

11-28-2022

An Educational Module Explaining The Effect of Cryotherapy on Post-Operative Opioid Consumption Following Orthopedic Surgery: A Quality Improvement Project

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An Educational Module Explaining The Effect of Cryotherapy on Post-Operative Opioid Consumption Following Orthopedic Surgery: A Quality Improvement Project

A DNP Project Presented to the Faculty of the
Nicole Wertheim College of Nursing and Health Sciences

Florida International University


In partial fulfillment of the requirements
For the Degree of Doctor of Nursing Practice

By

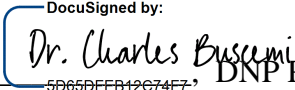
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Abstract

Background: The opioid crisis has stemmed from the undertreatment of pain. This inadequacy has led to increased use of opioids and a rapid rise in opioid-related fatalities. Opioids are used extensively in the perioperative period because of their beneficial pain-relieving and conscious-altering properties. Patients are often sent home with prescriptions for these habit-forming medications, leading to tolerance, addiction, and potential overdoses. This is especially true for very painful procedures, such as orthopedics. As a result, healthcare providers are at the forefront of making a change in the trajectory of the opioid crisis. One method is to find safe and effective non-opioid modalities to control postoperative pain. One such modality is the use of cryotherapy.

Methods: A comprehensive search was conducted using Google Scholar and PubMed databases to find research articles within the last 6 years on the effects of cryotherapy on postoperative opioid consumption following orthopedic surgery.

Results: Five research articles were selected for review. The articles investigated the effect of cryotherapy on postoperative opioid consumption in orthopedic surgery patients. It was shown that cryotherapy reduces postoperative opioid consumption following orthopedic surgery.

Keywords: Cryotherapy, postoperative opioid consumption, postoperative pain, orthopedic surgery

An Educational Module Explaining The Effect of Cryotherapy on Postoperative Opioid Consumption In Orthopedic Surgery: A Quality Improvement Project.

The United States is engaged in one of the most alarming public health crises to date. From the turn of the century to 2017, opioid-related deaths have increased from 0.3 to 9 per 100,000 people.¹ In 2020, that rate has soared to 17.8 per 100,000 people.² Although the origin is multi-factorial, healthcare and the over-prescription of opioids have been to blame. As the incidence of pain rises, patients are demanding quick fixes to resolve health problems instantaneously. The fast action and efficacy of opioids have led to increased prescriptions and opioid drug use.³ Most opioid abusers begin their addiction from prescription medications, some of which resulting from chronic pain after surgical procedures.⁴ Each time a patient refills an opioid prescription after surgery, there is a 44% increase in the rate of opioid misuse.⁵

Opioids are used extensively in the perioperative surgical period because of their ability to induce hypnotic states, blunt hemodynamic responses to surgical stress, and provide pain relief.⁶ Untreated acute pain can result in delirium, poor wound healing, longer hospital stays, increased cost, and the development of chronic pain, resulting in more opioid use.⁷ A vicious cycle occurs, leading to further opioid addiction and a rise in opioid-related deaths.

Background

In the 1990s, undertreated chronic pain became a mainstay in United States medicine due to growing patient expectations of fast and complete pain relief. Additionally, the aging population, improved survival rates of injuries and illnesses, and the increased frequency and complexity of surgery have contributed to the growing number of those living with chronic pain.³ Historically, the less frequently encountered chronic pain patient was referred to cognitive behavioral therapy. When insurance became less inclined to cover such treatments, the demand for pain-relieving medications led to an explosion in the financially driven pharmaceutical

market, resulting in opioids becoming commonplace in medicine.³ The efficacy of opioids and a saturated market have led to an easily accessible opioid supply causing tolerance, addiction, and overdose-related fatalities.

The opioid crisis has been difficult to curb because it is multi-factorial and is constantly evolving, but when used appropriately, the therapeutic effect of opioids is indeed beneficial.⁸ The increase in opioid use stems from the undertreatment of acute pain. As pain remains inadequately treated, chronic pain develops, and more prescriptions are written. As a result, more individuals are exposed to opioids, leading to dependence and addictions.⁸ Despite the high number of opioids prescribed to treat chronic pain, patient outcomes remain poor. Long-term opioids used to treat chronic pain can lead to a decreased quality of life, compromised mental and physical function, and lower return to work rates while still not adequately treating pain. The lack of pain management from opioids for chronic pain sufferers leads to centralized pain syndromes and neuropathic pain, resulting in more opioid prescriptions.⁹ Even when prescriptions end, a saturated market has led to the use of easily accessible illicit opioids.¹⁰

In the perioperative setting, opioids have become the mainstay treatment of the fifth vital sign: pain. Intraoperatively, their high efficacy and fast onset make them ideal adjuncts for pain control. High doses of opioids with long-lasting effects are often prescribed in the postoperative setting for temporary pain. The repeated use of these opioids suppresses the production of endogenous opioids, leading to physiologic dependence.⁴

Opioids induce their pain-eliminating effect on mu-opioid receptors. These receptors reside in brainstem neurons that are also responsible for controlling breathing.¹¹ As opioids are repeatedly administered, a physiologic tolerance develops, requiring an increase in dosing to achieve an equal analgesic effect. As dosing increases, so do the adverse effects, including

respiratory depression.⁸ In non-medical settings that lack trained personnel and anecdotes, it can be fatal. Therefore, a solution needs to be found in which pain is adequately controlled while reducing the need for opioids.

Scope of the Problem

Even though the United States comprises about 5% of the world's population, it is responsible for roughly 80% of its opioid consumption.⁴ In 2016, 42,000 deaths were opioid-related.¹⁰ According to the Centers for Disease Control and Prevention (CDC), that number rose to almost 92,000 in 2020.² The rapid and severe rise of opioid-related deaths led to an announcement from the United States National Safety Council that a person is more likely to die from an opioid overdose than a vehicle crash. This elevates opioid overdose to the fifth most common cause of death.¹² The absence of a solution will result in a continued surge in these alarming statistics.

Although opioid use was historically limited to Caucasian males, it now spans multiple patient demographics and socioeconomic populations. Opioid use is rising in low socioeconomic areas, middle-class communities, and counties dominated by manufacturing and service industries.³ At times, the lack of community resources leads to opioids as the remedy for pain.

Additionally, opioids are being utilized throughout the entire lifespan. The prevalence of neonates diagnosed with neonatal abstinence syndrome is rapidly increasing as the number of pregnant women filling opioid prescriptions rises.⁴ Teenagers and young adults participating in competitive sports are being prescribed opioids for sports-related injuries.⁴ As life expectancy lengthens, the rising prevalence of neuromuscular and autoimmune disorders in the aging population increases opioid use in this patient demographic.³ As more patient populations are exposed to opioids, the consequences of this crisis will continue to grow.

Consequences of the Problem

As more individuals become exposed to opioids, the incidence of tolerance, dependence, addiction, and opioid-related deaths will continue to escalate. From 1999-2013, the average rate of rise in opioid-related deaths was 8% per year. Since then, opioid-related deaths have increased by an average of 71% per year.¹ This includes an increase of 56% from 2019 to 2020.² Without action, this number will continue to climb annually.

In addition to fatalities, opioid use leads to other health problems, including hyperalgesia, pneumonia, ileus formation, as well as infection and cancer progression from a weakened immune response.⁴ Studies have shown that opioid-related health problems, especially postoperatively, lead to prolonged hospital stays and increased costs. Additionally, the risk of hospital readmission rises by almost 40%, and the risk of inpatient mortality increases 3.4-fold in postoperative patients with opioid-related health problems.¹³ Opioid-related morbidity and mortality are surging from a potentially rectifiable problem.

Knowledge Gaps

One knowledge gap is genetics' role in the effects of opioids in individual patients. Pharmacogenetics is a new field of research that studies how an individual's genetic makeup affects the action of opioids and can potentially predict the risk of opioid addiction. Whereas some patients' genetics may require more opioids, others may need less.¹⁴ Since opioids are often prescribed systematically, a better understanding of how a patient may react to opioids could help tailor pain management individually, reducing the risk of opioid addiction.

A second potential knowledge gap is the identification of risk factors that may predict the likelihood of opioid abuse. Some literature states that long-term opioid use postoperatively is independent of previous opioid use.¹⁵ More recent studies contradict this claim, showing that

patients who used opioids before surgery were less likely to take opioids 90 days after surgery than opioid naïve patients.¹⁶ Therefore, further research should focus on specific patient factors that may predict potential opioid misuse. This information can help anesthesia professionals tailor anesthetic to those who may be prone to opioid abuse.

Proposal Solution

Curbing the opioid crisis cannot be done without addressing the pain needs of surgical patients. Surgeons and anesthesia providers are in prominent positions to reduce opioid use while adequately treating pain. Although a more conservative approach to opioid prescriptions is beneficial, there is a need for safer and more effective nonopioid treatments.¹¹

With the understanding that curbing the opioid crisis will take interventions from multiple fronts, the proposed solution attempts to reduce the number of opioids used and prescribed throughout the perioperative setting. Finding safe and effective nonopioid methods to reduce pain will help decrease the number of opioids with which patients are leaving hospitals. This is especially true for excruciating procedures and those that have been shown to require more opioids than others. One area of research is cryotherapy's effect on postoperative opioid consumption compared to traditional opioid modalities in orthopedic surgery patients. The efficacy of cryotherapy could help decrease the number of prescription opioids being used postoperatively, curbing addiction and reducing opioid-related fatalities.

Rationale

In the United States, about 51 million people undergo an elective inpatient surgical procedure annually, and over 80% of them are prescribed opioids postoperatively.¹⁵ Long-term opioid use can be triggered by opioids prescribed during the perioperative period and could be surgery specific. It was shown that two of the procedures most associated with long-term opioid

use were orthopedic procedures: total knee and total hip arthroplasties.¹⁵ Long-term opioid use postoperatively may be independent of past opioid use. Opioid-tolerant patients require higher dosing and more prescriptions, whereas opioid naïve patients can become addicted to the pain relief that accompanies new prescription opioids. In each scenario, surgical pain needs to be addressed. Surgeons and anesthesia providers are in a challenging position to balance two critical clinical scenarios: the need to adequately treat acute surgical pain and the prevention of excessive opioid use postoperatively.¹⁵

Literature Review

This literature review aims to investigate established research on the effect of cryotherapy on postoperative opioid consumption in orthopedic surgery patients. The type of cryotherapy modality is not distinguished nor compared in this review. The literature search was conducted using the following PICO components:

Population (P): Patients undergoing orthopedic surgery

Intervention (I): The use of cryotherapy

Comparison (C): Traditional opioid modalities

Outcomes (O): Postoperative opioid consumption

Eligibility Criteria

The research articles included in this literature review were subjected to inclusion criteria to ensure the reliability of the evidence presented. Articles chosen must have been published within the last 6 years, written in English, and had full-text availability. Exclusion criteria included research regarding the pediatric patient population, the comparison of different cryotherapy modalities, and the comparison of cryotherapy to other pain-relieving methods other

than opioids. The studies chosen were believed to have met the objective of this literature review.

Information Sources

Research studies were found with the use of Google Scholar and PubMed databases. Keywords and appropriate Boolean operators were used to find articles with which to apply the inclusion and exclusion criteria. Database sources used for research and full-text articles were accessed through the Florida International University (FIU) library web portal services.

Search Strategy

Using keywords and Boolean operators led to a search that included: cryotherapy AND postoperative opioid consumption, OR postoperative opioid consumption AND orthopedic surgery. After implementing filters to find the highest level of evidence that met the inclusion criteria, PubMed returned 50 research articles. Using the same keywords, Boolean operators, and filters, Google Scholar returned 344 studies for 394 research articles. The results were imported into the reference program Endnote. Duplicate reports were removed, and papers were filtered based on title to find studies that matched the objective of this literature review.

The titles of 17 articles were approved for a review of the abstract. Investigation of the abstract resulted in the full-text analysis of 12 reports. Studies that were removed included pediatric patient populations, the comparison of different cryotherapy modalities, and comparison to other nonopioid pain-relieving modalities, such as peripheral nerve blocks and intra-articular injections of local anesthetics. This process resulted in five articles for literature review.

Results

Study Characteristics

All of the articles investigated for this literature review analyzed the effects of cryotherapy on postoperative opioid consumption in patients undergoing orthopedic surgery (Appendix A). Three studies were randomized controlled trials¹⁷⁻¹⁹ and two were systematic reviews.^{20,21} Two randomized controlled trials were non-blinded, whereas one was blinded. All three compared postoperative pain and opioid consumption between a cryotherapy group and a control group. The two systematic reviews focused on research that investigated the use of nonopioid modalities to combat postoperative pain.

