ABSTRACT OF INVESTIGATIVE PROJECT

Impact Of Nursing Interventions On Perioperative Throughput: A Review Of The Patient Undergoing Laparoscopic Cholecystectomy In The Ambulatory Surgery Setting Versus Acute Care Setting

Opportunities for increased efficiencies can be evaluated by assessing current processes and examining the components of each step to identify adjustments for improvements within a hospital's perioperative department. General systems theory identifies dynamic relationships exist within an open system and components of the perioperative department can be categorized into input, throughput and output. This framework was used to evaluate nursing interventions concerning throughput in an ambulatory and acute care setting. A retrospective chart review utilizing post anesthesia care unit interval times was completed to determine whether preemptive oral narcotic administration impacts times and pain levels of 125 outpatient laparoscopic cholecystectomy patients in these settings. Summary statistics and regression analyses were utilized to evaluate preemptive pain management interventions on perioperative throughput. This researcher found the ambulatory surgery center to be more effective in postoperative throughput and pain control than the acute care setting. The data supported decreased PACU time with the administration of 10mg of Oxycotin 60 minutes before a laprascopic cholecystectomy. As nurses, we should advocate administration of preemptive analgesia in the perioperative setting.

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Impact Of Nursing Interventions On Perioperative Throughput: A Review Of The Patient Undergoing Laparoscopic Cholecystectomy In The Ambulatory Surgery Setting Versus Acute Care Setting

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Impact of Nursing Interventions on Perioperative Throughput: A Review of the Laparoscopic Cholecystectomy Patient in the Ambulatory Surgery Setting versus Acute Care Setting

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INVESTIGATIVE PROJECT

An investigative report submitted in partial fulfillment of the requirements for the degree of Master of Science in Nursing at Northern Kentucky University

By

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CHAPTER I

The Research Problem

Introduction

Hospitals compete with ambulatory surgery centers for market share in a sector with hospital and non-hospital rivals. Revenue from outpatient procedures is difficult to capture with the intense competition that exists in the healthcare marketplace (Sandberg et al., 2005). Outpatient surgery is an increasingly vital component of a hospital's mission and growth forcing them to compete with free standing ambulatory surgery centers. Free standing rivals are pursuing a broader range of services threatening the hospital's core service lines. This requires hospitals to ensure on-time starts, quick turnover times, and fast patient discharge to maintain and gain outpatient revenue. The perioperative team must meet these demands while providing quality care to patients.

Current economic stressors have placed a burden upon healthcare institutions to remain productive and efficient while controlling costs (Sandberg et al., 2005). The changes in insurance reimbursements mandate maximum utilization and productivity from operating room space.

Throughput is defined as the time from admission to discharge from the surgical facility. To effectively manage the operating room, the entire perioperative team needs to facilitate processes that capitalize on utilization in all areas that ultimately impact operating room flow (Sandberg et al., 2005). Increased efficiencies can be evaluated by assessing current patient care processes. Perioperative throughput includes the preoperative, intraoperatvie

and postoperative care. This accounts for actual time of the patient's hospital admission until discharge.

The ambulatory perioperative setting sets the stage for efficiencies that are often times difficult for an acute care setting process. Given the magnitude of both the financial as well as best-practice initiatives, nursing interventions can support and provide high level of efficiency while continuing to ensure optimal surgical outcomes by providing a safe and successful perioperative experience (Costa, 2001).

Significance of the Study

In hospitals that provide both an ambulatory and acute care setting, nursing interventions have been identified that promote throughput in the perioperative setting. These care modalities target pain management and postoperative nausea. Unrelieved postoperative pain has been identified as a complication that increases post operative nausea, vomiting and delays discharge (Watt-Watson, Chung, Chan, & McGillion, 2004). Specific nursing interventions, actions can be identified that promote adequate pain management during a surgical patient's experience. Efficiencies and best-patient outcomes are directly related to effective postoperative pain management. The nursing interventions address patient participation, nurses' assessment and management skills, multidisciplinary partnership, organizational management, education and evaluation of pain management strategies (Bucknall, Manias, & Botti, 2001). Interventions that support patient's postoperative care need to be managed consistently.

The perioperative nurse is responsible for the care and coordination of the patient's surgical experience (Gardner, Nnadozie, Davis, & Kirk, 2005).

Effective pain management strategies need to be realized and initiated during the initial assessment to target the individual patient's needs throughout each step in the perioperative process (Kamming, Chung, Williams, McGrath, & Curti, 2004).

Review of laparoscopic cholecystectomy in both the ambulatory surgery and the acute care settings help assess the impact that perioperative nursing interventions have on throughput. Hospitals which offer the same surgery in an ambulatory surgery and an acute care setting provide the opportunity to investigate the impact of nursing interventions in two different care areas. Many times outpatient surgeries are performed in the acute care setting for physician convenience and the post anesthesia care units (PACU)-to-discharge times are perceived to be longer. By comparing the same patient with the same surgery in a different location in the same perioperative department, this study should support the nurses' role in efficiency at point of care. This study involved one anesthesia group, one hospital culture, and one set of perioperative policies and procedure and processes. This study identified the impact of the nursing care interventions in both the ambulatory care and acute care settings on throughput.

The significance of this study was to demonstrate that nursing interventions which support preoperative pain management impact discharge time in the perioperative setting. Evaluation of nursing interventions in the ambulatory setting versus the acute care setting can identify throughput processes in the different perioperative settings.

When one facet of the perioperative system is optimized, patient outcomes may be affected adversely. These adverse effects such as uncontrolled pain, nausea and vomiting directly impact throughput by delaying

discharge as well as other cases scheduled in the operating room. Therefore, in an effort to understand how process improvements can be made within this system, the inner workings need to be continually evaluated to ensure best outcomes (Copp, 2002). Best patient outcomes rely on successful pain management initiatives regardless of the perioperative setting (Chavis & Duncan, 2003).

Statement of the Problem

Surgical cases are based on surgeon's availability, operating room staff availability and patient. In a hospital setting, where outpatient surgeries are performed in both an ambulatory and acute care setting, patient care processes differ due to patient flow and acuity.

A patient having surgery at the hospital is admitted to a same day surgery unit, operating room, perianesthesia care unit and back to the same day surgery unit. This is unlike the ambulatory surgery unit where all the perioperative care is provided within the same unit. The ambulatory surgery center initiates discharge planning upon admission. Not much flexibility exists in an outpatient surgery schedule due to limited bed capacity and time constraints of the surgery schedule.

Purpose of the Study

The purpose of this study is to determine whether preoperative pain management interventions inititated in the laparoscopic cholecystectomy patient are effective in reducing postoperative pain in the ambulatory and acute care setting. The impact that nursing pain management interventions

have on throughput were evaluated by collecting data concerning outpatient surgical times from admission to discharge in both settings.

