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Evaluation of an Educational Intervention for Patients Undergoing Radical Cystectomy

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Abstract

Preoperative anxiety can increase stress and cause complications for patients who have upcoming surgery. This project evaluated the effectiveness of an educational intervention of a 4-minute video and opportunity to ask questions after had on the patient's preoperative anxiety levels prior to radical cystectomy with ileal conduit creation surgery. This project had a small sample size of 5 but found that the educational intervention did create a significant decrease in the average anxiety score reported by the patients scheduled for radical cystectomy with ileal conduit creation surgery ($p=0.018$). It is unclear whether the intervention itself or the extra time spent with the patient for answering questions and discussion was the reason for the decrease in anxiety.

Keywords: anxiety, preoperative anxiety, cystectomy, bladder cancer, education intervention, visual anxiety scale.

Evaluation of an Educational Intervention for Patients Undergoing Radical Cystectomy

Background

Bladder cancer is common in men and women and can be life-threatening if not treated. A surgical procedure called cystectomy with ileal conduit creation is a common treatment to complete in patients who have been diagnosed before bladder cancer spreads. Preoperative anxiety can delay surgery and is often related to expectations about the procedure, recovery, change in body image, or outcome. Any level of anxiety can influence patients mentally and physically. Patients with preoperative anxiety may not be able to understand information about their upcoming procedure or give consent and this can lead to procedures postponed or canceled (Tulloch & Rubin, 2018). Anxiety can also increase stress hormones such as adrenaline, cortisol, and vasopressin which can lead to increased heart rate, arterial pressure, respiration rate, and muscle tone (Zelma, et. al., 2019). Patients with bladder cancer that are preparing to undergo radical cystectomy with ileal conduit creation surgery can experience anxiety due to it being a long procedure with permanent body changes. Preoperative anxiety can be decreased by providing a preoperative educational intervention.

Bladder cancer is a common genitourinary cancer. Bladder cancer risk factors include smoking tobacco, advancing age, and male sex (Lenis, et. al., 2020). Bladder cancers can vary from nonaggressive/non-invasive tumors to aggressive/invasive life-threatening diseases (Lenis, et. al., 2020). A treatment for most forms of aggressive bladder cancer prior to metastasis is radical cystectomy usually with neoadjuvant chemotherapy prior. Radical cystectomy is a surgery for removal of the bladder, prostate, and seminal vesicles in men or bladder, uterus, fallopian tubes, ovaries, and anterior vagina in women (Lenis, et. al., 2020). Without the bladder a urinary diversion will be needed to drain urine from the kidneys. An ileal conduit is the

diversion created in over 80% of radical cystectomy patients due to the frailty of the patient population, familiarity of the operation to urologists, and reduced frequency of postoperative complications (Lenis, et. al., 2020). A pelvic lymph node dissection during the cystectomy procedure is an option to evaluate for nodal metastasis because it occurs in 8-24% of patients having the surgery (Lenis, et. al., 2020).

The creation of an ileal conduit involves an externalized stoma needing an ostomy appliance for urine collection that the patient will have to manage for the rest of life. This change in body image and responsibility of management can cause higher levels of preoperative anxiety. Education and stoma site marking preoperatively can reduce anxiety pre and postoperatively, assist with a better-situated stoma, and may lead to fewer complications (Harris, et. al., 2020).

Patient anxiety due to the underlying disease process of bladder cancer is also common. Bladder cancer accounts for an estimated 500,000 new cases and 200,000 deaths worldwide, with an estimated 80,000 new cases and 17,000 deaths in the United States alone (Lenis, et. al., 2020). Aggressive bladder cancers can sometimes advance prior to surgery and the patient will need further systemic treatment postoperatively, including chemotherapy. Also, radical cystectomy carries with it a 1.5-2% mortality rate at 30 days postoperatively and 66% of patients will have complications within the 90 days postoperative period (Lenis, et. al, 2020).

Purpose of Project

Evaluating patient preoperative anxiety levels and intervening with preoperative education has the potential to improve postoperative outcomes. This project evaluated a preoperative educational intervention’s ability to decrease anxiety. Evaluating patient preoperative anxiety levels and intervening with preoperative education can improve postoperative outcomes.

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Relevance to New Mexico

From 2015 to 2019 bladder cancer had an incidence rate of 13.9 per 100,000 people in New Mexico and the incidence rate of bladder cancer in the United States was 19.4 per 100,000 people (NIH, 2022). According to NIH (2022) an average of 3.7 people per 100,000 in New Mexico and 4.2 people per 100,000 in the United States die from bladder cancer. Bladder cancer is not the most common cancer found in New Mexicans, but it is diagnosed often and with limited urologists to treat urologic cancer it can increase risk of progression of disease. This project aims to help patients diagnosed with bladder cancer to have less preoperative anxiety and a successful post operative course.

PICOT Question

Reduction of preoperative anxiety in patients undergoing radical cystectomy could increase the patient's capability to retain knowledge learned and decrease postoperative complications. Preoperative educational interventions are used to decrease anxiety. The PICOT question for this project is "for patients planning to undergo radical cystectomy with an ileal conduit creation surgery for bladder cancer, how does the use of an educational intervention influence preoperative anxiety levels?"