Results of Individual Studies

Brouwers et al.¹⁷ used a non-blinded randomized controlled trial to investigate whether the use of cryotherapy reduced pain and opioid consumption after orthopedic surgery. A total of 102 patients were divided into two groups: one group received cryotherapy for the first 7 days postoperatively, while the control group did not. Patients in the cryotherapy group were given the same cryotherapy system to use in the hospital and at home with a schedule to follow. The primary outcomes of pain and postoperative opioid use were assessed daily during the first week, and at 2 and 6 weeks postoperatively. In this study, oxycodone was prescribed for needed analgesia.

It was shown that the cryotherapy group reported less pain and consumed less opioid medication during the first week postoperatively than the control group. Twenty-one percent of patients in the cryotherapy group required breakthrough analgesia with oxycodone compared to 40% of the control group.¹⁷ The cryotherapy group needed 47 oxycodone pills during the first week to combat breakthrough analgesia, whereas 97 oxycodone pills were used in the control

group. Cryotherapy resulted in a 48% reduction in postoperative opioid consumption during the first week.¹⁷ The study also showed that although reported pain levels were less in the cryotherapy group at 2 and 6 weeks postoperatively, they were not considered statistically significant.

This study was a randomized controlled trial, providing level I evidence. However, there were limitations. The most significant limitation was that self-reporting pain scores and opioid consumption following the first week could cause some results to be inaccurate and potentially unreliable. Additionally, if cryotherapy schedules were not followed precisely, it could have led to different outcomes. Finally, a placebo effect could alter the results since the trial was not blinded.¹⁷

A similar non-blinded randomized controlled trial was performed by Kuyucu et al.¹⁸ that involved 60 patients undergoing total knee arthroplasty randomly assigned to the cryotherapy group or the control group. For 27 patients, cryotherapy was performed 2 hours preoperatively, 6 hours postoperatively, and then 2 hours every day for the first 4 postoperative days. The other 33 patients did not receive cryotherapy. All patients were operated on by the same surgeon using the same surgical technique. The average pain score in the first postoperative week in the control group was 3.4 on a 10-point scale compared to 2.7 in the cryotherapy group. This resulted in fewer postoperative analgesics consumed by the cryotherapy group.¹⁸ The major limitation of this level I evidence was the small sample size. Additionally, more patients in the control group could affect the average pain score reported. Finally, reporting pain scores is a subjective measurement, which can be altered based on each patient's perception of pain and pain tolerance levels.

A secondary outcome used The Knee Society Scoring System (KSS) to evaluate pain, range of motion, and operative knee stability. It was found that the cryotherapy group scored higher on the KSS, indicating less pain, greater range of motion, and more stability than the control group.¹⁸ Although not wholly aligned with the objective of this review, this study indicates a potential area of further research regarding the use of cryotherapy in orthopedic surgery.

The final randomized controlled trial performed by Thijs et al.¹⁹ was double-blinded and investigated the pain scale rating and opioid consumption of patients undergoing total knee arthroplasty. Sixty patients were randomly divided into a cryotherapy group and a control group. Third-party medical staff performed the therapy, ensuring that researchers remained blinded. The 30 patients in the control group were connected to the cryotherapy apparatus but received treatment at 21 degrees Celsius as opposed to cryotherapy at 10-12 degrees Celsius. Therapy was given on a fixed schedule for the first 7 postoperative days. The same surgeon performed the procedure using the same surgical technique and closure. All patients received the same perioperative care except for the cryotherapy itself. Additionally, all patients were prescribed the same rehabilitation schedule. The narcotic used for breakthrough pain in the study was Tramadol.

The cryotherapy group reported a lower pain score postoperatively during the first 7 days than the control group. Their pain was also assessed before and after each cryotherapy treatment. Although both groups reported a decrease in pain after each treatment, it was only statistically significant in the cryotherapy group. Over the first postoperative week, the cryotherapy group consumed 2,350 milligrams (mg) of Tramadol for breakthrough pain compared to 4,150 mg in the control group.¹⁹ Cryotherapy decreased postoperative opioid consumption by almost 57%.

The small sample size was a limitation to this study, and outside factors could influence the self-reporting of pain scores, which the authors stated. However, the objective use of the number of opioids consumed may help reduce this limitation.

Chughtai et al.²⁰ performed a systematic review to investigate nonpharmacologic pain management following orthopedic surgery. The authors used PubMed, EBSCO Host, and SCOPUS literature search and included 52 articles in the study. Based on the research, the authors concluded that cryotherapy lowers pain scores and decreases postoperative opioid consumption following orthopedic surgery compared to control groups.²⁰ Although the articles referenced are more than 6 years old, the results presented correlate with more recent research. The authors state that the submitted evidence supports cryotherapy use in the perioperative period as a nonpharmacologic modality to decrease pain and limit postoperative opioid consumption.²⁰ Articles presented that contradicted this stance were believed to have significant flaws in study design, substantial limitations, or obvious bias.

Ni et al.²¹ performed a systematic review based on evidence found from a literature search using the Cochrane Library, MEDLINE, and Embase. Using relevant keywords, the authors sought randomized controlled trials comparing cryotherapy to a control group and the effects on pain and opioid consumption post-total knee arthroplasty. After exclusion criteria were implemented, 12 articles were included in the review. The authors found that cryotherapy has been shown to lower pain scores on postoperative day two and decrease the number of analgesics necessary during the postoperative period.²¹ However, differences in pain scores on postoperative day 1 were non-significant. This could be a result of the lingering effects of anesthesia modalities. According to the authors, more randomized controlled trials are needed.

Literature Review Discussion

Summary of the Evidence

The pathophysiology behind cryotherapy and its pain-limiting effects is not fully understood but is believed to have multiple mechanisms. Applying cold to the tissues lowers the temperature, causing vasoconstriction, which decreases blood flow. This decrease in blood flow reduces the inflammatory response to injury, decreasing swelling and pain sensation.¹⁷ The reduction in temperature also reduces nerve conduction velocity, decreasing pain sensed by the body.¹⁸ Finally, cooling the synovial fluid may reduce prostaglandins, which are pain mediators, limiting pain.²⁰ As a result, cryotherapy attacks pain from many angles, making it a multi-modal intervention and increasing its efficacy.

The evidence suggests that cryotherapy in the postoperative setting reduces opioid consumption following orthopedic surgery. Compared to control groups, patients undergoing cryotherapy have been shown to have less pain and consume significantly fewer opioids. It was demonstrated that cryotherapy could decrease the number of patients requiring breakthrough analgesia and reduce postoperative opioid consumption by up to 57%.¹⁹ Additionally, fewer opioids help to reduce adverse effects, including nausea, vomiting, constipation, and respiratory depression.¹⁷ Less pain also results in greater patient satisfaction, decreased length of hospital stay, and decreased cost.³ Further research can explore the effect of cryotherapy on postoperative range of motion, stability, daily function, and physical therapy.

Literature Review Conclusion

Curbing the opioid crisis will require using effective and opioid-free pain modalities. One area of research is cryotherapy's effect on postoperative opioid consumption compared to

traditional opioid modalities in patients undergoing orthopedic surgery. Cryotherapy has been shown to decrease pain and reduce the number of opioids consumed postoperatively. As a result, cryotherapy should be considered a standard pain modality to curb the opioid crisis.

Primary DNP Project Goal

With the understanding that curbing the opioid crisis will take interventions from multiple fronts, the proposed solution attempts to reduce the number of opioids used and prescribed throughout the perioperative setting. Finding safe and effective alternatives to pain management may result in increased quality of life, less exposure to opioids, and less opioid abuse and overdoses.¹⁶ This is especially true for excruciating procedures and those that have been shown to require more opioids than others.

The primary goal was to improve the knowledge of Certified Registered Nurse Anesthetists (CRNAs) on cryotherapy in orthopedic surgery patients to decrease postoperative opioid consumption. The objective was to examine traditional postoperative pain management with the use of opioids and replace them with evidence-based interventions to reduce opioid consumption. The efficacy of cryotherapy could help decrease the number of prescription opioids being used postoperatively, curbing addiction and decreasing opioid-related fatalities.

SMART Goals and Outcomes

Specific

CRNAs would understand evidence-based interventions for cryotherapy during the perioperative period for patients undergoing orthopedic surgery.

Measurable

The effectiveness of these interventions would be measured by analysis of a questionnaire provided to participants before and after an educational intervention. The

knowledge of participants regarding the opioid crisis, opioids, postoperative pain management, and cryotherapy would be assessed pre-and post-intervention. The goal was to increase knowledge after the intervention compared to before.

Achievable

CRNAs would have advanced knowledge to collaborate on developing guidelines to include cryotherapy during the perioperative period.

Realistic

CRNAs would be educated on the advantages of using cryotherapy during the perioperative period. Providing education on cryotherapy is a realistic proposition as pain control and opioid administration are highly prevalent in the perioperative setting. Even though healthcare professionals work different schedules and variable hours, online educational modules make education realistic in that perioperative personnel can partake in the education, regardless of schedule.

Timely

The outcome of this initiative would be the increased knowledge of cryotherapy use in the perioperative period and the development of guidelines for cryotherapy to be included in perioperative pain management. As a questionnaire was provided immediately after the educational intervention, evaluation of an increase in knowledge regarding cryotherapy was time-efficient.

Program Structure

The successful use of cryotherapy during the perioperative period would require a collaborative effort from multiple disciplines. An assessment was performed to identify the stakeholders and the value of this project. An analysis of the project's strengths, weaknesses,

opportunities, and threats would be utilized to evaluate the characteristics of the program's development.

The first step of the assessment was to identify critical stakeholders that this project affects. A stakeholder is a person or group with an interest or a concern in an organization or a project. Stakeholders include patients, providers, insurance companies, organization donors, and research committees in healthcare.²² With stakeholders identified, participants were presented with a questionnaire to gauge the current knowledge level regarding the opioid crisis, opioids, postoperative pain management, and cryotherapy. An educational intervention was performed for perioperative providers addressing the importance of nonopioid pain management postoperatively and how cryotherapy can decrease the number of opioids being consumed. After the intervention, the same questionnaire was provided to compare the knowledge difference before and after the educational intervention. Finally, the likelihood that each provider will adopt cryotherapy in their practice was gauged.

Strengths

This project's strength was providing patients with evidence-based care to improve outcomes. Decreasing postoperative pain while reducing the number of opioids consumed provides a healthier experience for the patient while avoiding potential detrimental events from the overuse of opioid pain medications. Improved patient outcomes offer part of an excellent patient experience, which increases the likelihood of new patient referrals. This helps build an organization's reputation that is attractive to current stakeholders.

A second strength was that the organization of interest advertises the use of technology, research, and academics to provide comprehensive orthopedic care. Using evidence-based practice to improve patient care would fit this self-prescribed culture. Introducing a program and

intervention that requires collaborative, multidisciplinary care would support this organization's advertisement.

Weakness

The major weakness of this project was the organization's requirement to acquire the necessary technology to implement cryotherapy. Implementing this nonopioid pain management intervention costs the organization for the equipment, training, and personnel needed to execute this treatment successfully. How the decreased administration of opioids would balance this in the postoperative period would remain to be seen.

A second weakness was the literature claiming that cryotherapy does not decrease opioid consumption postoperatively. Chughtai et al.²⁰ stated that these contradictions were flawed research designs and noncompliance with the prescribed regimen. For outpatient procedures, using resources on a technology that may not be used correctly could be viewed as a weakness by stakeholders. However, improved education to perioperative personnel and patients strives to improve compliance.

Opportunities

The opportunity for this project was for standardized use of cryotherapy during the perioperative period. Standardization will prevent confusion from differences in surgeon preference and alterations in nursing compliance. As a result, patients are provided the pain management care needed to improve outcomes after surgery.

Secondly, the use of cryotherapy could offer the opportunity to decrease opioid administration during the postoperative period. This can reduce the risk of adverse events during recovery and result in faster discharge home or to the surgical floor. Long term, the fewer opioids that are being prescribed reduce the risk of the development of tolerance and addiction.

Threats

The primary threat to this project was the lack of support from surgeons, anesthesia personnel, and nurses. Compliance will not be consistent without a collaborative effort to implement this intervention and adverse patient outcomes can occur. Additionally, a lack of investment may result in nurses not providing proper education to patients upon discharge regarding usage. An absence of patient and caregiver understanding will also result in decreased compliance, increased pain, and adverse patient outcomes.