Theoretical/Conceptual Framework

The theoretical framework used for this investigative study was based upon organizational systems theory. The basis for this theory is defined by von Bertalanffy's (1950) general system theory which identified that dynamic relationships exist within an open system and the significance that each component has upon that system. Individual components are interdependent within the system. The components of the perioperative process can be categorized into input, throughput and output. The input identifies the patient being entered into the system through communication between the surgeon and the surgery scheduling department of the hospital. The throughput is identified from the time the patient is admitted on the day of surgery to the perioperative department through discharge. The output is defined as a completed surgical procedure and the patient receiving optimal care and adequate pain management before discharge.

Research question

The focus of this study was the impact of patient care setting and pain management interventions. This PI attempted to answer specific care interventions affecting perioperative throughput.

1. Do laparoscopic cholecystectomy patients who receive oral narcotic analgesia 60 minutes preoperatively have less pain and use less narcotic post operatively in the acute care and ambulatory settings?

2. Is the post anesthesia and discharge time of laparoscopic cholecystectomy patients who receive preoperative oral narcotic analgesia shorter than those who do not receive preoperative oral narcotic analgesia in the acute care and ambulatory settings?

Variables

The independent variables in this study were the administration of preoperative oral narcotic analgesia. The conceptual independent variable was the preoperative administration of oral narcotic analgesia to all outpatients. The operational independent variable was the preoperative administration of oral narcotic analgesia to all outpatients undergoing a laparoscopic cholecystectomy in both the acute and ambulatory care setting.

The first dependent variable in this study is perioperative throughput which was defined as total perioperative time, from admission to discharge. General systems theory clearly defines the role that each interaction plays among healthcare providers and patients to achieve a positive surgical experience. Nursing interventions during the preoperative phase of perioperative throughput impact both a successful surgical procedure and timely discharge. Ultimately, perioperative interactions and processes occur to achieve quality patient care as well as minimal throughput times (Von Bertalanffy, 1950). The conceptual dependent variable was the perioperative time for all outpatients from the point of admission to discharge. The operational dependent variable was the perioperative time for all outpatient laprascopic cholecystectomy patients from the point of admission to discharge in both the acute and ambulatory care setting.

The second dependent variable identified was pain. Pain levels for patients during the perioperative experience impacted narcotic administration

and time spent in the hospital postoperatively. The conceptual dependent variable was the perioperative pain for all patients at the point of admission and at discharge. The operational variable was the pain levels for all outpatient laparoscopic cholecystectomy patients at the point of admission and the point of discharge (Shang & Gan, 2003).

CHAPTER II

Review of the Literature

Introduction

The outpatient perioperative arena continues to evolve as hospitals obtain the majority of revenues from outpatient services. Outpatient surgery accounts for a large portion of hospital revenues and is arguably the greatest target of free standing surgery center competition. Cost containment as well as technological advancements continues to drive surgical healthcare delivery to the outpatient setting. In the outpatient setting, time as well as facility constraints require the preoperative nurse to assess surgical patients and initiate effective pain management strategies to prepare for a timely discharge. The perioperative nurse needs to address pain management initiatives that support preemptive strategies upon admission to the perioperative department. Opportunities in effective postoperative pain management can be initiated at this point. In review of the literature, research indicates that patients unnecessarily suffer from postoperative pain due to insufficient preoperative preparation. Preoperative preparation needs to include proactive pain management strategies. Without these initiatives, outpatient discharge is delayed and perioperative throughput, the time the patient arrives at the hospital until discharge, is negatively impacted (Shang & Gan, 2003). This literature review addressed postoperative pain and preemptive analgesia, specifically oral narcotics.

Postoperative Pain

The American Pain Society, the Agency for Healthcare Research and Quality (AHRQ) and the Oncology Nursing Society have promoted evidence based guidelines to manage pain. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards state that patients have the right to appropriate evaluation and to treatment of pain. Studies have shown that inadequate pain management does occur, in spite of published guidelines (Devine et al., 1999; McNeill, Sherwood, Starck, & Nieto, 2001; Starck, Sherwood, Adams-McNeill, & Thomas, 2001). This has prompted investigation in how to effectively demonstrate best outcomes in line with clinical guidelines (Sherwood, McNeill, Starck, & Disnard, 2003).

Although pain management guidelines are established by regulatory bodies such as AHRQ and JCAHO, evidence would suggest that pain is not being addressed appropriately in the clinical setting. Unfortunately, various studies have shown the issue of undermanaged pain to be universal. Sherwood, McNeill, Starck, and Disnard (2003) cited an Australian study that reported nurse's perception of patient's pain was lower than the patient's actual pain rating (N=91). A prospective observational study was conducted to identify factors which may predict severe postoperative pain and patient dissatisfaction with analgesia management. The study found that nurses' assessments of pain were observed to be a great deal less than patients' actual postoperative pain levels. Pain intensity was assessed using the Present Pain Intensity (PPI) and the Visual Analogue Scales (VAS) of the McGill Pain Questionnaire (Thomas, Robinson, Champion, McKell, & Pell, 1998).

Meehan (1995) found the same to be true of cardiac surgical patients (N=101). Patient charts were reviewed retrospectively for 50 adult cardiac surgical patients. Then, the same information was collected for 51 adult cardiac surgical patients prospectively utilizing the VAS for pain assessment. The data confirmed cardiac patients were still experiencing inadequate pain relief. This phenomenon would suggest that patients are not receiving adequate postoperative pain intervention due to lack of judgment in determining pain intensity, as well as the patient's lack of understanding of pain control. The researchers propose the implementation of the McGill pain questionnaire to predict patients at high risk for postoperative pain, enabling nurses to address patient's needs and improve pain outcomes. Although implementation of tools such as the McGill pain questionnaire supports interaction between patient and provider, effective pain management is limited by insufficient understanding of analgesia options (Sherwood, McNeill, Starck, & Disnard, 2003).

The authors note, the nurse is the leader in effective postoperative pain management. Without appropriate assessment and diagnosis of postoperative pain, the patient may suffer. The perioperative nurse can proactively prompt a surgeon or anesthesiologist to employ various pain modalities such as preoperative pain analgesia. These nurse-directed multidisciplinary approaches support a win–win situation for both patient and hospital. Perioperative nurses have an impact on pain management and play an integral role in facilitating best outcomes as well as supporting the hospital's cost containment strategies. The perioperative nurse is instrumental in directing the outpatient surgical course, including the patient as a partner in assessing and addressing pain management. In addition, an awareness of

stewardship and economic responsibilities needs to be accomplished without sacrificing patient safety and comfort. By utilizing effective nursing interventions, postoperative pain management is successful and cost-saving strategies are addressed with shorter lengths of stay in the perioperative department (Sherwood, McNeill, Starck, & Disnard, 2003).