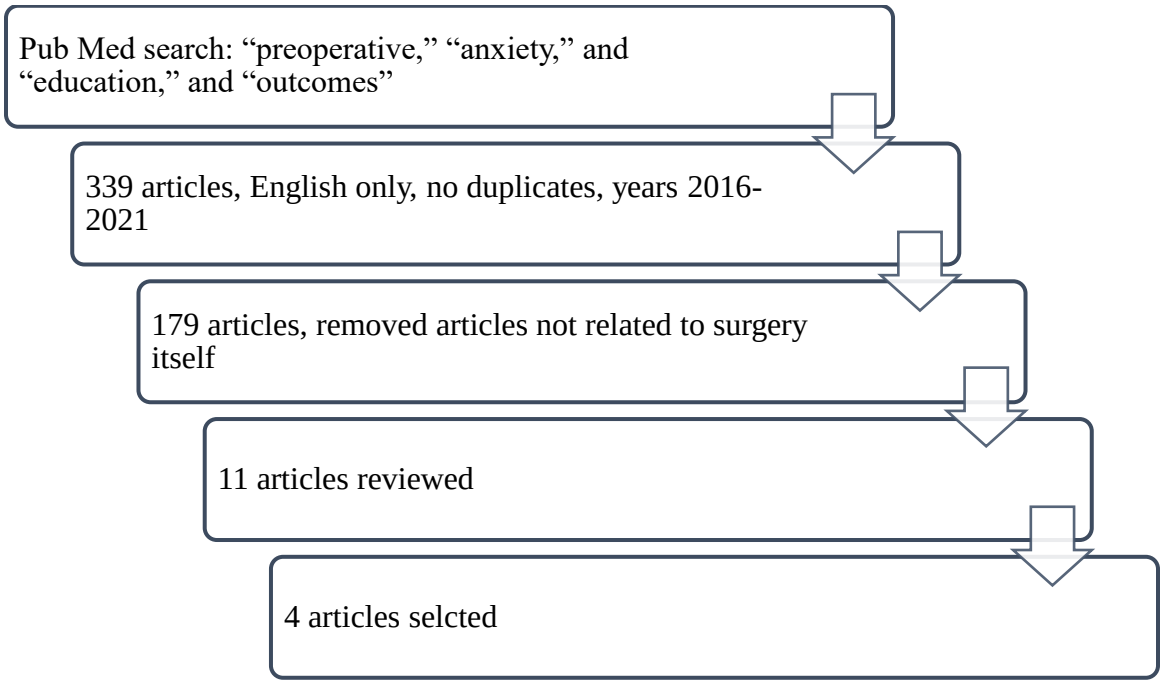
Literature Review

Literature Search

A literature search was completed using the terms "preoperative," "anxiety," and "education," and "outcomes" on the PubMed database. A total of 339 articles in English were narrowed down to 179 articles when duplicates were removed and published date between 2016 and 2021 was selected. A total of 11 articles were reviewed. Articles were eliminated if the focus

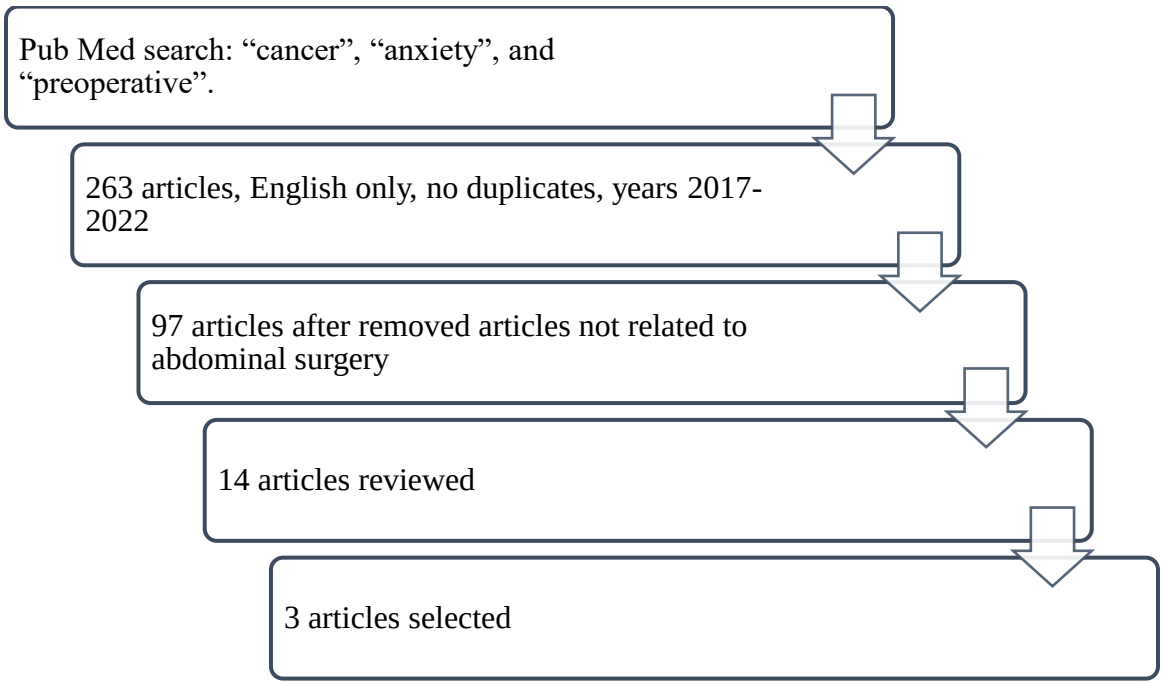
was on anxiety related to anesthesia and not the surgical procedure. Four articles were selected that focused primarily on preoperative anxiety and educational interventions and assessments.

Figure 1: First Literature Search Diagram



A second literature search of the PubMed database using terms "cancer," "anxiety," and "preoperative" was also completed. 263 articles in English published between 2017-2022 were retrieved as this search was completed in early 2022. Articles were eliminated if unrelated to abdominal surgery, examples removed included breast cancer surgery or brain cancer surgery, which left 97 articles total. 14 articles were selected from the 97 and reviewed in depth. A total of three articles were selected to be included in this review that focused on cancer and anxiety in the preoperative period.

Figure 2: Second Literature Search Diagram



Bladder Cancer

Bladder cancer has a high prevalence if 1.6 million people living worldwide with the disease and the lifetime risk for men to develop it is 1.1% and for women is 0.27%, men are diagnosed with bladder cancer at 3-4 times the frequency of women (Lenis, et. al., 2020). Risk factors for bladder cancer include advanced age (most diagnosed between age 74-80) and exposure to carcinogens (tobacco smoke, benzene chemicals, and aromatic amines) (Lenis, et. al., 2020). Non-Hispanic Caucasians have the highest age-adjusted incidence of 23.09 cases per 100,000 and African Americans have worse disease-specific outcomes and greater risks of unfavorable pathology (Lenis, et. al., 2020). Epidemiologic studies have also found there can be a hereditary component to developing bladder cancer and common variants in germline DNA were found in 14% of patients (Lenis, et. al., 2020). A combination of hereditary and carcinogen exposure can increase the risk of bladder cancer development.

Bladder cancer is a cancer of the cells that line the genitourinary where urine is contained including ureters, kidneys, bladder, and urethra. Bladder cancer can be low or high grade with higher grades correlating with deeper invasion into the bladder wall and into tissue outside the bladder (Lenis, et.al., 2020). Bladder cancer that invasive into the muscle (T2) is the most common stage of the disease that a patient undergoes radical cystectomy to treat, but lower grades (T1) that are refractory to treatment can also require this surgical intervention.

Anxiety and the Physiological Response

Anxiety is associated with stress and activates the neuroendocrine hypothalamic-pituitary-adrenal axis and the autonomic system (Zelma, et. al, 2019). Concentrations of stress hormones such as adrenaline, vasopressin, cortisol, prolactin increase in the body and can cause acceleration of heart rate, increase in arterial pressure, increase in respiration rate, increased muscle tone, dilation of pupils, and hyperglycemia (Zelma, et. al., 2019). These effects can be very uncomfortable for patients and can lead to chronic health conditions if not managed. When a patient has anxiety preoperatively, these increased stress hormones in the body can affect anesthesia during surgery, preoperative recovery, and even have long term behavioral and psychological adverse effects (Zelma, et. al., 2019). Long term effects of anxiety can decrease quality of life for patients after surgery.