Organizational Factors

As this intervention affects multiple healthcare disciplines, input from all of them will help determine the effectiveness of the treatment and any changes that need to be made. Each domain participating in the planning and evaluation will help increase support. Improved awareness regarding the success of cryotherapy can lead to standardized protocols. Once guidelines are in place, their effectiveness will need to be evaluated. Opioid consumption will be monitored and compared to previous patients who received the same surgery to analyze differences. At this time, feedback from the different disciplines regarding effectiveness, ease of use, and necessary changes will be evaluated. This feedback will be used to improve the project in the hope of continued positive patient outcomes.

Theoretical Framework

Theories provide a framework that is useful in practice and can offer questions to study through research. Middle-range theories are believed to be more suited for guiding research as they tend to be more specific and applicable to practice.²³ A combination of two middle-range theories served as the framework for the investigation to support these education interventions.

The theory of comfort describes patients' holistic care as more than just controlling pain. It includes physiological comfort, as well as mental, social, and environmental comfort. Outcomes of this particular theory include decreased pain, fewer readmissions, increased patient satisfaction, and improved psychological health.²³ Successful care of a patient goes beyond the immediate recovery period.

The second middle range theory was the theory of health-related quality of life. Although at times broad and confusing, it has been recognized that quality of life is multidimensional and includes physiological, psychological, and sociological domains.²³ Similar to the theory of comfort, the theory of health-related quality of life acknowledges the need to care for and protect the mental aspect of a patient's health. The inability to control pain and the resulting tolerance and addiction that may come from opioid use decreases patients' quality of life.

Methodology

Setting and Participants

The project included an online educational intervention provided to perioperative healthcare professionals. The participants were CRNAs who have graduated from FIU's nurse anesthesia program. These participants were chosen because providing interventions to control pain during the perioperative period is relevant to the education provided. Improved education on pain-controlling modalities can improve health care practice and result in positive patient outcomes.

As the schedules of healthcare professionals can be non-conducive to events at specific times and places, an online educational module was established for learning to occur at the provider's convenience. This helped to ensure that more professionals could partake in this

educational experience. Relevant education materials were provided to enhance the learning of these professionals.

Project Procedures

Before the project could move to the participants, approval from the FIU faculty had to be obtained (Appendix B). Next, permission must have been granted from the Internal Review Board (IRB) for the project to be launched (Appendices C & D). These approvals ensured that the project was ethical and participants' rights were protected.

Once approvals were received, CRNAs were recruited via personal e-mail to participate in the project, and informed consent was signed (Appendices E & F). Participants then completed a questionnaire regarding current knowledge related to the opioid crisis, effects of opioids, cryotherapy, and postoperative pain management. This questionnaire provided a baseline to compare the knowledge gained from the education intervention (Appendix G). Once the initial questionnaire was finished, an education module was completed. The education module presented information regarding the importance and relevance of the opioid crisis, the physiology of cryotherapy, and the effect that cryotherapy has been shown to have on postoperative opioid consumption (Appendix H). Additionally, conclusions were drawn regarding the importance of the literature and the impact that cryotherapy can have on the opioid crisis. Upon completion of the education module, the same questionnaire was completed again, and the scores were compared. It was hypothesized that scores would increase after participation in the module.

Protection of Human Subjects

Participants were informed of the project's purpose, the estimated time required, and that participation was optional. Additionally, questionnaires remained anonymous, so there was no

method to track answers back to the participant. Basic demographic information was asked for, such as gender, age, and the number of years of service, but these were optional. It was also shared that the project results would be displayed, and conclusions would be drawn based on the answers provided. Finally, questions were asked regarding the potential for practice changes or interest in further research from the participants to gauge the impact the education may have had on future practice. Consents for participation were signed electronically to ensure that all participants agreed that they had been adequately informed regarding their part of the project.

Data

Data were collected electronically via the Qualtrics system. The questionnaires were graded for accuracy pre-and post-education intervention. The scores were then compared to see if knowledge was gained from the education module. The data were analyzed to investigate whether practitioners would contemplate changing their current practice.

Discussion

The questionnaires showed if the educational intervention improved awareness and knowledge regarding cryotherapy. It also demonstrated how healthcare professionals can impact the postoperative patient experience and the opioid crisis. Improved knowledge and understanding can result in increased enthusiasm to use nonopioid pain management modalities to reduce the number of opioids being consumed in the postoperative setting.

One of the biggest obstacles to the regular use of cryotherapy in the perioperative setting is the support from perioperative healthcare professionals. Providing education and increasing knowledge can help trigger support to improve the patient experience and positively impact the opioid crisis. Improved support was assessed by practitioners claiming to contemplate changing their practice or a desire to pursue further information regarding the effects of cryotherapy.

Gaining the support of perioperative healthcare professionals can help guide future perioperative care toward using nonopioid pain-controlling modalities such as cryotherapy.

Timeline

This project took place over 5 months. Two months were dedicated to developing the questionnaire and educational intervention. This process included testing the questionnaire, education module, and data collection while receiving FIU faculty and IRB approval to launch the project. The education module was then available for access and completion over 1 month. After this month, an additional 2 months was allotted for data collection, analysis, and project write-up. After 5 months, it was apparent whether awareness and knowledge were increased regarding the use of cryotherapy for pain management and if there was increased support for its use during the perioperative period.

Results

Upon FIU faculty and IRB approval of the questionnaire and education module, the Qualtrics surveys were sent to the personal e-mails of a predetermined group of FIU CRNA faculty and alumni. The participants were given 2 weeks to complete the surveys when a reminder e-mail was sent to the same group of participants. A second reminder e-mail was sent after another week, and the survey was closed a week later. After 4 weeks of the study being available, there were 7 total participants. The pretest and posttest surveys were compared for accuracy to determine if learning occurred in response to the education module (Appendices I, J and K).

Four of the 7 participants were female, while 3 identified as male. Five participants were doctoral-prepared CRNAs, while 2 had completed their master's degrees. Years of anesthesia

experience were even, with 3 CRNAs practicing for 1-5 years and another 3 practicing for longer than 10 years. Only 1 participant had between 6-10 years of experience.

Of the 10 total questions included in the pretest and posttest questionnaires, 9 questions were analyzed for accuracy. One question helped determine if cryotherapy would be used in the participants' practice. Of the 9 questions explored, the percentage of correct answers from the pretest to the posttest increased with 8 questions. The most significant change was 1 question with 0 correct answers on the pretest to 6 participants answering correctly on the posttest. The smallest change from pretest to posttest was 1 additional participant responded correctly on the posttest for 3 of the 8 questions. For 2 of the 8 questions, every participant answered correctly on the posttest. In an evaluation of the likelihood of participants using cryotherapy in their practice, 3 participants claimed they would be somewhat or extremely likely on the posttest compared to just 2 on the pretest.

One question had full participation on the pretest, but only 1 participant answered the question on the posttest. It is unclear whether this question was intentionally or unintentionally neglected or if a technical issue prevented 6 participants from answering the question. Of the 7 participants who responded to the pretest, only 1 answered correctly. The 1 answer on the posttest was incorrect, decreasing the number correct on the posttest from the pretest.

Discussion

Of the 9 questions analyzed for accuracy, 8 had an increase in the number of participants who offered correct answers on the posttest compared to the pretest. Improved scores on the posttest indicate that learning occurred as a result of the education module. The education module raised awareness about the extent of the opioid crisis and the use of cryotherapy to decrease postoperative opioid consumption in orthopedic surgery. Compared to the pretest, the

posttest indicated that one additional practitioner would be somewhat or highly likely to utilize cryotherapy for orthopedic surgery patients. This showed growing support for the use of cryotherapy. An increased willingness to utilize cryotherapy can help decrease the number of opioids being used postoperatively, helping curb the opioid crisis and prevent opioid-related complications.

Strengths of this project included anonymous answers and the ability of CRNAs to complete the module at their convenience. Healthcare providers' schedules are not always conducive to learning at one time and place. The design of this project eliminated that potential issue. Additionally, the inherent risk of completing the project was no more than any usual work being performed on a computer, phone, or tablet.

Potential limitations of the project included technical issues that could arise or participants that clicked through answers without viewing the education module. Similarly, there was no way to monitor whether participants view the entire education module. This practice could have affected the conclusions drawn from the results. To minimize limitations, a participant could not advance to the posttest without beginning the education module; however, this does not address participants not viewing the entire education module before answering posttest questions.

Implications for Advanced Nursing Practice

The literature confirms that cryotherapy reduces postoperative opioid consumption in orthopedic surgery. The results of this project indicate that improved education and increased awareness regarding cryotherapy will increase the number of practitioners willing to use this opioid-sparing technique for controlling pain. The fewer opioids necessary for pain control can decrease the number of opioids patients are being prescribed for postoperative pain. This can

help reduce addictions and curb the opioid crisis. As a result, cryotherapy could become a standard nonopioid technique for pain control in orthopedic surgery, allowing advanced nursing practitioners to help control pain while reducing the number of opioids being prescribed.

Conclusion

The results of this project indicate that learning occurred regarding the effect of cryotherapy on postoperative opioid consumption in orthopedic surgery. They also suggest an increase in awareness regarding the use of cryotherapy and an increase in the willingness of CRNAs to utilize cryotherapy to help control pain. Literature has proven that cryotherapy can reduce postoperative opioid consumption in orthopedic surgery. Reducing the number of opioids consumed in the postoperative period can reduce opioid-related complications while adequately controlling pain. With fewer patients leaving hospitals with opioids, a decrease in addictions would be expected, helping to curb the lethal opioid crisis that consumes society.

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Appendix A

Literature Review Table

Authors	Purpose	Method	Design	Sample/Setting	Results	Conclusions
Brouwers HFG, de Vries AJ, van Zuilen M, van Kouswijk HW, Brouwer RW. The role of computer-assisted cryotherapy in the postoperative treatment after total knee arthroplasty: positive effects on pain and opioid consumption. <i>Knee Surgery, Sports Traumatology, Arthroscopy</i>. 2021.	To investigate whether cryotherapy is effective in reducing postoperative pain and postoperative opioid consumption following orthopedic surgery.	A single-center non-blinded randomized controlled trial. Level I.	102 patients were divided evenly into 2 groups: a cryotherapy group and a control group. The intervention group received cryotherapy for the first 7 postoperative days. Pain and opioid consumption were assessed daily for the first 7 postoperative days. Their pain was then assessed at 2 weeks and 6 weeks postoperatively.	Performed in one hospital. The sample size was 102 patients, 51 patients in each group.	Patients in the cryotherapy group had lower pain scores and required fewer opioids postoperatively than the control group during the first 7 postoperative days. The cryotherapy group required 48% fewer opioids than the control group. At 2 weeks and 6 weeks postoperatively, pain was less in the cryotherapy group, but not enough to be considered significant.	Cryotherapy can decrease pain levels and opioid consumption during the first postoperative week following orthopedic surgery.

<p>Kuyucu E, Bülbül M, Kara A, Koçyiğit F, Erdil M. Is cold therapy really efficient after knee arthroplasty? <i>Annals of Medicine and Surgery.</i> 2015;4(4):475-478.</p>	<p>To evaluate the effects of cryotherapy after total knee arthroplasty.</p>	<p>A single-center randomized controlled trial. Level I.</p>	<p>60 patients were randomly divided into 2 groups: a cryotherapy group and a control group. The experimental group received cryotherapy 2 hours preoperatively, at 6 hours postoperatively, and then for 2 hours daily for the first 4 postoperative days. Pain and analgesia requirements were monitored.</p>	<p>Performed in one clinic. The sample size was 60 patients. 27 patients received cryotherapy, 33 patients were in the control group.</p>	<p>Patients in the cryotherapy group reported lower pain scores and required less analgesia postoperatively than the control group. Patients also had higher scores using The Knee Society Scoring System (KSS), meaning less pain, greater range of motion, and greater stability in the operative knee.</p>	<p>Cryotherapy can decrease pain levels and the amount of required analgesia during the first 4 days postoperatively following total knee arthroplasty.</p>
<p>Thijs E, Schotanus MGM, Bemelmans YFL, Kort NP. Reduced opiate use after total knee arthroplasty using computer-assisted cryotherapy. <i>Knee Surgery, Sports</i></p>	<p>To investigate the effect of cryotherapy on postoperative pain and opioid consumption following total knee arthroplasty.</p>	<p>A double-blind randomized controlled trial. Level I.</p>	<p>60 patients were randomly placed into 2 groups: a cryotherapy group and a control group. The cryotherapy group received therapy at 10-12</p>	<p>The total number of patients was 60. There were 2 groups of 30 patients each.</p>	<p>The cryotherapy group reported lower pain scores than the control group. The cryotherapy group also consumed almost 57% fewer opioids</p>	<p>Cryotherapy lowered pain scores and significantly decreased the number of opioids required postoperatively compared to the control group.</p>