Kamming, Chung, Williams, McGrath and Curti (2004) reported that postoperative pain management outcomes in ambulatory surgery centers are inadequate in providing effective postoperative pain management. The researchers identified the incidence of moderate-severe postoperative pain to be as high as 31% to 40% for patients following outpatient surgery. Previous studies identified misconceptions of outpatients experiencing only mild to moderate pain levels following surgical procedures performed in the ambulatory care settings (Beauregard, Pomp, & Choiniere, 1998; Chung & McGrath, 2003; Rawal, Hylander, & Nydahl, 1997). For example, Rawal, Hylander, and Nydahl (1997) found that approximately 35% of ambulatory surgery patients experience moderate-to-severe pain in spite of analgesic interventions. Information was gathered by a questionnaire that evaluated the nature and severity of pain 48 hours post discharge in outpatients 5-88 years of age who had undergone procedures such as inguinal hernia repair, orthopedic, hand and varicose vein surgery (N=1035). The study concluded the need for better analgesic interventions as well as preoperative assessment and follow-up in the ambulatory setting (Rawal et al., 1997). By identifying outpatients at risk for significant postoperative pain, nursing interventions can initiate proactive postoperative pain management strategies in the preoperative setting. .

Arnstein (2002) addressed the problem of uncontrolled pain in the perioperative setting and described effective strategies and ongoing assessment of the presence and intensity of postoperative pain. According to reports by the US Department of Health and Human Services, 23 million surgical procedures are performed each year with only half of the patients receiving adequate postoperative pain relief. Arnstein (2002) stressed the use of preemptive pain relief. Although, adequate pain relief is mandated by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Centers for Medicare and Medicaid standards for pain assessments and implementation of measures that ensure ongoing pain relief, pain goes untreated. Nursing interventions at the point of care need to address acute as well as chronic pain. Strategies to manage pain are essential to best practice outcomes and have been recognized as the nurse's duty in accordance with accreditation agencies and case law. Research continues to show that the majority of hospital patients experience untreated or undertreated postoperative pain (Arnstein, 2002).

Facilities are required by regulatory agencies to evaluate pain management strategies. Opportunities for improvement can be realized by examining data from retrospective chart reviews, focus groups and patient interviews. Arnstein suggested hospitals review a minimum of 60 charts from a six month period including a diverse population of patients at risk for pain. Healthcare facilities can gather insightful information regarding pain management knowledge, attitudes and standard procedures within the organizational culture to address patient care accountability for providers (Arnstein, 2002).

Unavoidably, postoperative pain occurs after the majority of outpatient surgical cases. Perioperative nurses are challenged to remain a step ahead of the pain process. A thorough preoperative pain assessment and screening addresses the patient's history and previous interventions that may have been successful in treating pain. Prompting early pharmacological measures and adequate pain relief ensures a smooth and successful transfer to the recovery room and ultimately patient discharge. The researcher described a nursing intervention which was utilized as a communication tool between caregivers to acknowledge individual patient needs addressing pain management (Arnstein, 2002).

Postoperative pain management is an integral part of the patient's surgical experience. Nursing interventions at point of care can ensure a successful postoperative course through effective assessment and proactive strategies. The following section will address preemptive analgesia addressing the utilization of preoperative oral narcotic administration.

Preemptive analgesia

Management of acute perioperative pain should focus upon supporting pain control while ensuring patient comfort. Each patient should be treated in accordance with an individual treatment plan for pain. Various options of pain modalities are available to support acute pain in the perioperative setting. By assessing as well as identifying opportunities for pain control, pre-emptive pain management supports an effective option for postoperative pain management (Kamming et al., 2004).

Kamming et al. (2004) reviewed evidence-based options for postoperative pain management in the outpatient setting. In theory, the

administration of pain medication preoperatively should reduce pain by preventing the peripheral and central sensitization that occurs during surgery. The authors identified various pain management interventions including analgesia before surgery (preemptive analgesia) that provided opportunities for better postoperative pain control by targeting physiological response. Therefore, pharmacological intervention provides pain coverage before the pain stimulus is initiated. This in turn minimizes the patient's discomfort while supporting high patient satisfaction and effective postoperative care (Kamming et al., 2004).

Although studies (Kissin, 2000 ; Pavlin, Horvath, Pavlin, & Sima, 2003) support preemptive analgesia, it is noted that an extensive meta-analysis by Monriche and colleagues presented a lack of evidence to support preemptive measures with NSAIDs, narcotics, peripheral local anesthetics and caudal analgesia. In a systematic review, 93 randomized clinical trials of preincisional versus postincisional analgesia interventions were identified (N=3,761). The trials included a variety of preemptive analgesia intervention for surgical patients. Concerns were identified regarding the use of preoperative opioids within a number of negative studies and the differentiation in the effect of intraoperative opioid administration upon postoperative pain evaluations. Recordings of average pain scores for the first 24 hours were utilized for quantitative analysis and were defined as a clinically relevant measure. By limiting the time frame for postoperative pain assessment, the author acknowledged the possibility of positive findings being overlooked during the initial postoperative period. Although Moiniche, Kehlet and Dahl (2002) disputed the impact of timing as the variable in postoperative pain management, the authors did note benefits in aggressive, perioperative

interventions on postoperative pain. The researchers suggested that future studies focus upon protective analgesia rather than the timing of preemptive analgesia (Moiniche et al., 2002). Although this issue continues to remain controversial, evidence supports the implementation of preoperative management measures in reducing pain scores and enhancing best outcomes for postoperative outpatients.

In a study by Reuben, Steinberg, & Maciolek (2002), it was identified that preoperative administration of 10mg of controlled-released Oxycodone, in patients undergoing laparoscopic tubal ligations provided effective pain relief (N=50). A randomized, double-blinded study was conducted with healthy women presenting for elective ambulatory laparoscopic tubal ligation surgery in a university hospital's ambulatory surgery center. There were 50 patients who were administered either placebo (N=25) or 10mg of controlled-released Oxycodone (N=25) one hour before surgery. It was noted that patients who received this preemptive analgesic had lower post-operative pain scores, reduced postoperative nausea and vomiting, shorter discharge times and decreased use of analgesic post-operatively (Rueben et al., 2002).

Polomano, Rathmell, Krenischek, and Dunwoody (2008) described approaches to management of acute perioperative pain. Their discussion explored the various methods of pain management including preemptive analgesia. The authors addressed tissue injury, which is inevitably caused by surgical interventions. This injury, initiates a hypersensitivity of peripheral nociceptors and an increased excitability of neurons within the central nervous system. "Because the exact onset of tissue injury in scheduled surgical procedures is known, preemptive analgesia has the most potential in this situation" (Polomano, Rathmell, Krenischek, & Dunwoody, 2008, p. 37).