Surgery and Anxiety

Preoperative anxiety is a feeling experienced by many patients preparing to undergo surgery and has the potential to interfere with an elected procedure. Preoperative anxiety has been shown to have detrimental consequences for patients physically and mentally (Tulloch & Rubin, 2018). Elevated levels of preoperative anxiety can also lead to essential procedures being

postponed or canceled (Tulloch & Rubin, 2018) which can delay necessary and sometimes life-prolonging care.

Elevated levels of preoperative anxiety have also been found to be associated with postoperative pain, bleeding, discomfort, body image changes, and sometimes death (Togac & Yilmaz, 2020). Reducing preoperative anxiety levels in surgical patients can lead to shorter duration of hospital stay and positive outcomes. Harris et. al. (2020) states that reduction of anxiety levels in pre and post operative patients can shorten hospital stays as much as 30-50% and enable patients to participate in their post operative care earlier and more effectively.

Evaluation of Preoperative Anxiety

Being aware of a surgical patient's level of preoperative anxiety level is important. Tulloch & Rubin (2018) state evaluation of preoperative anxiety and assessing potential management strategies can help reduce negative clinical and economic implications. Tulloch & Rubin (2018) completed an observational prospective cross-sectional questionnaire-based study to determine levels of preoperative anxiety in 53 patients undergoing elective otorhinolaryngologic surgeries under general anesthesia.

Tulloch & Rubin (2020) used the Spielberger State-Trait Anxiety Inventory, a validated tool that has been used in over 3000 studies, and the Service Improvement questionnaire, an 8-question tool created for the study to evaluate patient anxiety levels. The Spielberger State Anxiety Inventory (STAI-S) assess anxiety at a specific moment in time and the Spielberger Trait Anxiety Inventory (STAI-T) assess a patient's baseline anxiety levels. Tulloch & Rubin (2020) found that if a patient had higher levels of trait anxiety, they also had higher state anxiety in the preoperative period. Tulloch & Rubin (2020) calculated the difference in the STAI-T and STAI-S scores of the patients and did not find that there was a statistical increase in anxiety

levels preoperatively. Tulloch & Rubin (2020) found that anxiety increased in female patients and patients who this was their first surgical procedure and that age differences did not show a difference in anxiety levels.

Cancer Surgery and Preoperative Evaluation of Anxiety

All surgical procedures can cause a patient to have anxiety preoperatively. Most non-cancer surgeries are to fix a problem for a patient. A diagnosis of cancer can be stressful to a patient along with preparing for a surgical procedure because there could be systemic treatment needed before or after the surgery as well.

The surgical treatment phase of cancer can cause symptoms of anxiety and depression in 12-19% of patients (Du, et. al., 2019). The surgical procedure, cancer recurring or metastasizing, and postoperative complications are all factors that can worsen anxiety. Anxiety can also be related to fear of death, pain, disfigurement, disability, and/or disruption of relationships throughout the perioperative period (Majumdar, et. al., 2019). Decreased quality of life due to anxiety after surgery can also occur. Preoperative anxiety can also be a risk factor for postoperative neurocognitive decline 3 months or more after surgery (Du, et. al., 2019).

Preoperative Education for Cancer Surgery

Patients undergoing surgery for cancer can experience anxiety for many reasons. These could include knowledge deficit about their cancer diagnosis, the surgical procedure itself, and management of the short and long-term side effects of treatment and recovery period from surgery (Steves & Scafide, 2021). Traditional and multimedia educational tools have improved patient satisfaction and decreased anxiety for patients undergoing surgery for cancer (Steves & Scafide, 2021). Decreasing preoperative anxiety levels could help a patient have a more positive surgical and recovery experience. Research completed by Steves & Schafide (2021) showed that

long-term outcomes such as quality of life and self-management behaviors improved with providing an educational process prior to surgery.

Bladder Cancer & Preoperative Evaluation of Anxiety

The impact of surgical educational interventions has been studied for more than 20 years, including teaching of skills, psychosocial support, recovery expectations, postoperative pain, and psychological distress (Klaiber, et. al., 2018). Klaiber, et. al. (2018) investigated the impact of preoperative patient education on the postoperative complications of pneumonia, deep vein thrombosis, pulmonary embolism, burst abdomen, in-hospital fall, and on mortality, postoperative pain, perioperative anxiety and depression, quality of life, and length of hospital stay in patients undergoing major planned abdominal surgery through a quantitative randomized controlled study. The intervention group of patients underwent a 1-hour preoperative seminar given by nursing staff on the day prior to surgery that covered how to prevent the postoperative complications mentioned and the principles of pain management and coping strategies and patients were provided a 48-page brochure covering these topics (Klaiber, et. al., 2018).

Klaiber, et. al. (2018) found that 10.8% of the patients that the educational intervention and 12.5% of the control had at least one of the postoperative complications and that mental health and quality of life scores were similar at baseline and on post operative day 30. There was not statistical significance in postoperative complication reduction or changes to post operative mental health or quality of life but patients that received the educational intervention did report they were highly satisfied with the information they received about postoperative recovery expectations and appreciated the opportunity to discuss concerns preoperatively helped prepare them for surgery (Klaiber, et. al., 2018). Limitations of this study included that it was the first randomized cluster study of this kind, the sample size was not very large (111 total with 50 in

intervention group and 61 in control group), nurses that worked with both groups also participated in the education intervention, and the seminar was only 1 hour long the day prior to surgery (Klaiber,et. al., 2018). Providing the educational intervention earlier in the preoperative period may be more beneficial because patients have time to review the information and could focus less on the major surgery happening the next day.

Some of the major abdominal surgeries require a creation of a new ostomy and can cause change in body image and responsibility that contributes to higher levels of preoperative anxiety. Harris, et. al. (2020) completed a quantitative, nonrandomized, prospective, and comparison cohort study to see if preoperative ostomy education was effective in reducing post operative anxiety in patients undergoing surgical creation of a new ostomy. Anxiety levels were measured using seven anxiety questions from the HADS Anxiety and Depression Survey. A 1-hour preoperative ostomy education and site marking session was provided by nursing in the intervention group while the control group only received standard post operative ostomy nurse teaching. Both groups completed the HADS anxiety scale post operatively. Results of the Klaiber, et. al. (2018) study showed that patients that received the preoperative education had shorter duration of stay in the hospital (mean 2.6 days to 4.1 days) and lower anxiety scores (mean HADS score 4.7 to 15.5, highest score is 21) than patients who only received post operative education on the new stomas. Preoperative ostomy education significantly lowered anxiety and hospital length of stay.