<p><i>Traumatology, Arthroscopy.</i> 2019;27(4):1204-1212.</p>			<p>degrees Celsius while the control group received therapy at 21 degrees Celsius. A third party provided the therapy to ensure the researchers remained blinded. Pain scores and opioid consumption was monitored for the first 7 postoperative days.</p>		<p>than the control group postoperatively.</p>	
<p>Chughtai M, Elmallah RD, Mistry JB, et al. Nonpharmacologic pain management and muscle strengthening following total knee arthroplasty. <i>J Knee Surg.</i> 2016;29(03):194-200.</p>	<p>To perform a review of the current literature regarding nonpharmacologic pain management following total knee arthroplasty.</p>	<p>Systematic literature review. Level I.</p>	<p>A literature search using PubMed, EBSCO Host, and SCOPUS. Only manuscripts in English were considered. The search was performed using relevant keywords.</p>	<p>863 abstracts were reviewed with 128 studies undergoing a full review. 68 reports were excluded and 18 more additional studies were found from references. A total of 52 research articles</p>	<p>3 of the studies specific to cryotherapy found that this modality reduces pain scores and significantly reduced postoperative opioid consumption. The other 3</p>	<p>The authors concluded that cryotherapy reduces pain levels and decreases opioid consumption postoperatively. Additionally, there seems to be no extra benefit between</p>

				were used for the review. Specifically, 6 research articles were used for review on cryotherapy.	studies compared different cryotherapy modalities and found no significant differences.	different cryotherapy modalities. However, that is beyond the scope of this review.
Ni S-H, Jiang W-T, Guo L, et al. Cryotherapy on postoperative rehabilitation of joint arthroplasty. <i>Knee Surgery, Sports Traumatology, Arthroscopy.</i> 2015;23(11):3354-3361.	To review the literature to determine the effectiveness of cryotherapy following joint arthroplasty.	Systematic literature review. Level I.	401 initial research articles were found. 371 studies were excluded for various reasons. 12 randomized controlled trials were used for this review.	12 randomized controlled trials were used for this review.	It was shown that cryotherapy reduced pain scores and decreased opioid consumption on postop day 2. It showed no difference on the first postoperative day.	Cryotherapy is effective at reducing pain scores and decreasing the number of opioids required on postoperative day 2.

Appendix B
Faculty Support Letter



**Nicole Wertheim College of
Nursing & Health Sciences**

February 2, 2022

Valerie Diaz DNP, CRNA, APRN Clinical
Assistant Professor
Department of Nurse Anesthesiology
Florida International University

Dear Dr. Diaz,

I thank you inquiring on the use of the FIU DNAP alumni list for participation in the Doctor of Nursing Practice (DNP) project conducted by Cody Wilson a entitled "An Educational Module Explaining the Effect of Cryotherapy on Postoperative Opioid Consumption in Orthopedic Surgery: A Quality Improvement Project" in the Nicole Wertheim College of Nursing and Health Sciences, Department of Nurse Anesthetist Practice at Florida International University. I have granted Mr. Wilson permission to conduct the project using our providers.

Evidence-based practice's primary aim is to yield the best outcomes for patients by selecting interventions supported by the evidence. This project intends to evaluate if a structured education targeting anesthesia providers will increase knowledge on the use Effect of Cryotherapy on Postoperative Opioid Consumption in Orthopedic Surgery.

We understand that participation in the study is voluntary and carries no overt risk. All Alumni Anesthesiology providers are free to participate or withdraw from the study at any time. The educational intervention will be conveyed by a 15-minute virtual PowerPoint presentation, with a pretest and posttest questionnaire delivered by a URL link electronically via Qualtrics, an online survey product. Responses to pretest and posttest surveys are not linked to any participant. The collected information is reported as an aggregate, and there is no monetary compensation for participation. All collected material will be kept confidential, stored in a password encrypted digital cloud, and only be accessible to the investigators of this study: Cody Wilson and Dr. Diaz.

Once the Institutional Review Board's approval is achieved, this scholarly project's execution will occur over two weeks. Cody Wilson will behave professionally, follow standards of care. We support the participation of our Anesthesiology providers in this project and look forward to working with you.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Valdes", is written over a light blue horizontal line.

Jorge A. Valdes, DNP, CRNA, APRN
Interim Chair, Department of Nurse Anesthesiology
Associate Professor

Appendix C
IRB Approval Letter



Office of Research Integrity
Research Compliance, MARC 414

Cody Wilson

A handwritten signature in black ink, consisting of the letters "EJ" in a cursive style.

April 7, 2022

**"An Educational Module Explaining the Effect of Cryotherapy on
Postoperative Opioid Consumption in Orthopedic Surgery: A Quality
Improvement Project"**

IRB-22-0139
111411

04/04/22

As a requirement of IRB Exemption you are required to:

- 1) Submit an IRB Exempt Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved prior to implementation.
- 2) Promptly submit an IRB Exempt Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.

discontinued.

or

Special Conditions: N/A

For further information, you may visit the IRB website at <http://research.fiu.edu/irb>

EJ

Appendix D

IRB Approval Detailed Report

Protocol Detail Report

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Report Comments

Protocol Information

Version # 1

Reference Number: 111411

Protocol Number: IRB-22-0139

Protocol Title: An Educational Module Explaining the Effect of Cryotherapy on Postoperative Opioid Consumption in Orthopedic Surgery: A Quality Improvement Project

Protocol Type: Original

Principal Investigator: Diaz, Valerie

Approval Date: 4/4/2022

Submittal Date: 4/4/2022

Effective Date: 4/7/2022

Author: Wilson, Cody

Renewal Date: 4/4/2027

Status: Approved

Next Review Date: 4/4/2027

Inactive Date:

Expiration Date: 4/4/2027

INSTRUCTIONS

1

Completing this IRB Exemption Form

1.1

This IRB Exemption Form is used for obtaining approval for exempt human subject research.

While filling out this form, some questions may have additional information in the blue "?" help icon located on the right of the question.

For additional assistance with completing this form, visit the Office of Research Integrity Topaz website located at:

<http://research.fiu.edu/irb/pages/topaz.html>

Save often by selecting the "Save" icon at the top of this form since the system does not automatically save your progress.

FORM TEMPLATE COMPLIES WITH REVISED COMMON RULE

This IRB Exemption Form template complies with the new IRB regulatory requirements (Revised Common Rule), which went into effect on January 21, 2019.

IMPORTANT: The Department of Justice (DOJ) has not signed onto the Revised Common Rule. If this study will be funded by a DOJ agency, then you cannot use this IRB Exemption Form template. Please contact Chris Grayson at 305-348-8379 or graysonc@fiu.edu to get special access to a different version of the IRB Exemption Form that is based on the Old Common Rule requirements.

ADMINISTRATIVE

2

Reference Number

2.1

This number is system generated.

111411

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Protocol Number 2.2

This number will be assigned after the protocol has been processed.

IRB-22-0139

Relation to Another FIU IRB Approved Study 2.3

Is this a sub-study, which is based off of a larger study (e.g., this study utilizes the data or participants from a larger study)?

Yes

No

Yes

2.3.1

No

2.3.2

Title 2.4

Provide the title of the project.

An Educational Module Explaining the Effect of Cryotherapy on Postoperative Opioid Consumption in Orthopedic Surgery: A Quality Improvement Project

Department 2.5

Select the FIU Principal Investigator's department.

CNHS Nursing Anesthesia

Principal Investigator 2.6

Provide the name of the FIU Principal Investigator (PI).

Students cannot serve as the PI. Courtesy and voluntary faculty members cannot serve as the PI.

Please Note: Undergraduate/Graduate student research projects are required to have an FIU faculty member with Graduate Faculty Status or Dissertation Advisor Status (DAS) serving as the Principal Investigator. Student researchers need to be listed separately in the "Protocol Associates" section below. Exceptions to this policy may be judged appropriate under particular circumstances and those exceptions shall be determined by the Office of Research and Economic Development.

Diaz, Valerie

vdiaz@fiu.edu

ext

Author 2.7

The Author is the person that is completing this application form. This is typically the same person as the Principal Investigator unless another individual is assisting with the completion of the application form (e.g., Project Coordinator).

The Author will be able to access and edit the initial submission as well as all future amendments, renewals, and interim submissions that are associated with this project.

Wilson, Cody

cwils089@fiu.edu

Persons reviewing the information contained herein are reminded of their confidentiality obligations pursuant to the FIU Confidentiality Agreements Policy #1710.070.

Protocol Detail Report

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Protocol Associates 2.8

Add all FIU Co-Investigators and FIU Key Associates that will be *engaged* in this project. Individuals are considered "engaged" if they will be intervening or interacting with human subjects (e.g., consenting subjects, collecting data, etc) and/or accessing coded or identifiable human subject data (e.g., data analysis). See the [OHRP Engagement Guidance](#) or contact the FIU IRB Office (ORI) for more information on whether someone is considered engaged.

Individuals that are designated as Co-Investigators can view and edit this application and will also receive email alerts.

Individuals that are designated as Key Associates cannot view and edit this application, but will receive certain email alerts.

Select the green "+" icon to the right to add the individual(s). Select only one role per person. List the responsibilities for each individual.

Wilson, Cody

Responsibilities Recruiting subjects, consenting subjects, collecting data, administering pre/post-test, data analysis

Comments

Co-Investigator Key Associate

Protocol Associates (Not Requiring TOPAZ Access) 2.9

Add all FIU Co-Investigators and FIU Key Associates that will be *engaged* in this project, but do not need the ability to view/edit the protocol or receive TOPAZ system email notices regarding this protocol.

For the "Role" column, designate if the individual is a Co-PI or Key Associate on the project. For the "Position" column, designate if the individual is a Faculty Member, Staff Member, Undergrad Student, Grad Student, or Post-Doc. "Responsibilities" might include data entry, recruiting subjects, consenting subjects, etc. Click "Add Row" to add each individual.

See the [OHRP Engagement Guidance](#) or contact the FIU IRB Office (ORI) for more information on whether someone is considered engaged.

First Name	Last Name	Role	Position	Department	Email	Panther ID	Responsibilities
------------	-----------	------	----------	------------	-------	------------	------------------

External Protocol Associates 2.10

Indicate if there will be any external (non-FIU) Co-Investigators or Key Associates *engaged* in this project. Individuals are considered "engaged" if they will be intervening or interacting with human subjects (e.g., consenting subjects, collecting data, etc) and/or accessing coded or identifiable human subject data (e.g., data analysis). See the [OHRP Engagement Guidance](#) or contact the FIU IRB Office (ORI) for more information on whether someone is considered engaged.

Yes

No

Yes 2.10.1

No 2.10.2

IRB Educational Training (Attachment) 2.11

Attachments: Diaz CITI Training Certificate.pdf, Cody CITI Training Certificate.pdf

All investigators and key personnel that are engaged in conducting research with human subjects are required to complete the web-based Collaborative Institutional Training Initiative Program (CITI) training in the protection of human research subjects. Indicate below if all of the individuals on this project have completed the required CITI IRB training. See the [IRB Training](#) web page for more information.

[Attach](#) the CITI IRB Training Completion Reports. Click the paper clip icon to the right to upload the documents.

Yes - CITI IRB Training has been completed by all project personnel.

No - CITI IRB Training has not yet been completed by all project personnel.

Persons reviewing the information contained herein are reminded of their confidentiality obligations pursuant to the FIU Confidentiality Agreements Policy #1710.070.

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Yes - CITI IRB Training has been completed by all project personnel.	2.11.1
No - CITI IRB Training has not yet been completed by all project personnel.	2.11.2
Good Clinical Program (GCP) Training (Attachment)	2.12

All researchers that are engaged in conducting one of the following types of research studies are also required to complete online GCP training:

1. NIH funded clinical trial (one or more human subjects are prospectively assigned to one or more interventions, which may include placebo or other control, to evaluate the effects of those interventions on health related biomedical or behavioral outcomes); or
2. FDA regulated clinical trial (involving drugs, devices, or biologics)

Indicate the type of project that you are conducting below. See the [IRB Training](#) web page for more information.

Attach the GCP Training Completion Reports if this study is an NIH or FDA Clinical Trial. Click the paper clip icon to the right to upload the documents.

