal relationship, clothing, returning to work, traveling, being active
When to call with questions
Resources – Ordering ostomy supplies and ostomy support websites

APPENDIX C: APPROVAL FROM HEALTH LITERACY COMMITTEE

Brooks, Hope S
Fri 2/22/2019 2:27 PM
To: Pate, Kim

Reply

Kim,

Your booklet has been approved by Corporate Health Literacy. It meets the Atrium Health Guidelines for health literacy and plain language.

Thanks,

Hope Schwanhausser Brooks
Senior Patient Experience Consultant
Population Health
720 E. Morehead Street, Suite 300
Office: 704-355-1910 Cell: 803-467-4762

Atrium Health
Carolinas HealthCare System is Atrium Health

APPENDIX D: DEMOGRAPHIC SURVEY

Confidential

Pre-Education Outpatient Clinic (Audit 1)

Record ID	_____
About Me **Please answer each question below.**	
Last 5 digits in my phone numbers	_____
Age range	◯ 20-30 ◯ 30-40 ◯ 40-50 ◯ 50-60 ◯ >60
Sex	◯ Male ◯ Female
Reason for ostomy	◯ Cancer ◯ Crohn's disease ◯ Ulcerative colitis ◯ Diverticulitis ◯ Other
What type of stoma will I have?	◯ Colostomy ◯ Ileostomy
This is my first surgery ever.	◯ Yes ◯ No
I feel comfortable understanding medical terms.	◯ Not comfortable ◯ Slightly comfortable ◯ Fairly comfortable ◯ Highly comfortable ◯ Extremely comfortable
I have other chronic illnesses like diabetes, high blood pressure, kidney disease, or asthma.	◯ Yes ◯ No
I am confident that I will have family support to help me care for my new stoma.	◯ Not confident at all ◯ Slightly confident ◯ Fairly confident ◯ Highly confident ◯ Extremely confident
Has anyone in my family had an ostomy?	◯ Yes ◯ No

APPENDIX E: PERMISSION TO UTILIZE STOMA SELF-EFFICACY SCALE

Pate, Kim
Wed 9/26/2018, 10:39 AM
b.vdborne@maastrichtuniversity.nl

Reply

Good afternoon Dr. van den Borne,

I am a nurse and graduate student working on my Doctorate in Nursing Practice. For my scholarly project, I would like to restructure the current method of providing education to our patients with a new ostomy. This would include building health literate education materials to supplement the didactic information provided and return demonstrations. I initially considered measuring length of stay and readmissions. However, with implementation of ERAS guidelines, we have significantly reduced those measures. In my literature review, I found your articles regarding the Stoma Self-Efficacy Scale (SSES), and I was hoping that you would allow me to use this as a measure for my scholarly project. Thank you kindly for your consideration of this request!

Kimberly Pate, MSN, RN, ACCNS-AG, PCCN
Surgical-Trauma Division Clinical Nurse Specialist
Central Division Clinical Nurse Specialist Coordinator

Carolinas Medical Center, A Magnet-designated facility
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Atrium Health
Carolinas HealthCare System is Atrium Health

Stoma Self-Efficacy Scale (SSES_

B

Borne, Hubertus van den (GVO) <b.vdborne@maastrichtuniversity.nl>
Wed 9/26/2018 3:59 PM
To: Pate, Kim

WARNING: This email originated from outside of Atrium Health (b.vdborne@maastrichtuniversity.nl).

Do not click links or open attachments unless you recognize the sender and are expecting the message.

Dear Kim,
Sure you may use the instruments we report in our paper. Just refer the paper I your references. Lots of success with your research.
Best regards,
Bart
Professor of Patient Education
Maastricht university
...