Togac & Yimaz (2020) completed a study to determine what the effects of preoperative individualized audiovisual education for surgical patients were on post operative anxiety and comfort including pain, nausea, and vomiting. Togac & Yimaz (2020) completed a randomized clinical trial with sample size of 124 patients about to have a laparoscopic cholecystectomy

surgery (gall bladder removal). Patients in the intervention group received education that included discussion, a video demonstration, and education booklet about the surgery. The intervention was completed in the patient's room prior to surgery and took 30-45 minutes. Topics discussed included the surgery itself, transfer to the operating room, postoperative care in the hospital and at home, and any other questions the patient had about the surgery were addressed (Togac & Yimaz, 2020). The control group received the booklet but did not have discussion or watch the video demonstration. Patients completed two anxiety scales, the Spielberg State-Trait Anxiety Inventory (STAI) part I and II. STAI-I determines anxiety under a specific condition (preoperative anxiety) while STAI-II measures anxiety regardless of situation and condition (Togac & Yimaz, 2020). Patients' comfort levels were recorded including pain level on visual analog scale, nausea, and vomiting.

Togac & Yimaz (2020) found that the STAI-I scores of control and intervention groups were similar preoperatively before educational intervention and that the STAI-I scores were lower after surgery in the group that received the audiovisual education along with the booklet. The pain scores and STAI-II scores were similar in both groups, but nausea and vomiting was less in the intervention group (Togac & Yimaz, 2020). This study did show that preoperative education can significantly reduce situational anxiety and increase comfort for patients undergoing laparoscopic cholecystectomy. Limitations for this study included a location of only one hospital and all education provided by the same researcher, and that only patient verbal and written responses were evaluated, not physiologic monitoring. Togac & Yimaz (2020) would have preferred to monitor stress hormone levels in the patients (cortisol and adrenocorticotropic hormone) as well as the levels reported on the STAI-I, STAI-II, and VAS pain scales had the

funding been available to the researchers. Preoperative audiovisual education was beneficial for the intervention group of this study.

Tulloch & Robin (2020) surveyed subjects to ask what types of educational interventions patients prefer prior to surgery. Over 50% would have like an educational leaflet explaining the surgical procedure and post operative course, 20% preferred more in-depth discussion with the surgeon on the day of the procedure, 12% wanted more information in the clinic setting, and 12% stated they would have preferred less information in the preoperative period (Tulloch & Robin, 2020). Identifying what type of education and what information is beneficial depends on the patient's learning style and level of anxiety.

Organizing Framework

Theoretical Model

The RE-AIM model was the framework used for this project. The RE-AIM model is an implementation tool for a variety of health promotion and disease management interventions (Kessler, et. al., 2012). The RE-AIM model is used in over 150 published studies as well as several grant applications (Kessler, et.al., 2012). RE-AIM stands for the five dimensions of a study: reach, effectiveness, adoption, implementation, and maintenance. Reach captures the percentage of people from a given population, effectiveness refers to positive and negative outcomes of an intervention, adoption is the percentage of setting and staff that have agreed to participate, implementation is the delivery of the intervention and its costs, and maintenance is outcomes on a long-term basis (Sweet, et. al., 2014). This model emphasizes the importance of focuses on all five dimensions when planning an intervention. The RE-AIM model was an appropriate choice for this project because it involved a specific population (people who are undergoing cystectomy for bladder cancer), was effective (a decrease in preoperative anxiety),

had adopted a setting for the study (the urology clinic), had a plan for implementation (short educational video) and low costs, and had a goal for maintenance to continue intervention (after project completed will still provide education to all patients undergoing surgery).

Project Design

This project used a non-experimental, prospective, descriptive, inferential analysis design to evaluate the implementation of an educational intervention on adult preoperative cystectomy patients who had been diagnosed with bladder cancer. Approval for this project from the University of New Mexico Institutional Review Board and from the University of New Mexico Hospital Urology clinic director were obtained prior to start date.

Procedural Steps

This quality improvement project was completed on the clinically based inquiry of effectiveness of a preoperative educational intervention decreasing preoperative anxiety levels in patients planning to undergo radical cystectomy with ileal conduit creation surgery. At the patient's preoperative visit there was an offer to watch a 4-minute video about the surgery and its recovery that was created by the project author. Patients were also offered participation in this project and an informed consent was signed prior to intervention. The patient was asked to circle their anxiety level on the six-faced visual anxiety scale and fill out the demographic data of age and gender form. None of the 5 patients that were offered the intervention chose not to participate in the project, but if they did then there would still be an offer to watch the educational intervention video. After the patients watched the video a chance to ask any questions was presented. Once all questions were answered the patients were asked to rate the video's effectiveness and the current anxiety level on the visual scale after education. Unique

number identifiers were assigned to each participant at time of intervention. After data analysis was completed any links between patient identifiers and information were destroyed.

Setting and Population

The setting was an outpatient ambulatory urology clinic at a public hospital (University of New Mexico) in a metropolitan city in the Southwest United States of America. This clinic had two urologic surgical oncologists that can perform cystectomy with ileal conduit creation surgery for bladder cancer diagnosis. When the surgery was scheduled and the patient is undergoing a preoperative evaluation and assessment clinic visit was when the educational intervention was provided, and anxiety level and demographic information collected. The University of New Mexico urology clinic staff notified the author when the patient who qualified for the project was at a preoperative visit so the educational intervention can be completed by the author every time.

The participants that qualified for this project were adult patients aged 18 years or older of all genders who have been diagnosed with bladder cancer and are planning to undergo radical cystectomy with ileal conduit creation surgery. Patients undergoing cystectomy with ileal conduit for non-cancer reasons will not be included. Patients that did not speak English were also not included due to unavailability of the intervention video in other languages. Also, patients were eliminated from participation if they had prior diagnosis of anxiety disorder.

Steps for Implementation

The steps for implementation were done in the order as follows:

1. Project proposal: April 2022
2. UNM IRB/UNMH Clinic Approval: August 2022
3. Data Collection: August - December 2022

4. Data Analysis: February 2023
5. Formulate Final Report: February 2023 - April 2023
6. Final Presentation of Findings: April 2023

Instruments

Demographic data collection tool

The demographic data collection survey (Figure 1) was provided to all participants in this project. The survey asked what age group the patient falls into (18-49, 50-79, or 80+) and what gender the patient identifies as (male, female, or non-binary). Both questions had an option stating that the participant prefers not to answer.