<input type="checkbox"/> Clinical Trial (NIH Funding)	
<input type="checkbox"/> Clinical Trial (FDA Regulated - Drugs, Devices, or Biologics)	
<input type="checkbox"/> Clinical Trial (No NIH Funding and not FDA Regulated)	
<input checked="" type="checkbox"/> Not Applicable (Not a Clinical Trial)	
Clinical Trial (NIH Funding)	2.12.1
Clinical Trial (FDA Regulated - Drugs, Devices, or Biologics)	2.12.2
Clinical Trial (No NIH Funding and not FDA Regulated)	2.12.3
Not Applicable (Not a Clinical Trial)	2.12.4
Conflict of Interest	2.13

Does anyone on this study team, their spouses, or dependent children have a financial interest (including salary or other payments for services, equity interests, or intellectual property rights) that would reasonably appear to be affected by the research, or a financial interest in any entity whose financial interest would reasonably appear to be affected by the research?

<input type="checkbox"/> Yes	
<input checked="" type="checkbox"/> No	
Yes	2.13.1
No	2.13.2
EXEMPTION REVIEW TYPE	3

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Protocol Detail Report

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Exemption Category Number	3.1
----------------------------------	------------

Indicate the Exemption Category Number(s) that you feel would be appropriate for this protocol. The most commonly used categories are Categories #1, #2, and #4. Final determination will be made by the Office of Research Integrity.

Note: The detailed [Exempt Review Categories](#) Listing is available on the FIU IRB website.

- | | | |
|-------------------------------------|---|--|
| <input type="checkbox"/> | Exemption Category #1 (Educational Practices Research in an Educational Setting) | |
| <input checked="" type="checkbox"/> | Exemption Category #2 (Educational Tests, Survey Procedures, Interview Procedures or Observation of Public Behavior) | |
| <input type="checkbox"/> | Exemption Category #3 (Benign Behavioral Interventions) | |
| <input type="checkbox"/> | Exemption Category #4 (Secondary Research for which Consent is not Required) | |
| <input type="checkbox"/> | Exemption Category #5 (Research and Demonstration Projects with Department or Agency Heads that Study Public Benefit or Service Programs) | |
| <input type="checkbox"/> | Exemption Category #6 (Taste and Food Quality Evaluation and Consumer Acceptance Studies) | |

Exemption Category #1 (Educational Practices Research in an Educational Setting)	3.1.1
--	-------

Exemption Category #2 (Educational Tests, Survey Procedures, Interview Procedures or Observation of Public Behavior)	3.1.2
--	-------

Exemption #2: Educational Tests, Surveys, Interviews, and Observations	3.1.2.1
---	----------------

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording).

Exemption #2: Use of Children in Surveys or Interviews	3.1.2.2
---	----------------

For research proposed under this category, will the research involve surveys or interview procedures with children? If yes, your research will not be eligible for this Exemption category.

- | | | |
|-------------------------------------|-----|--|
| <input type="checkbox"/> | Yes | |
| <input checked="" type="checkbox"/> | No | |

Yes	3.1.2.2.1
-----	-----------

No	3.1.2.2.2
----	-----------

Exemption #2: Use of Children in Observations	3.1.2.3
--	----------------

For research proposed under this category, will the research involve observations of the public behavior of children, during which an investigator participates in the activities being observed? If yes, your research will not be eligible for this Exemption category.

- | | | |
|-------------------------------------|-----|--|
| <input type="checkbox"/> | Yes | |
| <input checked="" type="checkbox"/> | No | |

Yes	3.1.2.3.1
-----	-----------

No	3.1.2.3.2
----	-----------

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Protocol Detail Report

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Exemption #2: Information Obtained	3.1.2.4
---	----------------

For research proposed under this category, one or more of the following criteria will need to be selected in order to be considered for Exemption #2.

Select "2.1" if you will be collecting anonymous data.

Select "2.2" if you will be collecting identifiable (or coded) "non-sensitive" data.

Select "2.3" if you will be collecting identifiable (or coded) "sensitive" data.

Sensitive data are considered as data that could potentially put the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation.

- 2.1 - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects
- 2.2 - Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation
- 2.3 - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects (requires Limited IRB Review)

2.1 - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects	3.1.2.4.1
--	------------------

2.2 - Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation	3.1.2.4.2
---	------------------

2.3 - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained directly or through identifiers linked to the subjects (requires Limited IRB Review)	3.1.2.4.3
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Exemption Category #3 (Benign Behavioral Interventions)	3.1.3
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Exemption Category #4 (Secondary Research for which Consent is not Required)	3.1.4
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Exemption Category #5 (Research and Demonstration Projects with Department or Agency Heads that Study Public Benefit or Service Programs)	3.1.5
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Exemption Category #6 (Taste and Food Quality Evaluation and Consumer Acceptance Studies)	3.1.6
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EXEMPTION REQUIREMENTS	4
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Minimal Risks	4.1
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Will the research expose participants to discomfort or distress beyond that normally encountered in daily life? If yes, your research will not be eligible for Exempt review.

Yes

No

Yes	4.1.1
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No	4.1.2
----	--------------

Protected Health Information (PHI)	4.2
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Will you be accessing or using identifiable protected health information (PHI) from medical records (other than the use of a limited dataset)? If yes, your research will not be eligible for Exempt review.

Note: Studies that involve the access or use of PHI through authorization forms or requests for waivers/alteration of authorization are not eligible for Exempt Review.

For more information, visit the [Privacy Practices and HIPAA](#) web page.

Yes

No

Yes	4.2.1
-----	--------------

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No	4.2.2
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Prisoners	4.3
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Will prisoners (or their data and/or specimens) be participants and examined as a subpopulation in this research study? If yes, your research will not be eligible for Exempt review.

Yes

No

Yes	4.3.1
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No	4.3.2
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Deception	4.4
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Will this study involve deception (i.e., providing false or incomplete information to participants for the purposes of misleading research subjects)? If yes, your research will not be eligible for Exempt review.

Yes

No

Yes	4.4.1
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No	4.4.2
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FDA Regulations	4.5
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For research proposed under Exemption Categories 1-5, is the research subject to FDA regulations? If yes, your research will not be eligible for Exempt review.

Yes

No

Yes	4.5.1
-----	-------

No	4.5.2
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PROJECT OVERVIEW	5
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Project Starting Date	5.1
------------------------------	------------

Provide the date that you are planning to begin the research with human subjects (e.g., date to begin recruitment or access a database). Click the calendar icon below to select your starting date.

Please use a future starting date.

Sunday, May 1, 2022 12:00 AM

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Project Completion Date

5.2

Provide the date that you are planning to finish the research with human subjects (e.g., date that you will be finished with all data analysis). Click the calendar icon below to select your completion date.

Saturday, October 1, 2022 12:00 AM

Funding

5.3

Indicate if funding is (or will be) associated with this project.

- Yes
- No

Yes

5.3.1

No

5.3.2

Student Research Project

5.4

Is this study being conducted in relation to an undergraduate or graduate research project?

Please answer yes to this question if one of the following apply :

1. This protocol submission is for a student research project; or
2. This protocol submission is for a faculty research project, but a student researcher will be conducting a sub-study using coded or identifiable data from this main faculty research project.

- Yes
- No

Yes

5.4.1

Relation of Student Research Project

5.4.1.1

Please select how this protocol submission is related to a student research project.

- This protocol submission is for a student research project
- This protocol submission is for a faculty research project, but a student will be conducting a sub-study with data from the faculty research project

This protocol submission is for a student research project

5.4.1.1.1

This protocol submission is for a faculty research project, but a student will be conducting a sub-study with data from the faculty research project

5.4.1.1.2

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Type of Student Project (Attachment)

5.4.1.2

Select the type of student project that this study falls under.

Attach a copy of the five page UGS proposal if the study is part of a Thesis or Dissertation. Click the paper clip icon to the right to upload your document.

Graduate Research

A study being conducted by a graduate student, but not part of a Thesis or Dissertation.

Student Investigator Details

5.4.1.3

Provide the following details about the primary student investigator that will be conducting the student research project.

First Name	Last Name	Email Address	Phone Number	Panther ID
Cody	Wilson	cwils089@fiu.edu	614-937-6796	1936909

No

5.4.2

Type of Project

5.5

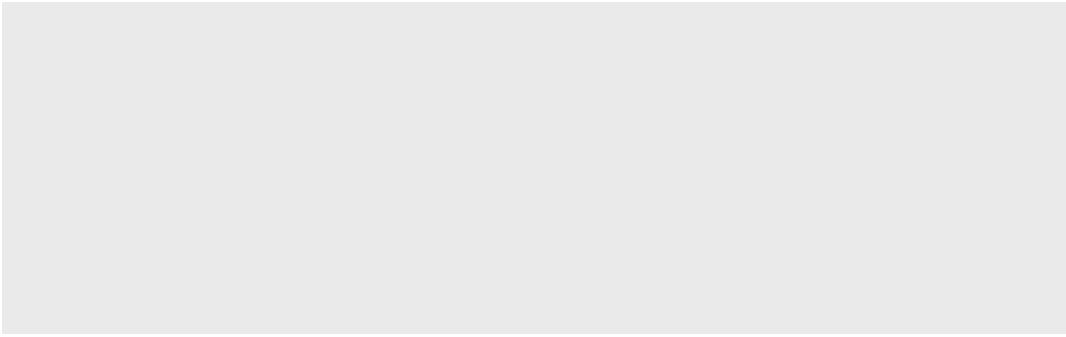
Indicate the type of project you will be conducting by selecting the green "+" icon on the right. Select all that apply for this project.

Data Collection Study

5.5.1

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-
- -
 -



-
- [Redacted]
 - [Redacted]
-



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Domestic Site Details 5.8.1.2

Attachments: Letter of Support.pdf

Provide the details below for each site/location that will be used in the research study. Examples of tasks done at a site might include activities such as recruitment, consenting, data collection, etc.

Note: If the research will take place at FIU, then please list FIU and the Building and Room Number in the Address column (e.g., FIU MARC 430).

Click "add row" for each additional site that you need to add.

Location Name	Address	City	State	Phone Number	Task(s) Done at Site
Florida International University	11200 SW 8th St.	Miami	FL		None. All recruitment, consenting, educational intervention, pre- and post-testing, and data analysis will be done virtually. "NO DATA ANALYSIS WILL BE DONE AT FIU"

International Site (Foreign) 5.8.2

SUBJECT POPULATION 6

Duration of Participation 6.1

Estimate the time required from each participant, including individual interactions, total time commitment, and long-term follow-up, if any.

Participation is expected to span a total of approximately 2 months. The online pre-test and post-test are expected to take 20 minutes. Pre-test 5 minutes, post-test 5 minutes, and educational session 10 minutes.

Number of Participants 6.2

The number of participants is defined as the number of individuals who agree to participate even if all do not prove eligible to complete the study. If datasets are being used, then provide the number of datasets that will be accessed.

Approximately 10.

Gender of Subjects 6.3

Indicate the gender of the subjects.

Both

Age of Subjects 6.4

Select the age range(s) of the subjects. Click the green "+" symbol to the right of the screen to make your selection(s). Select all that apply.

25-59 Years 6.4.1

60+ Years 6.4.2

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Participant Populations 6.5

Specify the participant population(s) to be included. Click the green "+" symbol to the right of the screen to select the populations. Select all that apply.

Adults 6.5.1

Other Populations 6.6

If you chose "Other" in the previous question, please indicate the other population below. Otherwise, put "N/A" for your response.

N/A

SUBJECT RECRUITMENT 7

Identification of Subjects 7.1

Describe how potential participants will be identified (e.g., individuals known to investigator, record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.

Potential participants will be identified via personal email retrieved from an email list supplied by the chair of the department of Nurse Anesthesiology at Florida International University.

The alumni email addresses are the personal commercial emails, not FIU emails, that FIU graduates voluntarily supplied after graduating from the university. Such emails are not the property of FIU and FIU records are not being accessed by the PI and Co-Pi. FERPA regulations are maintained. The email addresses are not linked to names or any personal identifier so that participant anonymity is maintained.

Recruitment/Advertising Process (Attachment) 7.2

Attachments: Recruitment Letter.pdf

Describe the recruitment process; including the setting in which recruitment will take place. Describe the types of advertisements that will be used (e.g., ads, flyers, website postings, recruitment letters, and/or oral written scripts). Explain how the process respects potential participants' privacy.

Attach copies of the proposed recruitment materials. Click the paper clip icon to the right to upload your document(s).

Recruitment Letter will be distributed via personal email where potential participants are blind copied to maintain privacy. See letter attached here.

Participation is anonymous and data are reported as a group. Responses to online pre-test and post-test surveys may not be linked to any participant. In this way, all participants' privacy is maintained.

All pre-test and post-test surveys will be delivered via Qualtrics, an Online survey product for which the URL link is provided.

Collected data will be maintained on the Qualtrics secure website under password protection. Data will only be accessible to the investigators in this study: Dr. Valerie Diaz and Cody Wilson.