These physiological changes potentiate a significant pain response in the surgical patient. Pre-emptive analgesia is utilized as an adjunct to prevent hypersensitivity of the nervous system while addressing acute post-operative pain before it occurs. Preemptive analgesia can include opioids, local anesthetics and NSAIDs (Polomano, Rathmell, Krenischek, & Dunwoody, 2008).

Limited research was found regarding specific studies identifying narcotics as a preemptive pain measure. Many of the studies on perioperative efficiencies only addressed operating room throughput without evaluation of the entire perioperative process, including the post anesthesia care and discharge times.

As demonstrated by research reviewed on postoperative pain management, it is imperative to demonstrate the impact of nursing interventions in the outpatient perioperative setting for best patient outcomes. By evaluating current practice in a hospital performing outpatient surgery in the ambulatory and acute care settings, the impact of preemptive analgesia in the perioperative setting will be evaluated for its implications upon throughput.

Chapter III

Chapter III are the methods that were used to assess the study population by examining data that measured throughput time and pain levels of patients undergoing laparoscopic cholecystectomy in the ambulatory and acute care settings. Statistical analyses showed whether there was a correlation between preemptive analgesia and throughput times, pain levels and narcotic administration.

Design

A quantitative, correlational study was utilized to investigate the impact of preemptive oral narcotic analgesia on patients pain levels thereby determining perioperative throughput in an ambulatory surgery center and acute care surgical unit within the same healthcare facility. A retrospective chart review was conducted to analyze the impact that nursing pain management interventions have on throughput of outpatient laparoscopic cholecystectomy patients in both settings. Patients admitted to ambulatory and acute care perioperative settings were identified. The time intervals measured included time of hospital admission to PACU admission and from PACU admission until discharge and were collected for patients admitted to both the acute care and ambulatory care settings. The times of interest in this study are two-fold. Times were collected comparing preemptive narcotic analgesia administration in the preoperative setting. Nursing interventions was assessed to identify the impact of these factors upon throughput times.

The research question identified in this study was to establish a cause-and- effect relationship linking the impact of nursing interventions and

throughput in the perioperative setting. Therefore, a qualitative study describing human phenomenon would not be appropriate.

Time constraints as well as economics factors support an investigative project that utilizes data that is readily available. The information the PI collected demonstrated comparability with similar potential factors. These include surgeons and anesthesia providers as well as the surgical units being part of the same perioperative department (Polit & Beck, 2008).

Setting

The retrospective chart review was completed in a 450 bed tertiary care Midwestern hospital, housing a seven suite ambulatory surgery center unit and a seventeen suite acute care surgical unit. This healthcare facility completes approximately 7,000 inpatient and 10,000 outpatient surgical procedures each year. The ambulatory surgery center in this study is a department of the hospital and both ambulatory surgery center and acute care surgical unit are under the direction of the same nurse administrator. Anesthesia care is provided by the same physician group and anesthesia providers are rotated through the ambulatory surgery center and acute care surgical unit.

Sample

The target population is surgical patients who have undergone outpatient laparoscopic cholecystectomy in the acute and ambulatory care setting at a Midwestern hospital. The convenience sampling included patients within a period of time that affords the PI 125 cases performed at the study institution as suggested by the Burkardt Consulting Center. Data were

collected utilizing a retrospective chart review. Inclusion criteria identify laparoscopic cholecystectomy patients who have undergone a general anesthetic and were discharged within 23 hours of admission of admission with an ASA physical status classification of three or less (Appendix A). Exclusion criteria were scheduled inpatients, patients to be admitted for greater than 23 hours, an ASA physical status classification of four or five, or patients that have undergone bile duct exploration.

Instruments

An excel spreadsheet customized by the PI was used to record patient information (age /ASA criteria) and preemptive oral narcotic administration (drug /dosage/time). Times of interest included time of hospital admission to PACU admission and from PACU admission until discharge and was collected for patients admitted to both the acute care and ambulatory care settings. Preoperative and postoperative pain levels were recorded using a scale of 0-10 preoperatively, postoperatively and at the time of discharge. Patient's expressed their level of pain on a scale from 0-10, 0 indicating no pain and 10 indicating the worst pain imaginable (D'Arcy, 2007). Information was manually collected by the PI and recorded on an electronic spreadsheet for statistical analysis (see Appendix B).

Data Collection

Data collection began after approval of the Institutional Review Board at university and study institution. Data were manually collected from paper perioperative records. Information included date of procedure and an encrypted patient identifier. Patients who have undergone outpatient

laparoscopic cholecystectomy were identified from the study institution's electronic operating room scheduling system. The medical records department provided the paper charts upon written request of the PI. The PI manually collected data from hospital records and enter the data into a secure hospital based computer network. Demographic data included age of the patient. Preoperative and postoperative pain levels were recorded using the numeric scale of 0-10 (see Appendix B).

The reliability of the data collection tool is designed to provide consistent information in two perioperative care settings. The investigator was dependent on the quality and legibility of documentation by care providers. Information collected in regards to pain level can vary due to subjectivity and patient's expectations. The validity of the criterion being measure is straightforward in regards to time data and narcotic administration (Polit & Tatano Beck, 2008). Face validity of the data collection tool occurred with approval from the chair of anesthesiology, perioperative director and the advisor to the research council.

Human Subject Protection

This study posed no apparent physical, emotional, economic, psychological or economic risks to the subjects or their medical information. Retrospective review of medical records and data collection was completed by the PI. Information was gathered in a secure location in the perioperative department of the study institution. Patient's paper records were housed in a locked file cabinet in a locked office until returned to the facility's medical record department. Any information collected as paper documentation such as the data collection tool was secured in a locked file cabinet in a locked

office. Data was entered into a secure password-protected computer and stored on the PI's hard drive. The PI had exclusive access to the information collected and patient identification was encrypted to maintain confidentiality. No identifying information was entered into the computer. The study institution was presented with only aggregated information and findings upon conclusion of the inquiry. Since completion of the study, the data collected has been secured and will be shredded by the PI in 3 years (Polit & Tatano Beck, 2008).

Data Analysis

A statistical research consulting center at the university reviewed the investigators project and data collection tool through electronic correspondence. Following data retrieval, three different regression analyses were used to analyze the independent or predictor variables; location (ambulatory versus acute), preoperative analgesia (yes vs. no) and preoperative pain level (0-10). The following dependent variables were analyzed using regression analyses; postoperative pain level (0-10), postoperative narcotic needed (yes vs. no) and length of stay in PACU. Regression testing determined whether one or more of the variables identified were related to a particular response and proved useful in determining preemptive pain management nursing interventions in both the ambulatory and acute care settings (Polit & Tatano Beck, 2008).