Figure 1: Demographic Data Collection Survey

Please circle your response:				
Age:	18-49	50-79	80+	Prefer not to answer
Gender:	Male	Female	Non-binary	Prefer not to answer

Visual Analog Scale for Anxiety

The tool used for this project to measure anxiety was the six-faced facial visual anxiety scale (VAS) (Figure 2) for assessing preoperative anxiety developed by Cao, et. al. (2017). This tool has six faces that correlate to different levels of anxiety in the preoperative state. The tool is intended to be used to evaluate surgical patients' levels of anxiety clearly and easily. Cao, et. al. (2017) completed a preliminary study to validate this tool and found it displayed evidence of interval scale properties of rank order and equality between points on the scale. The six-facial VAS was determined to be a valid tool for assessing the severity of acute anxiety in patients and

could be implemented in practice without adding additional work burden for clinical staff providing care to surgical patients (Cao, et. al., 2017).

Figure 2: The Six-Faced Visual Analog Scale (Cao, et. al, 2017)

Anxiety Level	None	Mild	Mild-Moderate	Moderate	Moderate-High	Highest
Faces						

Effectiveness of Educational Intervention

Educational effectiveness of the intervention video was also collected. The participant was provided a Likert scale of zero to five, with zero being "not effective at all" and 5 "extremely effective" and were asked to rate the video.

Figure 3: Effectiveness of Education Score

Please circle the level of effectiveness of the education:

Not effective at all	A little effective	Mildly beneficial	Moderately effective	Highly effective	Extremely effective
0	1	2	3	4	5

Data Analysis Plan

Descriptive statistics were completed and included a comparison of the ages and genders of the participants. Data analysis was completed by comparing patient-reported anxiety scores from before the intervention and after the intervention. These results were analyzed in a paired t-test to evaluate for significance. Patient-reported effectiveness of the educational intervention on a Likert scale was also averaged.

Potential Barriers

Potential barriers to this project included small sample size. There were only 14 radical cystectomy surgeries completed in 2021 at the facility so obtaining a larger sample size would be

challenging. Also, a barrier would be patient declination to participate, which did not happen with this project. Third the educational intervention was only available in English so patients that do not speak English would not be able to participate.

IRB Concerns

An IRB concern of this project was breach of confidentiality of data due to patient name and demographic data collected on the consent forms. Each patient was assigned a unique identifying number at time of intervention and no names were stored with data. Consent forms were stored separately and were kept inside a locked document box in a locked drawer at the author's office. The consents will be kept in this box for two years after completion of the project then destroyed. University of New Mexico Institutional Review Board approval (See Appendix C) and University of New Mexico Urology Clinic director approval (See Appendix D) was requested prior to initiation of project.

The anxiety scale, demographics, and effectiveness of education results were stored in an excel spreadsheet for further statistical analysis after collection with the patient deidentifying number. The anxiety scales, demographic, and effectiveness forms did not have any patient information on them and were kept separate from the consent forms.

Project Results

Participants

There were participants willing to participate in this project. The population consisted if one female and four males. The age groups represented indicated 20% was 80+ years of age and 80% were 50-79 years of age. Table 1 illustrates the demographic characteristics.

Table 1: Demographic Characteristics

Participant	Pre-Score	Post-Score	Gender	Age Group	Effectiveness
1	2	2	F	80+	3
2	3	1	M	50-79	3
3	5	2	M	50-79	3.5
4	4	1	M	50-79	3
5	3	2	M	50-79	22
Average	3.4	1.6			.9

	Number	Percent
Gender		
Female	1	20%
Male	4	80%
Age Group		
50 -79	4	80%
80+	1	20%

Anxiety Levels

Anxiety levels were measured by use of the Visual Analog Scale (Cao, et. al., 2017) before and after the educational intervention. The anxiety level pre-intervention ranged from 2-5, with a mode of 3. The anxiety levels post intervention ranged from 1-2 with a mode of 2. Table 2 illustrates the anxiety levels of participants pre- and post-intervention (also see Appendix A).

Table 2: Anxiety Levels

Anxiety Levels		
	Range	Mode
Pre-Intervention	2-5	3
Post Intervention	1-2	2

Perception of Intervention Effectiveness

Participants were asked to evaluate the effectiveness of the educational intervention on their anxiety levels on a scale of zero to five. The effectiveness scores ranged from 2-3.5 (one

participant circled a 3 and a 4 so these two scores were averaged to 3.5), with a mean of 2.9 and mode of 3. Table 3 illustrates perceptions of the intervention's effectiveness.

Table 3: Perceptions of Effectiveness of Education

Effectiveness of Educational Intervention	
Range	Mean/Mode
2-3.5	3

Comparison of Pre-and Post-Intervention Anxiety Levels

A paired T-test was calculated to determine and compare the mean pre-intervention score to the post-intervention score. The mean for the pre-intervention score was 3.75 (sd=1.14), and the mean on the post intervention score was 1.5 (sd=0.55). A significant decrease from the pre-intervention to post invention was found ($t=2.77, p<0.05$). The results indicate the educational intervention reduced anxiety levels in patients undergoing radical cystectomy surgery. Table 4 illustrates the results of the paired t-test.

Table 4: Paired T-Test

t-Test: Paired Two Sample for Means		
	Pre	*Post*
Mean	3	1.6
Variance	1.3	0.3
Observations	5	5
Pearson Correlation	0.080	
Hypothesized Mean Difference	0	
df	4	
t Stat	3.087	
P(T<=t) one-tail	0.018	
t Critical one-tail	0.018	
P(T<=t) two-tail	0.036	
t Critical two-tail	2.776	

Limitations

Limitations of this study include the small sample size and lack of sampling from equal amounts of genders (one female, four males, and no non-binary patients) or age groups (one from 80+ and four from 50-79). A larger sample size could have included more age groups as the anxiety levels for cancer diagnosis could be higher in younger patients. A larger sample size would also provide a larger collection of data for analysis.

Another limitation was the educational intervention video and forms were not available in any other languages. This video needs interpretation and forms need translation to other languages for use for all patients.

The final limitation was that the educational intervention was completed with a discussion for the patients to ask questions after. The patients did not ask the same questions after the intervention, and some spent more time with the author than others. It is questionable if this extra time and discussion was the reason for the decrease in anxiety or if it was the educational intervention itself.

Organizational Impact/Implications to Practice and Policy

The organizational impact of this project is that standardized educational interventions such as the video provided can be beneficial for patients in decreasing preoperative anxiety levels. The patients did not score the video itself as highly effective but the majority of anxiety levels in patients did decrease. Part of this may be the time for questions provided after the video as well. If patients leave an appointment without getting all their questions answered it could increase preoperative anxiety levels.