The alumni email addresses are the personal commercial emails, not FIU emails, that FIU graduates voluntarily supplied after graduating from the university. Such emails are not the property of FIU and FIU records are not being accessed by the PI and Co-Pi. FERPA regulations are maintained. The email addresses are not linked to names or any personal identifier so that participant anonymity is maintained.

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Participant Compensation or Incentives 7.3

Indicate if participants will receive compensation or other incentives to participate in the research study.

Yes

No

Yes 7.3.1

No 7.3.2

METHODS & ACTIVITIES 8

Explanation of Methods & Activities (Attachment) 8.1

Attachments: Questionnaire Edited.pdf,DNP Edu PPT.pdf

Identify and describe all interactions that are to be performed solely for the research study. Explain the methods and procedures to be followed with an emphasis on implications for subjects' experiences. Describe data to be collected. List the names of the different data collection forms that you will be using if conducting surveys, interviews, and/or focus groups.

Attach data collection forms to be used by clicking on the paper clip icon to the right.

With their consent, participants will complete an anonymous online pre-test survey to assess their knowledge, perceptions, and current clinical practices regarding the effect of cryotherapy on postoperative opioid consumption in orthopedic surgery. The survey is to be completed individually and is expected to take up to 5 minutes to complete. Then, the participants will complete an online educational PowerPoint based on the results of a related literature review. Participants will be asked to complete the post-test, which will be identical to the pre-test. The online post-test survey is expected to take up to 5 minutes to complete. The PowerPoint is attached here.

Participants will be asked to complete the post test, which mirrors the pretest. The post test survey is expected to take up to five minutes to complete.

Data will be collected using the pre-test/post-test survey form attached. No identifiable private information is to be collected. Demographic data, including gender, age, level of education, and years of experience will be obtained as part of the survey.

Additionally, the online pre-test/post-test survey will be used to collect data related to participants' knowledge, perceptions, and practices related to cryotherapy and postoperative opioid consumption in orthopedic surgery. NO DATA ANALYSIS WILL BE DONE AT FIU. ALL DATA ANALYSIS WILL BE COMPLETED VIRTUALLY. NO FACE TO FACE OR IN PERSON ACTIVITIES WILL TAKE PLACE.

Types of Activities 8.2

Carefully identify all of the activities that will be involved in the research by clicking on the green "+" icon to the right. Identify ALL that apply to the research.

Internet or Email Data Collection 8.2.1

Surveys or Interviews (Individual) 8.2.2

Use of Secondary Data/Specimens 8.3

Indicate below if this study will involve the use of pre-existing secondary data or secondary specimens.

Yes

No

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Yes	8.3.1
No	8.3.2
Miscellaneous or Additional Information	8.4
<p>This area can be used to incorporate any additional information or attachments that pertain to this study (i.e., information or attachments that do not pertain to any of the other questions above).</p> <p>None</p>	
BENEFITS & RISKS	9
Benefits to Subjects	9.1
<p>List the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants. <i>Compensation is not to be considered a benefit.</i></p> <p>Potential benefits to participants include improved knowledge of the effect of cryotherapy on postoperative opioid consumption in orthopedic surgery.</p>	
Benefits to Society and/or Others	9.2
<p>List the potential benefits that society and/or others may expect as a result of this research study.</p> <p>It is expected that this study will benefit society by guiding practitioners to using cryotherapy to decrease postoperative opioid consumption in orthopedic surgery.</p>	
Risks, Harms, and/or Discomforts	9.3
<p>Justify why this project involves no more than minimal risk. Consider the range of risks, including physical, psychological, social, legal, and economic.</p> <p>The probability and magnitude of risk, harm, or discomfort anticipated in research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests and is therefore considered minimal.</p>	
INFORMED CONSENT	10
Informed Consent in Exempt Research	10.1
<p>The use of informed consent is not required and its use is <u>optional</u> for "exempt" research projects (unless the study involves deception). It is "suggested" for exempt research projects to utilize an "informational letter" (<i>an informational letter provides the subjects with a brief overview of the study, but it does not require the subject to provide their informed consent to participate</i>). However, the use of an informational letter is also <u>optional</u> (unless specifically requested by the IRB). Investigators have the option of deciding if they would like to utilize either of these documents in their exempt studies.</p>	
<p>Persons reviewing the information contained herein are reminded of their confidentiality obligations pursuant to the FIU Confidentiality Agreements Policy #1710.070.</p>	

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Informed Consent or Informational Letter 10.2

Will you be utilizing an informed consent document or an informational letter for this study?

Note: If the study involves deception, you will need to answer "yes" to this question.

Yes

No

Yes 10.2.1

Explanation of Consent Procedures (Attachment) 10.2.1.1

Attachments: Consent revised.pdf

Indicate the consent process and document(s) that will be used in the study. See [Consent for Research](#) for guidelines and sample templates.

Attach copies of your Informed Consent Form (or Informational Letter) by clicking on the paper clip icon to your right.

PROCEDURES

If you agree to be in the project, we will ask you to do the following things:

1. Complete an online 10 question pre-test survey via Qualtrics, an Online survey product for which the URL link is provided.
2. Review the educational PowerPoint Module lasting 10 minutes via Qualtrics, an Online survey product for which the URL link is provided.
3. Complete the online 10 question post-test survey via Qualtrics, an Online survey product for which the URL link is provided.

RISKS AND/OR DISCOMFORTS

The main risk or discomfort from this research is minimal. There will be minimal risks involved with this project, as would be expected in any type of educational intervention, which may have included mild emotional stress or mild physical discomfort from sitting on a chair for an extended period of time, for instance. However, if participant becomes fatigued, he may opt out.

BENEFITS

The following benefits may be associated with your participation in this project: An increased understanding on the effect of cryotherapy on postoperative opioid consumption in orthopedic surgery.

The overall objective of the program is to increase the quality of healthcare delivery and improve healthcare outcomes for our patients.

ALTERNATIVES

There are no known alternatives available to you other than not taking part in this project. However, if you would like to receive the educational material given to the participants in this project, it will be provided to you at no cost.

CONFIDENTIALITY

The records of this project will be kept private and will be protected to the fullest extent provided by law. If, in any sort of report, we might publish, we will not include any information that will make it possible to identify you as a participant.

Records will be stored securely, and only the project team will have access to the records.

There is no cost or payment to you for receiving the health education and/or for participating in this project.

RIGHT TO DECLINE OR WITHDRAW

Your participation in this project is voluntary. You are free to participate in the project or withdraw your consent at any time during the project. Your withdrawal or lack of participation will not affect any benefits to which you are otherwise entitled.

The investigator reserves the right to remove you without your consent at such time that they feel it is in the best interest.

Participant is provided the opportunity to accept or decline when prompted by the survey software after reading the consent letter.

No 10.2.2

CONFIDENTIALITY & PRIVACY 11

Information on Confidentiality and Privacy 11.1

Please review the [IRB Data Management Security Tips](#) for a listing of the best practices for securing data. Click the blue "?" icon to the right to learn about the differences between confidentiality and privacy.

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Data Storage Methods 11.2

Select the different methods that will be used for storing your data. Please select the green "+" icon to the right to make your selections. Select all that apply.

Laptop Computer 11.2.1

Survey Website Database 11.2.2

Provisions to Protect Privacy 11.3

Describe the provisions to protect the privacy interests of the participants.

All data regarding participant knowledge, perceptions, and practices regarding cryotherapy and postoperative opioid consumption in orthopedic surgery will be collected anonymously. Only investigators will have access to the information collected.

FERPA Student Education Records 11.4

Researchers are required to follow the Family Educational Rights and Privacy Act (FERPA) requirements when accessing, using or disclosing FIU student education records for research purposes.

For more information, visit the [FIU Student Education Records \(FERPA\) web page](#) . In addition, you can view the regulatory requirements at [34 CFR Part 99](#).

Will individually identifiable FIU student education records be accessed, used, or disclosed in this research study?

Yes

No

Yes 11.4.1

No 11.4.2

Associating a Participant to a Study 11.5

You should select "Yes" to this question if it will be possible for you to associate a participant to your study (e.g., via a name on a signed consent form, via a name in the Sona System, etc.).

You should select "No" to this question if it will not be possible for you to associate a participant to your study (e.g., the names of subjects are never collected or provided to the researchers).

Yes - It will be possible for me to associate a participant to my study

No - It will not be possible for me to associate a participant to my study

Yes - It will be possible for me to associate a participant to my study 11.5.1

No - It will not be possible for me to associate a participant to my study 11.5.2

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Associating Data to an Individual 11.6

Does the research require the access or collection of personally identifiable data about human subjects?

Personally identifiable data are considered data about a human that can be associated to a subject through one of the following methods:

1. Direct identifier (i.e., name, birthdate, social security number, medical record number, mailing address, etc.) or
2. Indirect identifier (i.e., a unique code that links the data back to the subject via a master key).

Note: You will need to mark "yes" if you will be working with coded data (regardless of whether you will have access to the master key).

- Yes - I will be accessing or collecting "personally identifiable data" (or "coded data")
- No - I will only be accessing or collecting "anonymous data" (not possible for anyone to link back to a subject)

Yes - I will be accessing or collecting "personally identifiable data" (or "coded data") 11.6.1

No - I will only be accessing or collecting "anonymous data" (not possible for anyone to link back to a subject) 11.6.2

Explanation of Anonymous Data 11.6.2.1

Describe the variables that will be collected for your study. Provide an explanation as to how the study will be conducted such that it will not be possible to link the data back to the subjects at any point during or after the study.

Participation takes place via a URL link generated by Qualtrics, a web-based platform and is therefore anonymous. There is no identifiable private information collected. Collected data only includes responses to the survey questions regarding the education module. No survey questions ask for responses that can provide identifiable information about participants. The URL link will be distributed via email where potential participants are BLIND copied to protect privacy (bcc email only). The measured variable is knowledge base. Responses correspond to the education module distributed to all participants. Responses are multiple choice items, no free text responses. The measurement is provider's knowledge of the effect of cryotherapy on postoperative opioid consumption in orthopedic surgery.

A unique identifier is assigned by Qualtrics to the participant which links the pre and the post test data

Confidentiality of Data 11.7

Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Be sure to address both the electronic and hard copy versions of your records in your explanation.

All data will be collected anonymously. No identifiable private information will be collected as part of the online pre-test and post-test surveys. Only investigators will have access to the completed pre-test and post-test surveys. There will be no hard copy forms. Data collected from the online pre-test and post-test surveys will be tabulated anonymously to electronic spreadsheets, which will be maintained on a password protected laptop computer.

Data Protection Methods 11.8

Select the different security methods that will be used for protecting your stored data. Please select the green "+" icon to the right to make your selections. Select all that apply.

Password Protection 11.8.1

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Location of Data

11.9

Provide the physical location(s) where the data will be stored (e.g., provide the campus, building, and office room number). If data will not be physically stored anywhere (e.g., it will only be stored on a network, website, SharePoint, etc), then please indicate this below.
Only anonymous data will be collected. This anonymous data will be stored on a password protected laptop.

Transportation of Data

11.10

Indicate if data will need to be transported (physically or electronically).

- Yes, data will need to be physically or electronically transported
 No, data will not need to be physically or electronically transported

Yes, data will need to be physically or electronically transported

11.10.1

Procedures for Securing the Data

11.10.1.1

Indicate how you will secure the data during physical and/or electronic transport to minimize the risks of data loss. Indicate the steps that will be taken to minimize the duration of the transit.

Electronic data will be maintained under password protection to which access will be limited to the PI, Co-PI.

No, data will not need to be physically or electronically transported

11.10.2

Breaking Confidentiality

11.11

Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality.

There are no foreseeable circumstances in which it would be necessary to break confidentiality.

AFFIRMATION OF COMPLIANCE

12

Persons reviewing the information contained herein are reminded of their confidentiality obligations pursuant to the FIU Confidentiality Agreements Policy #1710.070.

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Office Use Only	13.1
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The FIU Office of Research Integrity will use this remaining "Office Use Only" section for administrative purposes after the protocol has received its exemption determination. The investigator does not need to complete anything within this section.

IRB Exemption Memorandum	13.2
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Attachments: Initial Approval

The FIU Office of Research Integrity will use this area to attach a PDF copy of the most recent IRB exemption memorandum.

IRB Approval Type	13.3
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The FIU Office of Research Integrity will use this area to display the approval type that was used for the initial review (i.e., Exempt).

Note: This approval type designation will remain the same for all subsequent amendments.

Exempt Determination

IRB Exemption Category	13.4
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The FIU Office of Research Integrity will use this area to display the final determined exemption category number(s).

Category 2	13.4.1
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Additional IRB Approval Details	13.5
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The FIU Office of Research Integrity will use this area to reference any additional details that pertain to this approved project.