For postoperative pain level and length of stay in PACU, multiple regressions were utilized. Using a 5% significance level and a medium effect size using G-Power to realize a power of .95, 125 observations were needed

to be collected. Postoperative narcotic needs were evaluated using logistic regression.

Research Rigor

"Rigor is the striving for excellence in research that involves discipline, scrupulous adherence to detail and strict accuracy" (Fain, 2004, p.7). By conducting a quantitative study that examined data which had previously been documented, opportunities to manipulate the raw data were not a factor. The PI collected the data throughout the course of the study using one collection tool. This ensured consistency in the information collected and safeguarded confidential information regarding patients as well as care providers.

Recommendations established by the research consulting center determined that 125 charts were reviewed. Randomization was not a factor with this study because it was a retrospective chart review.

Chapter IV

Introduction

The purpose of this quantitative, correlational, retrospective chart review was to determine if the administration of oral narcotic preoperatively would improve pain control and decrease length of hospital stay for patients undergoing outpatient laparoscopic cholecystectomies. One hundred and twenty five charts were reviewed and data were collected on procedures performed in the ambulatory and acute care setting.

Inclusion criteria included patients undergoing outpatient laparoscopic cholecystectomies in both the acute and ambulatory care setting. These patients underwent a general anesthetic and were discharged within 23 hours of admission to the facility. An ASA status classification of three or less was included in the criteria. Exclusion criteria included: (a) scheduled inpatients, (b) patients admitted greater than 23 hours, (c) ASA status classification of four or five, and (d) patients who had undergone a bile duct exploration.

Analysis

Data were manually collected from 125 charts (N=125). Information collected included the patient's day of surgery, time spent within the perioperative department and administration of pre and postoperative narcotics. Three different regression analyses were used to analyze the independent or predictor variables; location (ambulatory versus acute), preoperative analgesia (yes vs. no) and preoperative pain level (0-10). Regression testing was used to determine whether one or more of the variables identified were related to a particular response and useful in

determining preemptive pain management nursing interventions in both ambulatory and acute care settings.

For postoperative pain level and length of stay in PACU, multiple regressions were utilized. Using a 5% significance level and a medium effect size using G-Power to realize a power of .95, 125 observations were collected. Postoperative narcotic needs were evaluated using logistic regression.

Presentation of Data

Data collected in this study included: (a) age, (b) anesthesia classification, (c) acute care or ambulatory setting, (d) admission time to the facility, (e) preoperative oral narcotic administration, (f) preoperative pain level , (g) time from PACU admission till discharge, (h) postoperative pain level, (i) postoperative narcotic, type, dose and frequency, and (j) pain level at discharge.

Summary statistics utilizing descriptive data which included frequencies and percentages were performed on all patients in this study undergoing outpatient laparoscopic cholecystectomy assessing the patient's age, pain levels, post anesthesia care unit time and operating room time. The mean age was 46.95 years (*SD* 13.58). The minimum age was 17 years and the maximum age was 88 years. The median age was 47 years. The mean preoperative pain level was .89 (SD 1.95). The minimum pain level was 0 and the maximum pain level was 10. The median preoperative pain level was 0. The post anesthesia care units stay (PACU) for each patient was measured in minutes. The mean stay was 201 minutes (SD 79.15). The minimum stay was 72 minutes while the maximum stay was 666 minutes. The median PACU

stay was 182 minutes. The mean postoperative pain level was 5.3 (SD 2.98). The minimum postoperative pain level was 0 and the maximum pain level was 10. The median postoperative pain level was 5.0. The mean discharge pain level was 3.35 (SD 1.62). The minimum pain level was 0 and the maximum pain level was 10. The median pain level upon discharge was 4.0. The operating room mean time was 399.13 minutes (SD 92.29). The minimum procedure time was 200 minutes and the maximum time was 735 minutes. The median time was 392 minutes.

Outpatient laparoscopic cholecystectomy surgery was performed in both the ambulatory and acute care setting at this facility. The location of the patient's surgery was dependent upon surgeon preference and patient acuity. The percentage of surgeries performed in the acute care setting was 85.6% (n=108) and in the ambulatory care setting was 13.6% (n=17). Table 1 shows the majority of outpatient laparoscopic cholecystectomies were performed in the acute care setting.

Table 1

Location of study setting

	Frequency	Percent
Ambulatory	17	13.6
Acute Care	108	86.4
Total	125	100.0

The American Society of Anesthesiologist (ASA) Physical Status Classification is assigned preoperatively as an indication of health status (Barash, Cullen, & Stoetling, 2006). The ASA classifications of all sample

patients were ASA I - 9.6% (n=12), ASA II – 83.2% (n= 104), and ASA III – 5.6% (n=7) and ASA IV – 1.6% (n=2). The study sample was predominantly ASA classification of II (n=104) representing patients with mild moderate systemic disease. Twelve patients were an ASA classification I, normally healthy. The other patients were ASA classification III (n=7), with severe systemic disease, not incapacitating and ASA IV (n=2), with severe systemic disease, potentially life threatening. The ASA score data were collected to document the health status of the study group. The majority of patients undergoing outpatient laparoscopic cholecystectomies were ASA II as identified in Table 2.

Table 2

American Society of Anesthesiologist (ASA) Physical Status Classification

	Frequency (n)	Percent (%)
I	12	9.6
II	104	83.2
III	7	5.6
IV	2	1.6
Total	125	100.0

The researcher attempted to first ask the following question: Does the administration of an oral narcotic 60 minutes preoperatively support preventative pain management strategies in the laparoscopic choleystectomy patient in both the acute and ambulatory care setting? The PI found patients reported less pain and required less postoperative narcotic with the administration of 10 mg of Oxycotin 60 minutes preoperatively.

Patients receiving preoperative narcotics were given 10 mg of Oxycotin within one hour of undergoing a laparoscopic cholecystectomy. The percentage of laparoscopic cholecystectomy patients who received 10 mg of Oxycotin were 10.4% (n=13). The percentage of those who did not receive a preoperative narcotic were 89.6 %(n=112). The 10 mg of Oxycotin was ordered by the surgeon and was administered in the preoperative holding area within 60 minutes of the scheduled surgery time. There were more patients who did not receive Oxycotin than did preoperatively as seen in Table 3.

Table 3

Received Preoperative Narcotic

	Frequency (n)	Percent (%)
No	112	89.6
Yes	13	10.4
Total	125	100.0

Pain medication was administered to patients in the ambulatory and acute care setting upon arrival to the post anesthesia care unit. Postoperative pain medication administered to outpatient laparoscopic cholecystectomy patients in both settings included Dilaudid 10.5% (n=13), Fentanyl 58.4% (n=73), Morphine 40% (n=50), Percocet 67.2% (n=84) and Oxycotin 1% (n=2). Fentanyl and Percocet were predominantly utilized in both the ambulatory and acute care settings for postoperative pain control (see Table 4).