Dedicating more time for education and questions for patients in any appointment, especially a preoperative visit is the most important implication for practice from the project.

Patients were able to feel less anxious about a surgical procedure after the education and this could decrease risk of complications and even decrease hospital stay duration.

Future Directions

Additional research needs to be done on patients who have received preoperative anxiety reducing education to see if it does lead to positive outcomes. The educational intervention provided could also be changed for different surgical procedures and offered to a larger patient population than only patients undergoing radical cystectomy with ileal conduit. It is unclear whether the intervention or the extra time spent with the patient was the reason for the decrease in anxiety. Further research with me a larger sample size should be performed to determine how educational interventions might decrease preoperative anxiety with post operative outcomes.

Conclusion

Preoperative anxiety can cause complications for patients in surgery and in the post-operative period. While the project had a small sample size of 5 subjects, the results indicate a significant decrease in anxiety levels in patients pending surgery for a radical cystectomy with ileal conduit creation through the implementation of a brief educational video intervention. This information is important to improve care provided at the project clinic. The project also adds to the literature regarding anxiety levels and pending surgical procedures. The researcher's advanced practice has been expanded through an increased awareness of anxiety and interventions to reduce levels.

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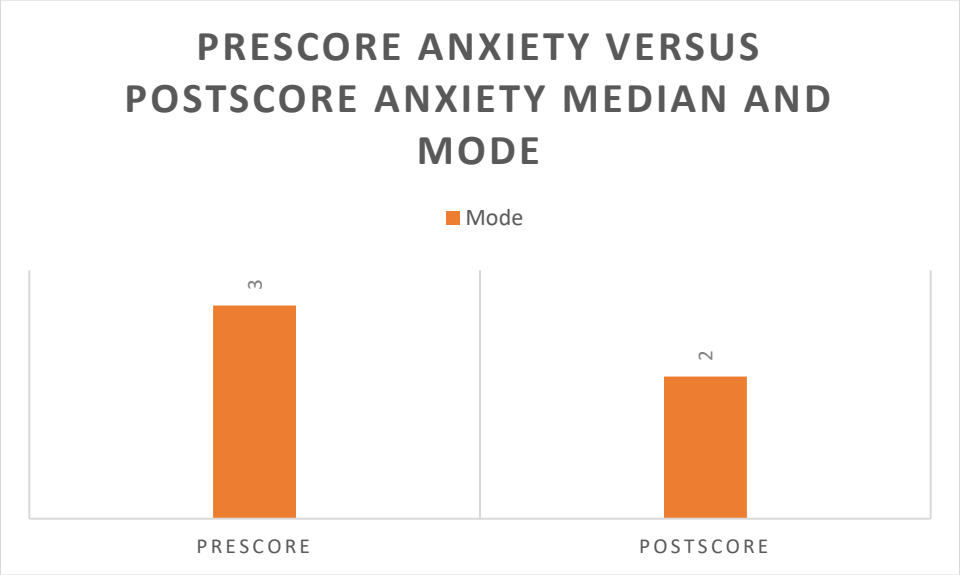
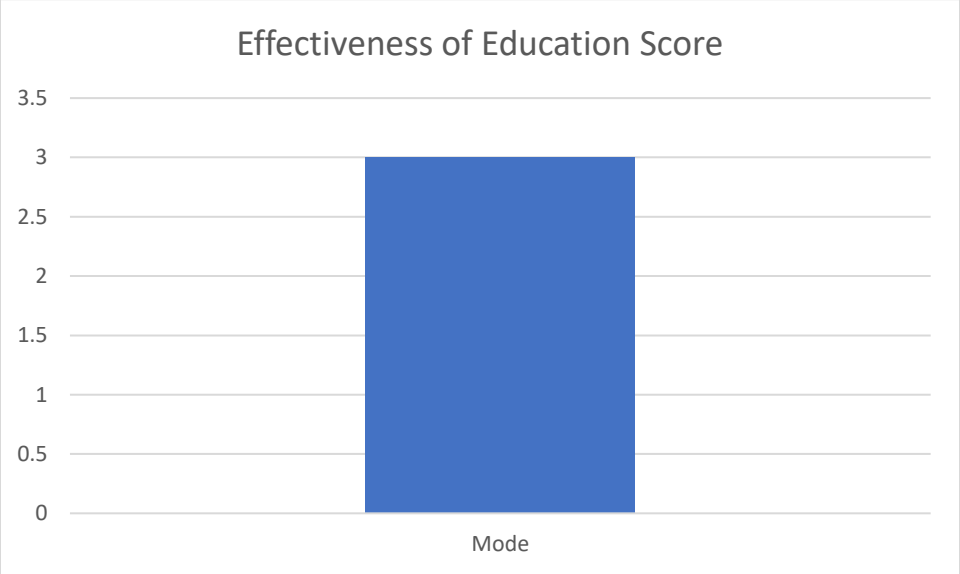
Appendix A: Anxiety Pre/Post Score Modes



Appendix B: Effectiveness of Educational Intervention Mode



Appendix C: UNMH IRB Approval Letter

Human Research Protections Program

September 15, 2022
Sharon Schaaf
SSchaaf@salud.unm.edu

Dear Sharon Schaaf:

On 9/15/2022, the HRRC reviewed the following submission:

Type of Review:	Initial Study
Title of Study:	Evaluation of an Education Intervention to Decrease Anxiety Among Patients Undergoing Radical Cystectomy
Investigator:	Sharon Schaaf
Study ID:	22-298
Submission ID:	22-298
IND, IDE, or HDE:	None
Submission Summary:	Initial Study
Documents Approved:	• Schaaf Hendle Consent 9-14.pdf • Schaaf Hendle Data Collection Tool 9-8.pdf • Schaaf Hendle Effectiveness of Education Survey.pdf • Schaaf Hendle Post-Survey.pdf • Schaaf Hendle Pre Survey.pdf • Schaaf Hendle Protocol 9-8.pdf • Schaaf Hendle UNM Research Approval Letter.pdf
Review Category:	EXPEDITED: CATEGORIES (7)(b) Social science methods
Determinations/Waivers:	Requires a signed Consent form. Informed Consent waived for screening/recruitment only. HIPAA Authorization Addendum Not Applicable.
Submission Approval Date:	9/14/2022
Approval End Date:	9/13/2023
Effective Date:	9/15/2022

The HRRC approved the study from 9/14/2022 to 9/13/2023 inclusive. If modifications were required to secure approval, the effective date will be later than the approval date. The "Effective Date" 9/15/2022 is the date the HRRC approved your modifications and, in all cases, represents the date study activities may begin.