IRB Authorization Agreement (IAA)

Individual Investigator Agreement (IIA)

IRB Authorization Agreement (IAA)	13.5.1
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Individual Investigator Agreement (IIA)	13.5.2
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Other Notes	13.6
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The FIU Office of Research Integrity will use this area to record any additional notes regarding the project.

Persons reviewing the information contained herein are reminded of their confidentiality obligations pursuant to the FIU Confidentiality Agreements Policy #1710.070.

Appendix E

Participant Recruitment Letter



Nicole Wertheim College of Nursing & Health Sciences

An Educational Module Explaining the Effect of Cryotherapy on Postoperative Opioid Consumption in Orthopedic Surgery: A Quality Improvement Project

Dear FIU Alumni CRNA:

My name is Cody Wilson and I am a student from the Anesthesiology Nursing Program Department of Nurse Anesthetist Practice at Florida International University. I am writing to invite you to participate in my quality improvement project. The goal of this project is to improve health care provider knowledge on the effect of cryotherapy on postoperative opioid consumption in orthopedic surgery. You are eligible to take part in this project because you are an FIU alumni CRNA.

If you decide to participate in this project, you will be asked to complete a consent form for participation. Next, you will complete a pretest questionnaire, which is expected to take approximately 5 minutes. You will then be asked to view an approximately 15 minute long educational presentation online. After watching the video, you will be asked to complete the posttest questionnaire, which is expected to take approximately 5 minutes. *No compensation will be provided.*

Remember, this is completely voluntary. You can choose to be in the study or not. If you'd like to participate or have any questions about the study, please email or contact me at cwils089@fiu.edu or 614-937-6796.

Follow this link to the Survey:

Take the Survey

Or copy and paste the URL below into your internet browser.

https://fiu.qualtrics.com/jfe/form/SV_efFTrAHqfggorY

Thank you very much.

Sincerely,

Cody Wilson, RN, BSN, SRNA

Appendix F

Participant Consent



CONSENT TO PARTICIPATE IN A QUALITY IMPROVEMENT PROJECT

“An Educational Module Explaining the Effect of Cryotherapy on Postoperative Opioid Consumption in Orthopedic Surgery: A Quality Improvement Project.”

SUMMARY INFORMATION

Things you should know about this study:

- **Purpose:** Educational module concerning use of cryotherapy to decrease postoperative opioid consumption in orthopedic surgery.
- **Procedures:** If you choose to participate, you will be asked to complete a pretest watch a voice PowerPoint, and then a post-test
- **Duration:** This will take about a total of 20-minute total.
- **Risks:** The main risk or discomfort from this research is minimal
- **Benefits:** The main benefit to you from this research is increase the participants knowledge of the use of cryotherapy to decrease postoperative consumption in orthopedic surgery.
- **Alternatives:** There are no known alternatives available to you other than not taking part in this study.
- **Participation:** Taking part in this research project is voluntary.

Please carefully read the entire document before agreeing to participate.

PURPOSE OF THE PROJECT

The goal of this project is to decrease postoperative opioid consumption in orthopedic surgery through an educational intervention targeting certified registered nurse anesthetists (CRNAs). You are being asked to participate in this quality improvement project.

NUMBER OF STUDY PARTICIPANTS

If you decide to participate, you will be one of approximately 10 people in this study.

DURATION OF THE PROJECT

Your participation will require about 20 minutes of your time.

PROCEDURES

If you agree to be in the project, we will ask you to do the following things:

RISKS AND/OR DISCOMFORTS

There are no foreseeable risks with you for participating in this project.

BENEFITS

The following benefits with your participation in this project: An increase in your knowledge surrounding the effect of cryotherapy on postoperative opioid consumption in orthopedic surgery.

ALTERNATIVES

There are no known alternatives available to you other than not taking part in this project. However, if you would like to receive the educational material given to the participants in this project, it will be provided to you at no cost.

CONFIDENTIALITY

The records of this project will be kept private and will be protected to the fullest extent provided by law. If, in any sort of report we might publish, we will not include any information that will make it possible to identify you as a participant. Records will be stored securely, and only the project team will have access to the records.

PARTICIPATION: Taking part in this research project is voluntary.

COMPENSATION & COSTS

There is no cost or payment to you for receiving the health education and/or for participating in this project.

RIGHT TO DECLINE OR WITHDRAW

Your participation in this project is voluntary. You are free to participate in the project or withdraw your consent at any time during the project. Your withdrawal or lack of participation will not affect any benefits to which you are otherwise entitled. The investigator reserves the right to remove you without your consent at such time that they feel it is in the best interest.

RESEARCHER CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues relating to this research project, you may contact Cody Wilson at (614) 937-6796 or cwils089@fiu.edu and Dr. Valerie Diaz at 305-348-9027 or vdiaz@fiu.edu.

IRB CONTACT INFORMATION

If you would like to talk with someone about your rights pertaining to being a subject in this project or about ethical issues with this project, you may contact the Florida International University Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

PARTICIPANT AGREEMENT

I have read the information in this consent form and agree to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. By clicking on the "consent to participate" button below I am providing my informed consent

Appendix G

Pretest and Posttest Questionnaire

Pretest and Posttest Questionnaire: An Educational Module Explaining the Effect of Cryotherapy on Postoperative Opioid Consumption in Orthopedic Surgery: A Quality Improvement Project

PERSONAL INFORMATION (Optional)

1. **Gender:** Male Female
2. **Age:** _____
3. **Level of Education:** Masters Doctoral (DNP, DNAP, EdD, PhD)
4. **Years of Experience:** Less than 1 year 1 to 5 years 6 to 10 years More than 10 years

QUESTIONNAIRE

1. Which of these factors contributes to the complexity of modern day pain management?
 - A. Undertreated pain goes away spontaneously
 - B. Higher survival rates from illnesses and traumas
 - C. Lower pain tolerances
 - D. Increased frequency and simpler surgical procedures
2. Each time a patient refills an opioid prescription after surgery, the rate of opioid misuse increases by:
 - A. 10%
 - B. 23%
 - C. 44%
 - D. Number of refills have no effect
3. The United States is responsible for what percentage of the world's opioid use?
 - A. 50%
 - B. 80%
 - C. 30%
 - D. 70%
4. The majority of opioid abusers began their addictions from:
 - A. Prescription medications
 - B. Psychiatric instability
 - C. Taking extra medications from family and friends
 - D. The need to find an escape

5. The procedures with the highest postoperative opioid consumption are (select 2):
 - A. Total knee arthroplasty
 - B. Laparoscopic cholecystectomy
 - C. Posterior lumbar fusion
 - D. Total hip arthroplasty

6. Opioid-related complications that occur post-operatively have been shown to increase the risk of hospital admission by what percentage?
 - A. 22%
 - B. 30%
 - C. 40%
 - D. 54%

7. Which of these is believed to be one physiologic mechanism that accounts for the effectiveness of cryotherapy in limiting pain?
 - A. Decreased temperature inactivates mu receptors.
 - B. Increased body temperature helps to fight postoperative infections.
 - C. Slowed nerve conduction velocity decreases stimulation to the brain.
 - D. Cryotherapy temporarily immobilizes the joint, reducing pain.

8. The cooling of synovial fluid is believed to have what direct effect on limiting pain?
 - A. Decreased swelling
 - B. Decreased nerve conduction
 - C. Decreased fluid shifts
 - D. Decreased prostaglandin

9. In randomized control trials, cryotherapy has been shown to reduce postoperative opioid consumption by as much as:
 - A. 24%
 - B. 48%
 - C. 57%
 - D. 72%

10. How likely are you to consider using cryotherapy for postoperative pain management in your anesthetic plan for orthopedic surgery cases?
 - A. Not likely
 - B. Somewhat likely
 - C. Likely
 - D. Very likely

Appendix H

Education Module

6/26/22

An Educational Module Explaining the Effect of Cryotherapy on Postoperative Opioid Consumption in Orthopedic Surgery: A Quality Improvement Project

Cody Wilson
Florida International University

FIU Nicole Wortham College of Nursing & Health Sciences

1

Learning Goals

- Increase awareness of cryotherapy
- Improve education on cryotherapy
- Gain support for the use of cryotherapy in the postoperative period

FIU Nicole Wortham College of Nursing & Health Sciences

2

1

Complexity of Pain Management¹


- Undertreated acute pain becomes chronic
- Aging population
- Higher survival rates from illnesses and trauma
- Increased frequency and complexity of surgery

FIU Nicole Wortham College of Nursing & Health Sciences


3

6/26/22

Opioids^{1,2,3}



- Fast-acting
- Powerful pain relief
- Induce hypnotic states
- Blunt hemodynamic responses to surgical stress
- Repeated use suppresses endogenous opioids, leading to dependence, tolerance, and addiction
- Acts on mu-opioid receptors, which control breathing


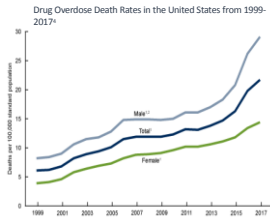


FIU Nicole Wurtheim College of Nursing & Health Sciences

4

The Opioid Crisis

The United States comprises about 5% of the world's population but is responsible for 80% of its opioid consumption.⁴




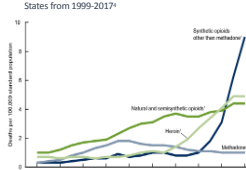
FIU Nicole Wurtheim College of Nursing & Health Sciences

2

5

The Opioid Crisis

Each time an opioid prescription is refilled after surgery, the rate of opioid misuse increases by 44%⁵



FIU Nicole Wurtheim College of Nursing & Health Sciences

6

6/26/22

Orthopedic Surgery^{6,7}

```
graph LR; A[Procedures requiring long-term postoperative opioids] --> B[Total knee arthroplasty]; A --> C[Total hip arthroplasty]; B --> D[Estimation exceeds 640,000 procedures per year in U.S.]; C --> E[Estimation exceeds 450,000 procedures per year in U.S.]
```

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7

Solution

```
graph LR; A[Adequate pain control] --> C((+)); B[Opioid sparing] --> C; C --> D[Cryotherapy]
```

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3

8

Cryotherapy

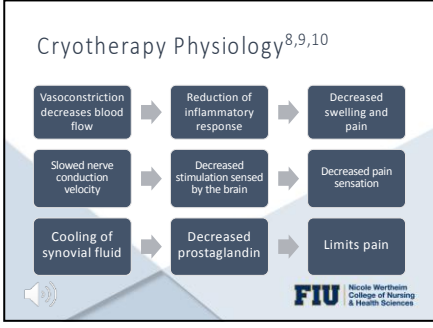
Application of cold temperatures to the effected tissues

Believed to have pain-limiting effects through multiple mechanisms

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9

6/26/22



10

Literature Summary

Brouwers et al ⁸	Kuyucu et al ⁹	Thijs et al ¹¹
<ul style="list-style-type: none">• RCT• Cryotherapy resulted in a 48% reduction in postoperative opioid consumption	<ul style="list-style-type: none">• RCT• Cryotherapy resulted in lower postoperative pain scores and less opioid consumption	<ul style="list-style-type: none">• RCT• Cryotherapy decreased postoperative consumption by 57%.

4

11

Literature Summary, cont.

Chughtai et al ¹⁰	Ni et al ¹²
<ul style="list-style-type: none">• Systematic review of 52 articles• Cryotherapy decreased pain scores and postoperative opioid consumption	<ul style="list-style-type: none">• Systematic review of 12 articles• Cryotherapy reduces pain scores and decreased postoperative opioid consumption

12

6/26/22

Summary

- Deaths from opioid overdoses are rapidly rising
- Anesthesia professionals are at the forefront of controlling pain while limiting postoperative opioid consumption
- Cryotherapy is a multimodal intervention proven to limit postoperative opioid consumption following orthopedic surgery

FIU Nicole Wertheim College of Nursing & Health Sciences

13

Thank You!