Table 4

Patients Who Received Postoperative Narcotic

	Yes (n)	No (n)	Yes (%)	No (%)
Dilaudid	13	112	10.4	89.6
Fentanyl	73	54	58.4	41.6
Morphine	50	75	40	60
Percocet	84	41	67.2	32.8
Oxycontin	2	123	1.6	98.4

Administration of various narcotics was identified for relief of postoperative pain. Post surgical pain management was directed by the anesthesiologist/nurse anesthetist caring for the patient. Selection of narcotics for postoperative pain relief was dependent upon the choice of narcotic administered by the anesthesia provider during the surgical procedure. The majority of patients received more than one type of pain medication for relief of post-surgical pain. Postoperative pain was managed in 40.8% (n=51) with two different narcotics, 26.4% (n=33) with three different narcotics, 4.8% (n=6) with four different narcotics and 1.6% (n=2) with five different narcotics. Most of the patients (n=92) received two or more narcotics for postoperative pain control in the PACU setting as seen in Table 5.

Table 5

Administration of Multiple Narcotics for Postoperative Pain

	Frequency (n)	Percent (%)
0	7	5.6
1	26	20.8
2	51	40.8
3	33	26.4
4	6	4.8
5	2	1.6
Total	125	100.0

Pain assessments in the post anesthesia care unit were completed during admission to PACU, following administration of pain medication and before discharge in both the ambulatory and acute care settings. An assessment of postoperative pain was completed before the patient was discharged from the facility in which they had surgery. Preoperative and postoperative pain levels were recorded using a scale of 0-10 preoperatively, postoperatively and at the time of discharge. Patient's expressed their level of pain on a scale from 0-10, 0 indicating no pain and 10 indicating the worst pain imaginable (D'Arcy, 2007). The mean pain score for a patient before discharge in the ambulatory surgery setting was 3.12 (n=17). The mean pain score before discharge in the acute care setting was 5.64 (n=108). The ambulatory surgery unit's patients reported less pain upon discharge (see Table 6).

Table 6

Comparison of Mean Pain Score

Location	Mean	n	Std Deviation
Ambulatory	3.12	17	3.039
Acute Care	5.64	108	2.853
Total	5.29	125	2.995

One hour before surgery, a preoperative narcotic was administered to 13 of the 125 patients undergoing outpatient laparoscopic cholecystectomies. The postoperative pain score for patients immediately before discharge receiving a preoperative narcotic was 3.38 (n=13). The postoperative pain score for patients immediately before discharge who did not receive a preoperative narcotic was 5.52 (n=112). Patients who received a preoperative narcotic before surgery reported less pain upon discharge. (see Table 7).

Table 7

Comparison of Mean Pain Score after Preoperative Narcotic

Received preoperative narcotic	Mean	n	Standard deviation
No	5.52	112	2.832
Yes	3.38	13	3.664
Total	5.30	125	2.984

Presentation of Data Related to the Research Questions

The researcher attempted to show the impact of preoperative pain management interventions upon throughput times in the ambulatory and acute care setting. This was accomplished by asking whether the administration of an oral narcotic 60 minutes before undergoing laparoscopic cholecystectomy decreases postoperative time. The administration of an oral narcotic 60 minutes before surgery decreased PACU time by 55 minutes.

Data measuring post anesthesia care unit time for patients in the ambulatory and acute care settings was collected. The time was measured in minutes for both areas. The average length of stay for patients (n=17) in the ambulatory setting was 176.47 minutes while the average length of stay for the patient (n=108) in the acute care setting was 206.74 minutes. Patients in the ambulatory care setting were discharged approximately 30 minutes earlier than those patients in the acute care setting (see Table 8).

Table 8

PACU Time (in minutes) Ambulatory versus Acute Care Setting

Locations	Mean	n	Standard Deviation
Ambulatory	176.47	17	62.50
Acute Care	206.74	108	80.85
Total	202.59	125	79.06

Data measuring post anesthesia care unit time in minutes for patients who received a preoperative narcotic in the ambulatory and acute care settings was collected. The average length of stay for patients (n=13) who

received a preoperative narcotic within 60 minutes of surgery was 152.38 minutes. The average length of stay for patients (n=112) who did not receive a preoperative narcotic was 207.62 minutes. Patients who received a preoperative narcotic were discharged approximately 55 minutes earlier than those patients who did not (see Table 9).

Table 9

PACU Time (in minutes) for Patients Receiving Preoperative Narcotic

Received preoperative narcotic	Mean	n	Standard deviation
No	207.62	112	80.57
Yes	152.38	13	41.54
Total	201.87	125	79.15

This study examined the impact of nursing interventions on the perioperative throughput: of laparoscopic cholecystectomy patients in the ambulatory surgery setting versus acute care setting. Multiple variables from 125 charts were reviewed including ASA scores, postoperative pain scores, preoperative and postoperative narcotic administration and PACU times.

Based on multiple regression analysis, this study did not provide enough evidence to conclude patients who received oral narcotic analgesia 60 minutes preoperatively had less pain. Also, it was impossible to compare narcotic usage due to the different narcotics with different dosing schemes extracted from the patient's charts. The logistic regression analysis performed did not find enough evidence to conclude that patients who received oral

narcotic analgesia 60 minutes preoperatively were less likely to use narcotics post-operatively.

When using summary statistics, the reported postoperative pain levels were significantly less for patients who received 10 mg of Oxycotin within 60 minutes of the surgical procedure. Patients who received a preoperative narcotic were discharged approximately one hour sooner than those patients who did not. Based on the multiple regression analysis of the results of this study, there is enough evidence to conclude that the PACU length of stay for patients who receive preoperative oral narcotics is shorter than those who do not receive preoperative oral narcotics (p-value=.023).

In summary, the administration of preemptive analgesia 60 minutes before a laparoscopic cholecystectomy demonstrates a decrease in the level of pain reported postoperatively. Also, the administration of 10 mg Oxycotin preoperatively significantly reduces the length of in the PACU.

Chapter V

The outpatient surgery market continues to expand as innovation and economic constraints drive the health care market. Hospitals must ensure a safe and quality surgical experience for patients while being mindful of costs. Understanding the implications of interventions which can impact throughput in a perioperative department can support initiatives which are cost effective and support quality patient outcomes.

This study examined the impact of preemptive analgesia upon throughput in the ambulatory and acute care settings of a Midwestern hospital. Data were collected from 125 patients undergoing outpatient laparoscopic cholecystectomy. The information collected included ASA scores, medications, pain levels and included various times during the perioperative experience. Physician preference determined whether the patient was scheduled in the ambulatory or acute care setting.