APPENDIX F: THE STOMA SELF-EFFICACY SCALE

Confidential

Please select one answer for each questions addressing how comfortable you are taking care of your stoma. **How confident are you that you can:**	
Apply the stoma collection materials before leakages appear?	◯ Not confident at all ◯ Slightly confident ◯ Fairly confident ◯ Highly confident ◯ Extremely confident
Prevent having leakages?	◯ Not confident at all ◯ Slightly confident ◯ Fairly confident ◯ Highly confident ◯ Extremely confident
Take care of the stoma in the right way at home?	◯ Not confident at all ◯ Slightly confident ◯ Fairly confident ◯ Highly confident ◯ Extremely confident
Prevent having skin problems?	◯ Not confident at all ◯ Slightly confident ◯ Fairly confident ◯ Highly confident ◯ Extremely confident
Prevent having stoma bleeding and damage?	◯ Not confident at all ◯ Slightly confident ◯ Fairly confident ◯ Highly confident ◯ Extremely confident
Apply the stoma collection materials in the way you are taught?	◯ Not confident at all ◯ Slightly confident ◯ Fairly confident ◯ Highly confident ◯ Extremely confident
Prevent having obstruction?	◯ Not confident at all ◯ Slightly confident ◯ Fairly confident ◯ Highly confident ◯ Extremely confident
Follow the stoma therapist's instructions for handling the stoma?	◯ Not confident at all ◯ Slightly confident ◯ Fairly confident ◯ Highly confident ◯ Extremely confident
Follow the doctor's advice for taking care of your stoma and nutrition pattern?	◯ Not confident at all ◯ Slightly confident ◯ Fairly confident ◯ Highly confident ◯ Extremely confident

Confidential

Take care of the stoma the right way outdoors?	○ Not confident at all ○ Slightly confident ○ Fairly confident ○ Highly confident ○ Extremely confident
Take care of the stoma when you are ill?	○ Not confident at all ○ Slightly confident ○ Fairly confident ○ Highly confident ○ Extremely confident
Wear most of the clothes you like?	○ Not confident at all ○ Slightly confident ○ Fairly confident ○ Highly confident ○ Extremely confident
Carry out light duties in and around the house?	○ Not confident at all ○ Slightly confident ○ Fairly confident ○ Highly confident ○ Extremely confident
Total Score	_____

APPENDIX G: IRB APPROVALS

Taylor, Jared D
Mon 1/7, 1:28 PM
Pate, Kim

Reply

Hello,

The CHS IRB has reviewed your protocol and determined it does not meet the definition of Human Subject research Instead it qualifies for Quality Improvement, and therefore, does not require IRB oversight. You may proceed with this project.

Let me know if you have any further questions. Thanks

Jared D. Taylor
IRB Program Coordinator

Atrium Health
Carolinas HealthCare System is Atrium Health
704-355-6568
Mailing: P.O. Box 32861 Charlotte, NC 28232-2861
Shipping/Express Mail: 1540 Garden Terrace, Suite 503, Charlotte, NC 28203

IRB Notice - 19-0111 Inbox ×

IRB uncc-irb@uncc.edu via adminliveunc.onmicrosoft.com Sun, Mar 24, 9:30 AM
to me, kpower15, uncc-irbis, mjcoffma, smorto10

To: Kimberly Pate

From: Office of Research Compliance

Date: 3/24/2019
RE: Determination that Research or Research-Like Activity does not require IRB Approval
Study #: 19-0111

Study Title: The Impact of Standardized, Health Literate Education Materials for Postoperative Patients with a New Ostomy

This submission was reviewed by the Office of Research Compliance, which has determined that this submission does not constitute human subjects research as defined under federal regulations [45 CFR 46.102 (e or l) and 21 CFR 56.102(c)(e)(l)] and does not require IRB approval.

Study Description:

The purpose of this DNP scholarly project (quality improvement project) is to determine if supplementing the current education process for new ostomates with standardized, health literate written education materials will improve patient self-efficacy for management of their new ostomy. A secondary aim is to determine if a decrease in the rate of postoperative complications among this patient population occurs after the supplemental education materials are integrated into patient care.