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Before 9/13/2023 or within 45 days of study closure, whichever is earlier, you are required to submit a continuing review. You may submit a continuing review by navigating to the active study and clicking the "Create Modification/CR" button.

<Delete if not applicable: Because it has been granted exemption, this research is not subject to continuing review. >

Please use the consent documents that were approved by the HRRC. The approved consents are available for your retrieval in the "Documents" tab of the parent study.

If the study meets the definition of an NIH Clinical Trial, the study must be registered in the ClinicalTrials.gov database. Additionally, the approved consent document(s) must be uploaded to the ClinicalTrials.gov database.

As a reminder, it is the responsibility of the principal investigator or delegated study team member, to re-consent former and/or current participants as directed in the "Determinations/Waivers" section of this letter.

This determination applies only to the activities described in this submission and does not apply should you make any changes to these documents. If changes are being considered these must be submitted for review in a study modification to the HRRC for a determination prior to implementation. If there are questions about whether HRRC review is needed, contact the HRPO before implementing changes without approval. A change in the research may disqualify this research from the current review category. You may submit a modification by navigating to the active study and clicking the "Create Modification/CR" button.

If your submission indicates you will translate materials post-approval of English materials, you may not recruit or enroll participants in another language, until all translated materials are reviewed and approved.

In conducting this study, you are required to follow the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library.

Sincerely,

Walter Dehority, MD
HRRC Chair

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cc: <For international or collaborative research, the local research ethics committee or equivalent, as applicable>
<If the research is conducted or funded by the Department of Defense (DOD), attach associated minutes and send to:>
Director, Defense Research and Engineering
ddre@dtic.mil
<If the research is conducted or funded by the Department of the Navy (DOD), attach associated minutes and send to:>
Under Secretary of the Navy
1000 Navy Pentagon
Washington, D.C. 20350-1000
<If the research is conducted or funded by the Environmental Protection Agency (EPA), the Environmental Protection Agency (EPA) Human Subjects Research Review official.>

Abbreviated Investigator Responsibilities
NOTE: For a full unabbreviated version of the **Investigator Manual**, please visit the HRPO website at https://hsc.unm.edu/research/hrpo/.

What will happen after HRRC review?
The HRPO will provide you with a written decision indicating that the HRRC has approved the Human Research, requires modifications to secure approval, or has disapproved the Human Research.

- If the HRRC has approved the Human Research: The Human Research may commence once all other organizational approvals have been met. HRRC approval is usually good for a limited period of time which is noted in the approval letter.
- If the HRRC requires modifications to secure approval and you accept the modifications: Make the requested modifications and submit them to the HRRC. If all requested modifications are made, the HRRC will issue a final approval. Research cannot commence until this final approval is received. If you do not accept the modifications, write up your response and submit it to the HRRC.
- If the HRRC defers the Human Research: The HRRC will provide a statement of the reasons for deferral and suggestions to make the study approvable, and give you an opportunity to respond in writing. In most cases if the HRRC's reasons for the deferral are addressed in a modification, the Human Research can be approved
- If the HRRC disapproves the Human Research: The HRRC will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing.

In all cases, you have the right to address your concerns to the HRRC directly at an HRRC meeting.

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What are my obligations after HRRC approval?

1. Do not start Human Research activities until you have the final HRRC approval letter.
2. Do not start Human Research activities until you have obtained all other required institutional approvals, including approvals of departments or divisions that require approval prior to commencing research that involves their resources.
3. Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
   a. Delegate responsibility to the research staff in accordance with the staff's training and qualifications.
   b. Assure that all procedures associated with the research are performed, with the appropriate level of supervision, only by individuals who are licensed or otherwise qualified to perform them under the laws of New Mexico and policies of The University of New Mexico Health Sciences Center.
   c. Monitor the research study and perform quality management activities to ensure the protection of participants and the quality of the research data.
4. Obtain the legally effective informed consent from human participants or their representatives, using only the currently approved informed consent documents, and provide a copy to the participant, if applicable. a) Ensure that only HRRC-approved investigators obtain informed consent from potential participants.
5. If unavailable to conduct the research personally, as when on sabbatical leave or vacation, arrange for another HRRC-approved investigator on the study to assume direct responsibility or notify the HRRC of alternate arrangements.
6. Maintain accurate and complete research records, including but not limited to, original signed informed consent and authorization documents, and retain these records according to HRRC policy and the applicable regulatory retention terms.
7. Fully inform the HRRC of all locations in which human participants will be recruited for this project and obtain and maintain current HRRC approvals/letters of cooperation when applicable.
8. Ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
9. Update the HRRC office with any changes to the list of study personnel.
10. Personally conduct or supervise the Human Research.
    a. Conduct the Human Research in accordance with the relevant current protocol as approved by the HRRC.
    b. When required by the HRRC, ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the HRRC.
    c. Do not modify the Human Research without prior HRRC review and approval unless necessary to eliminate apparent immediate hazards to participants.
    d. Protect the rights, safety, and welfare of participants involved in the research.
11. Submit to the HRRC:

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   a. Proposed modifications as described in this manual. (See "How do I submit a modification?")
   b. A continuing review application as requested in the approval letter. (See "How do I submit continuing review?"
   c. A continuing review application when the Human Research is closed. (See "How Do I Close Out a Study?")
12. Report any of the information items listed in Appendix A-1 to the HRRC within five business days.
13. Submit an updated disclosure of financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.
14. Do not accept or provide payments to professionals in exchange for referrals of potential participants ("finder's fees.")
15. Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments.")
16. See additional requirements of various federal agencies in Appendix A-2 through A-9 of the Investigator Manual. These represent additional requirements and do no override the baseline requirements of this section.

If the HRRC directs or your study is selected for an onsite post-approval review, cooperate with HRPO Quality Improvement program staff to complete it.

Research Data and Study Records
Researchers and staff should have systems or practices for maintaining the essential Research Records that they create in order to be able reasonably to support research findings, justify the uses of research funds and resources, and protect any resulting intellectual property.

During the life of a study and beyond its closure, many information security and storage policies pertain to the maintenance and archival of study documents and research data. These policies and procedures include those of the researcher's department, UNM HSC, the State of New Mexico, Federal privacy laws (such as HIPAA, FERPA, FOIA, New Mexico IPRA), Federal regulations (FDA, OHRP, DHHS, etc) as well as the data confidentiality requirements associated with research funding (e.g. National Institutes of Health, Department of Defense (DOD), etc.).