The PI identified the impact of preemptive analgesia upon the amount of pain patients reported after undergoing an outpatient laparoscopic cholecystectomy. Surgical pain management strategies were found to be reactive rather than proactive in 90% (n=112) of the patients. Only 10% (n=13) of the 125 patients studied received a preoperative narcotic. Pain scores reported demonstrated that patients receiving 10 mg of Oxycotin were discharged home with mean pain levels of 3.38. In contrast, patients who did not receive preemptive analgesia reported pain scores at 5.52 at the time of discharge.

Rawal, Hylander, and Nydahl (1997) found that approximately one third of ambulatory surgery patients experience moderate-to-severe pain in spite of postoperative analgesic interventions. This study demonstrated the

need for better analgesic interventions as well as preoperative assessment (Rawal et al., 1997). Therefore, this study's findings would suggest that preemptive analgesia may be an intervention utilized to support postoperative pain management.

Secondly, this study found the patients who received a preoperative oral narcotic 60 minutes before undergoing a laparoscopic cholecystectomy had shorter PACU stays. The average length of stay for a patient who had received 10mg of Oxycotin was 55 minutes.

Limitations

The PI extracted information from paper charts. Occasionally, it was difficult to decipher the staff's handwriting. This required the PI to search elsewhere in the chart for data which was time intensive.

One surgeon prescribed oral narcotic preoperatively for laparoscopic cholecystectomy patients. By using one surgeon's patients, this limited the data collected to a select group of patients. Variability in surgeon experience and expertise was not included in the data collected.

The patients who received the oral narcotic were scheduled in the ambulatory surgery center rather than in the acute care setting. The ambulatory surgery center initiates discharge planning upon admission. Not much flexibility exists in an outpatient surgery schedule due to limited capacity and time constraints of the daily surgery schedule. The data collected may limit the impact of the preemptive analgesia in contrast to the expected throughput in an ambulatory surgery center.

There was only one type of narcotic administered preoperatively. The administration of other narcotics and non-steroidal anti inflammatory agents

may be useful in supporting postoperative pain management strategies. Oxycotin is acknowledged as a potent narcotic and the utilization of this drug exclusively may limit pain management options in the perioperative setting.

Implications for Research

The study examined the impact of the administration of 10 mg of Oxycotin 60 minutes before a laparoscopic cholecystectomy. Administration of a preoperative narcotic significantly decreased the length of time spent in the PACU. There was not enough evidence available to demonstrate a relationship between postoperative pain and administration of a preoperative narcotic, ASA score and the age of patients. Further study may demonstrate how location (ambulatory versus acute), and administration of a preoperative narcotic impact the throughput and pain levels of patients.

The significance of location can be evaluated by measuring pain levels in the acute and ambulatory setting after administration of a preoperative narcotic. In this study, the patients receiving Oxycotin 10 were limited to the ambulatory surgery center. By administration of an oral narcotic in both settings, the data may reveal location having an impact upon throughput. The PI found the ambulatory setting demonstrated a proactive approach to postoperative pain management unlike the acute care setting. The utilization of effective nursing interventions was vital in providing successful postoperative pain management and cost-saving strategies with shorter lengths of stay in the perioperative department (Sherwood, McNeill, Starck, & Disnard, 2003).

The data collected on the utilization of oral narcotics for postoperative pain management could be used to develop further studies regarding preemptive analgesia. This could include different narcotics or non-steroidal therapies administered in the preoperative setting. Data collected in further studies could include more than one surgeon or various anesthesia provider groups.

Implications for Theory

Organizational systems theory was the theoretical framework used for this investigative study. The basis for this theory is defined by von Bertalanffy's (1950) general system theory which identifies that dynamic relationships exist within an open system and the implication that each component has upon that system. Individual components are inter-reliant within the system. The components of the perioperative process were identified in three parts: input, throughput and output. A spreadsheet was created by the PI and data were collected retrospectively. The input was identified as the patient's preoperative medication. Throughput was defined as the time the patient was admitted to the perioperative department through discharge home. The output was defined as a completed surgical procedure and the patient and adequate pain management before discharge home. It is through this theory that the PI was able to identify there was a decrease in the patient's PACU stay after receiving an oral narcotic preoperatively.

Implications for Practice

Nursing intervention provides opportunities for effective pain management strategies in perioperative patients. At the study site, the PI had

the opportunity to investigate the impact of nursing intervention on throughput in the ambulatory and acute care settings for the outpatient laparoscopic cholecystectomy patient. Patient care was provided by the same groups of physicians and anesthesia in both settings. Preemptive analgesia was implemented in the ambulatory care setting by the surgeon. These ambulatory surgery patients experienced less pain 3.38 (n=13) as compared to patients who did not receive 10 mg of Oxycotin preoperatively 5.52 (n=112). These patients also spent less time in the PACU. The patients receiving a preoperative narcotic spent 152.38 (n=13) minutes in the PACU as compared to those who did not receive the preoperative narcotic 207.62 (n=112). This data supports proactive pain management strategies. Without these initiatives, outpatient discharge is delayed and perioperative throughput is negatively impacted (Shang & Gan, 2003).

To effectively manage the operating room, collaborative efforts are required among the surgical team to facilitate processes impacting operating room flow (Sandberg et al., 2005). Increased efficiencies should be continually evaluated through review of current patient care processes such as preemptive analgesia. Multidisciplinary team members have a role in ensuring this best practice in treating postoperative pain through the identification of evidence based pain management strategies such as ensuring surgical patients receive a preoperative analgesic.

Educational opportunities for the perioperative team can be facilitated by the chair of anesthesia, director of surgical services, perioperative management team and educators. Pain management strategies should include the administration of preemptive analgesia to ensure best patient

outcomes. These strategies provide an interdisciplinary approach to effective postoperative pain management in the surgical patient.

Summary and Conclusions

Richmond, Bromley and Wolff (1993) as cited by Farris and Fiedler (2001) found the administration of both intravenous and intramuscular morphine preoperatively decreased the requirements for postoperative pain management in patients undergoing total abdominal hysterectomy. These patients were found to have less pain postoperatively and significantly lower doses of intravenous morphine were administered postoperatively (38.4 mg morphine versus 48.3 mg morphine; $P<.05$) (Farris, D. & Fiedler, M., 2001).

An approach which utilizes a combination of modalities of pain control with various analgesic effects supports best practice to provide adequate postoperative pain management. Laboratory studies substantiate the administration of analgesia prior to acute pain stimulus decreases sensory changes. Although, there is still some debate within the literature, further research should be done to support effective postoperative pain management strategies (Layzell, 2008).