PI responsibilities for document and data security are particularly critical during times of study transition, as when a PI is leaving UNM HSC, is transferring PI responsibilities or is closing a study. Be prepared ahead of time and discuss transition and/or long-term storage plans with your department Chair/ Research Chair. Assure that information regarding these plans are documented in a standard place and are using an established process, so that an incoming PI and department personnel can find, understand and follow it.

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Appendix A-1 Reportable New Information
Report information items that fall into one or more of the following categories to the HRRC within 5 business days. Reference SOP: New Information (HRP-024).

1. Information that indicates a new or increased risk, or a new safety issue, for example:
   a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
   b. Protocol violation that harmed participants or others or that indicates participants or others might be at increased risk of harm.
   c. Complaint of a participant that indicates participants or others might be at increased risk of harm or at risk of a new harm.
   d. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk.
   e. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
   f. Changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.
2. Harm experienced by a participant or other individual, which in the opinion of the investigator are unexpected and related or possibly related to the research procedures.
   a. A harm is "unexpected" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the HRRC in terms of nature, severity, frequency, and characteristics of the study population.
   b. A harm is "related or possibly related" to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm.
3. Non-compliance with the federal regulations governing human research or with the requirements or determinations of the HRRC, or an allegation of such non-compliance.
4. Failure to follow the protocol due to the action or inaction of the investigator or research staff.
5. Change to the protocol taken without prior HRRC review to eliminate an apparent immediate hazard to a participant.
6. Breach of confidentiality.
7. Complaint of a participant that cannot be resolved by the research team.
8. Premature suspension or termination by the sponsor, investigator, or institution.
9. Incarceration of a participant in a study not approved by the HRRC to involve prisoners.
10. Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g., FDA Form 483).

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11. Written reports of study monitors.
12. Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants).
13. Unanticipated Problems Involving Risks to Subjects or Others, including any event or problem that is serious, unexpected, and related to the research, where "related" means the event or problem might reasonably be regarded as caused by, or probably caused by, the research.
14. Disciplinary action against the investigator or research staff by federal, state, and local regulatory agencies.

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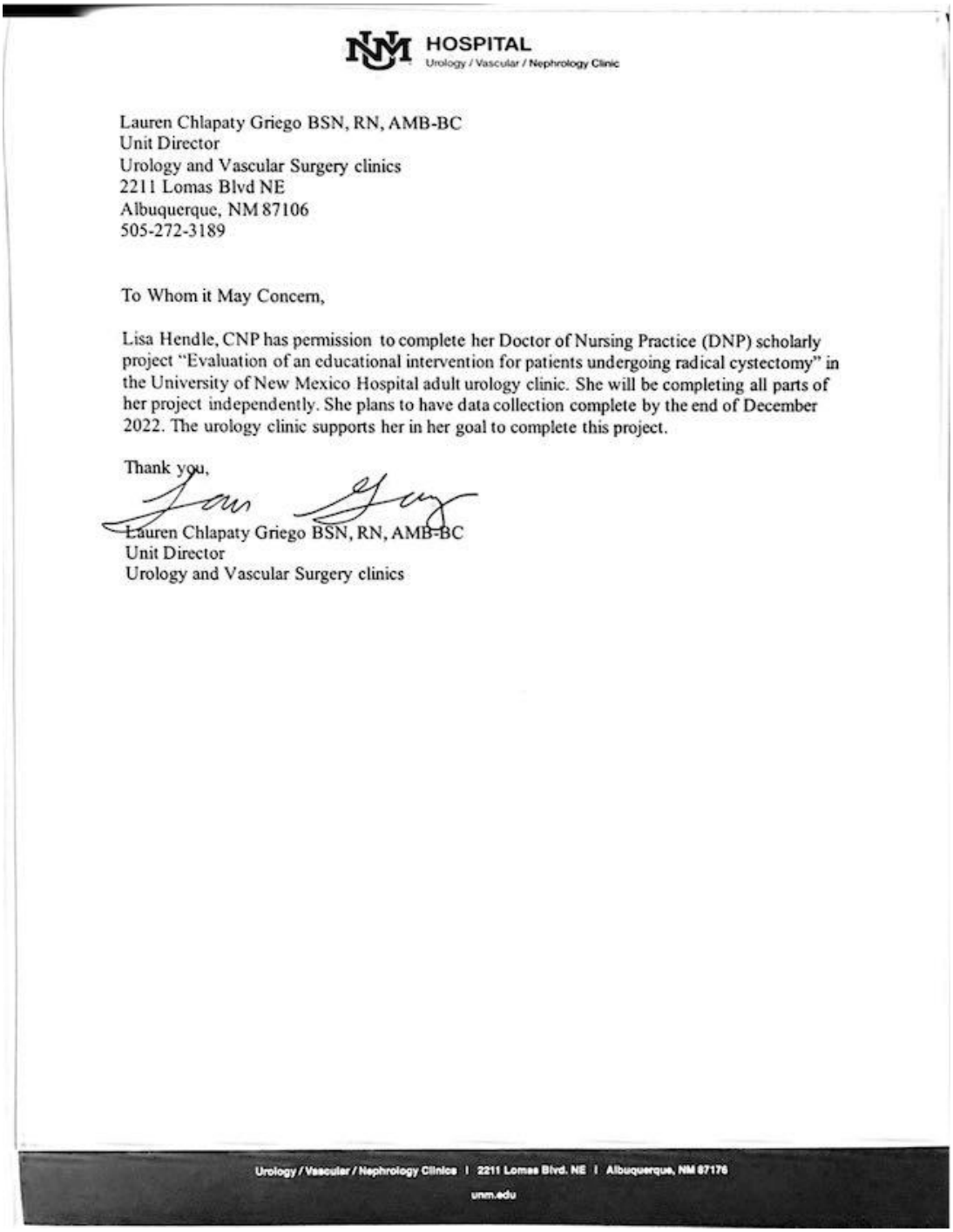
Appendix D: Urology Clinic Director Approval Letter



HOSPITAL
Urology / Vascular / Nephrology Clinic

Lauren Chlapaty Griego BSN, RN, AMB-BC
Unit Director
Urology and Vascular Surgery clinics
2211 Lomas Blvd NE
Albuquerque, NM 87106
505-272-3189

To Whom it May Concern,

Lisa Hendle, CNP has permission to complete her Doctor of Nursing Practice (DNP) scholarly project "Evaluation of an educational intervention for patients undergoing radical cystectomy" in the University of New Mexico Hospital adult urology clinic. She will be completing all parts of her project independently. She plans to have data collection complete by the end of December 2022. The urology clinic supports her in her goal to complete this project.

Thank you,

Lauren Chlapaty Griego BSN, RN, AMB-BC
Unit Director
Urology and Vascular Surgery clinics

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