This investigative project substantiated the findings of previous studies (Arnstein, 2002; Rueben et al, 2002) addressing nursing intervention in the preoperative stage and the impact upon postoperative pain management. The data demonstrated the positive impact of preemptive analgesia on throughput initiatives and patient comfort. This study also found the ambulatory surgery center is more effective in postoperative throughput and pain control than the acute care setting. This is significant because the study site has both an acute care and ambulatory care setting. Further research could be useful in

promoting proactive pain management strategies in the ambulatory and acute care settings.

APPENDIX A

ASA Physical Status Classification

ASA I - Healthy, no systemic disease.

ASA II - Mild to moderate systemic disease not life-style limiting (asymptomatic hypertension, diabetes without end-organ dysfunction).

ASA III - Severe systemic disturbance which is life-style limiting (exercise induced angina, severe asthma limiting activity, status post cerebral vascular accident with weakness).

ASA IV - Severe systemic disturbance which is life-threatening (congestive heart failure, rest angina).

ASA V - Moribund patient with little chance of survival submitted to a procedure as a last resort

American Society of Anesthesiologists Physical Status Classification

Anesthesiology 24:111, 1963

(Barash, P., Cullen, B., & Stoetling R., 2006, p.478)

APPENDIX B

Data Collection Tool - Outpatient Lapraroscopic Cholecystectomy Procedures

Date of procedure	Study Code #	Age of patient	ASA status	Location of surgery ambulatory vs. acute	Preemptive narcotic type/ time/dose	Admission to post anesthesia care unit times	Post anesthesia unit care times till discharge	Holding Room Pain Level 0-10	First Postop Pain Level 0-10	D/C Pain Level	Type amount Frequency of analgesia in PACU	Total Perioperative Time

APPENDIX C

03/31/2011 13:37 513-865-1141 PAGE 0

Northern Kentucky University
Institutional Review Board (IRB) for th
Protection of Human Subjects
IRB Administrator, AC 616, 859-572-5
irb@nku.edu

This revised application submitted 12.15.09 as part of reply to comments mks

For IRB Committee Use Only
IRB # 10-080
Date Received 12.15.09
Date Posted 12.15.09
Alternate institution IRB #

APPLICATION FOR IRB REVIEW

Please type information directly into this form, attached any documents, and forward to the Research, Grants & Contracts Office, AC 616, Attn: IRB Administrator. Handwritten packets will be returned. DO NOT fold, staple or fax.

IRB Administrative Use ONLY

Approval Status/Campus Level Review - This Protocol for the use of human subject(s) has been reviewed by the Northern Kentucky University Institutional Review Board.

✓ Exempt Review Expedited Review Full Review NOT Approved

NKU IRB Member / Chairperson: [redacted] Date: 1/12/10

PROJECT TITLE: Impact of Nursing Interventions on Perioperative Throughput

Application Type Check 'New" to submit a study for the first time, 'Revise' to change or modify a currently approved study, or 'Continue' to extend or renew a currently approved study. For currently approved studies, enter the IRB number.	*Choose One*:	1. __X__ New study 2. _____ Revise current study IRB # _____ 3. _____ Continue current study with no changes IRB # _____
	Complete if applicable:	1. _____ Funded research project # _____ 2. _____ Teaching course #_____
Project Start & End Dates (Note - Research may not begin prior to IRB approval)	Estimated Start Date 01/01/2010	Estimated End Date 01/01/2011

PRINCIPAL INVESTIGATOR (last name, first name)	**Department**	
[redacted]	Nursing	
Campus Address (building & room; if none, enter 'none')	**Current Email**	
None	[redacted]	
Home Mailing Address (Street, City, State, ZIP)	**Campus Phone (if none, enter home phone)**	
[redacted]	[redacted]	
CITI Training completed? (check one) Attach CITI Completion Certificate	__X__ Yes _____ No	Note: Scores of 80% required on all six modules; individual programs may require additional modules.
Rank (check one)	_____ NKU Faculty/Staff __X__ NKU Student _____ Non-NKU Researcher	
FACULTY ADVISOR (If principal investigator is a student)	**Department**	**Campus Phone**
[redacted]	Nursing	[redacted]
Campus Address (building & room)	**Current Email**	
[redacted]	[redacted]	
CITI Training completed? (check one) Attach CITI Completion Certificate	__X__ Yes _____ No	Note: scores of 80% required on all six modules; individual programs may require additional modules.
Rank (check one)	__X__ NKU Faculty/Staff _____ NKU Student _____ Non-NKU researcher	

NKU IRB Cover Sheet (revised 07.09) Page 1

NOTE: If additional persons (e.g., faculty, staff, students) are involved in recruiting participants, conducting this research, interacting with participants, collecting data, or working with data that are not anonymous, complete needed information on page three.

Principal Investigator & Faculty Advisor Assurance

The original signature of the principal investigator (and faculty advisor if applicable) is required before this application can be processed. Scanned and faxed signatures, signature stamps and proxy signatures are not accepted.

I certify that:

- The information provided in this application, and all attachments, is complete and correct.
- I have ultimate responsibility for protecting the rights and welfare of human subjects, the conduct of this study, and the ethical actions of subjects when participating in this research.
- I will obtain informed consent or assent from all human subjects as required.
- I will make no change to the human subjects protocol or consent form(s) without approval by the NKU IRB.
- I have completed the CITI Educational training required to conduct this project. (Scores of 80% required on each module)
- I will report unanticipated problems, adverse effects, and new information that may affect the risk-benefit assessment to the NKU IRB office (859-572-5168).
- The proposed research has not yet begun, is not currently underway, and will not begin until IRB approval has been obtained.

[redacted] 11/9/2008
Date

11-9-09
Date

Incomplete packets submitted to the NKU IRB may delay the review process significantly.

ADDITIONAL RESEARCHERS OR MULTIPLE PRINCIPAL INVESTIGATORS

Complete information below for any persons (e.g., NKU students, faculty, and staff, or other non-NKU personnel) involved in recruiting participants, conducting this research study, interacting with participants, collecting data, or working with data that are not anonymous. If no other persons are involved, leave this section blank. An additional page for more researchers can be found on RGC website.

Other Researcher 1 - Name		Department
Campus Address (building & room; if none, enter home address)		Current Email
CITI Training completed? (check one) Attach CITI Completion Certificate	____ Yes ____ No	Note: Scores of 80% required on all six modules; individual programs may require additional modules
Rank (check one)	____ NKU Faculty/Staff ____ NKU Student ____ Non-NKU researcher	

Other Researcher 2 - Name		Department
Campus Address (building & room; if none, enter home address)		Current Email
CITI Training completed? (check one) Attach CITI Completion Certificate	____ Yes ____ No	Note: Scores of 80% required on all six modules; individual programs may require additional modules
Rank (check one)	____ NKU Faculty/Staff ____ NKU Student ____ Non-NKU researcher	

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