Cody Wilson: cwils089@fiu.edu or (614) 937-6796
 Dr. Valerie Diaz: vdiaz@fiu.edu or (305) 348-9027

FIU Nicole Wertheim College of Nursing & Health Sciences

14

5

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1. Shapira-A, Shenley L, Ciccone D. Opioid Crisis: No Easy Fix to Its Social and Economic Determinants. *Am J Public Health*. 2018;108(2):302-306.
2. Vukobratovic M, Kraljic D, Stankovic V, Stankovic D. The Opioid Crisis: A Comprehensive Overview. *Can J Anaesth*. 2018;65(10):1018-1028.
3. Gurev R, Spick A, Berthouet L, et al. Effect of optimal free analgesia on post-operative period in cardiac surgery: a retrospective matched-cohort study. *BMC Anesthesiol*. 2018;18(2):136.
4. *Intelligence & Medical Affairs*. *Warner M. Drug-Induced Deaths in the United States, 1999-2017*. *NCHS Data Brief*. 2018;328(1):1-8.
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7. Fisher BE, Hoffman B, Zhou C, Liu G, Sharma S, Sharma S, Alexander M. Impact of total knee replacement practice: cost-effectiveness analysis of data from the Osteoarthritis Initiative. *BMC*. 2017;26(1):113.
8. Boucsein H, de Witte AG, van Zuijlen M, van Rossum H, Broeze W. The role of computer-assisted cryotherapy in the postoperative treatment after total knee arthroplasty: possible effects on pain and opioid consumption. *Knee Surgery, Sports Traumatology, Arthroscopy*. 2018.
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11. Thijs L, Schouten M, Benthien H, et al. Reduced opioid use after total knee arthroplasty using computer-assisted cryotherapy. *Knee Surgery, Sports Traumatology, Arthroscopy*. 2015;21(6):1288-1293.
12. Ni S-H, Jung W-T, Goo L, et al. Cryotherapy on postoperative rehabilitation of post arthroplasty. *Knee Surgery, Sports Traumatology, Arthroscopy*. 2015;21(12):2759-2763.

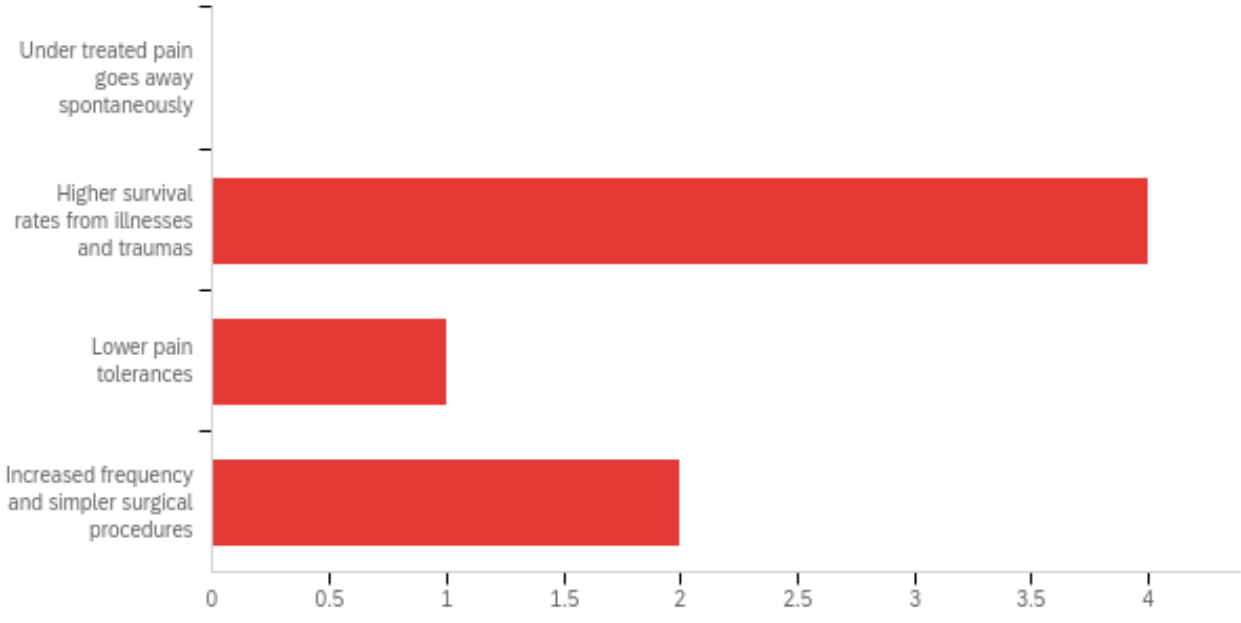
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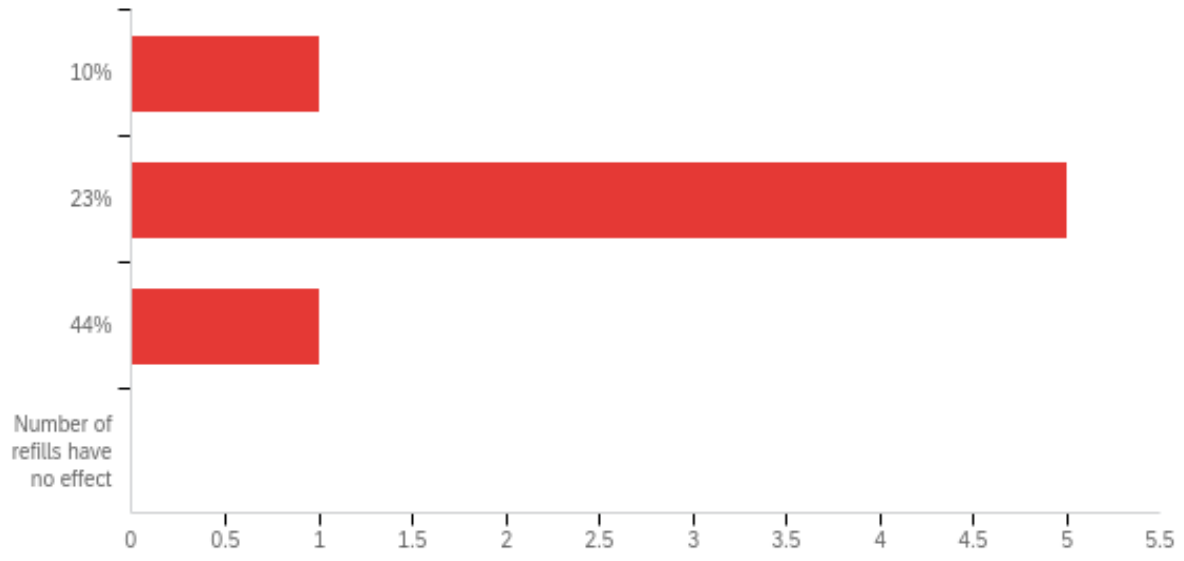
Appendix I
Pretest Results Report

Pretest Report

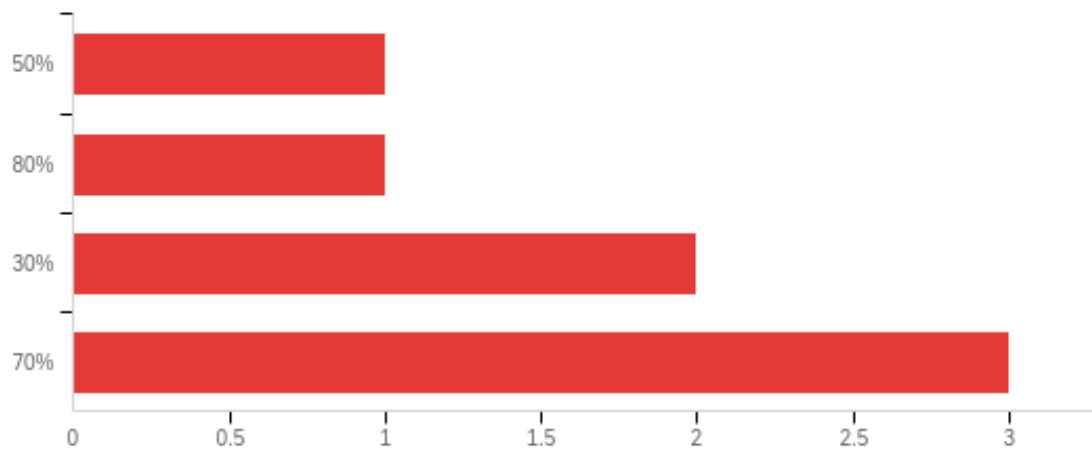
1. Which of these factors contributes to the complexity of modern day pain management?



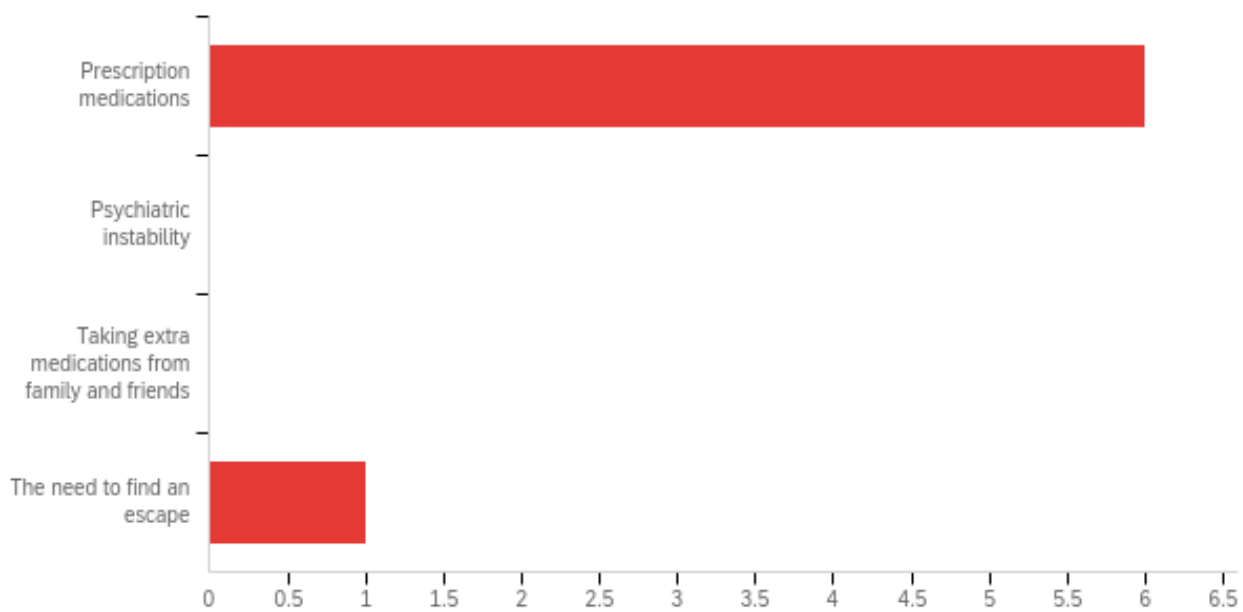
2. Each time a patient refills an opioid prescription after surgery, the rate of opioid misuse increases by:



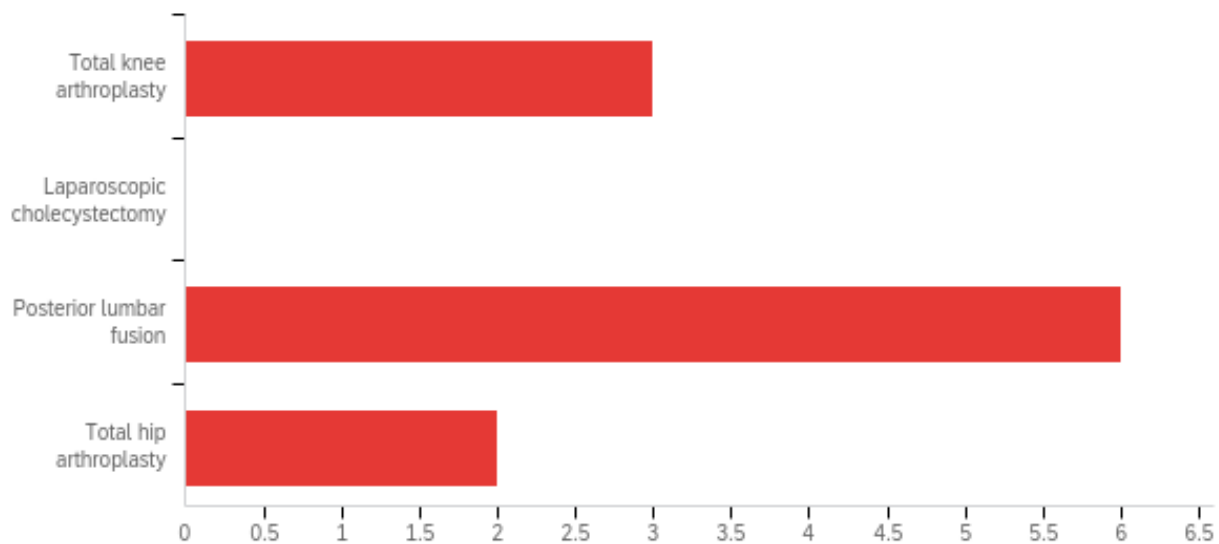
3. The United States is responsible for what percentage of the world's opioid use?



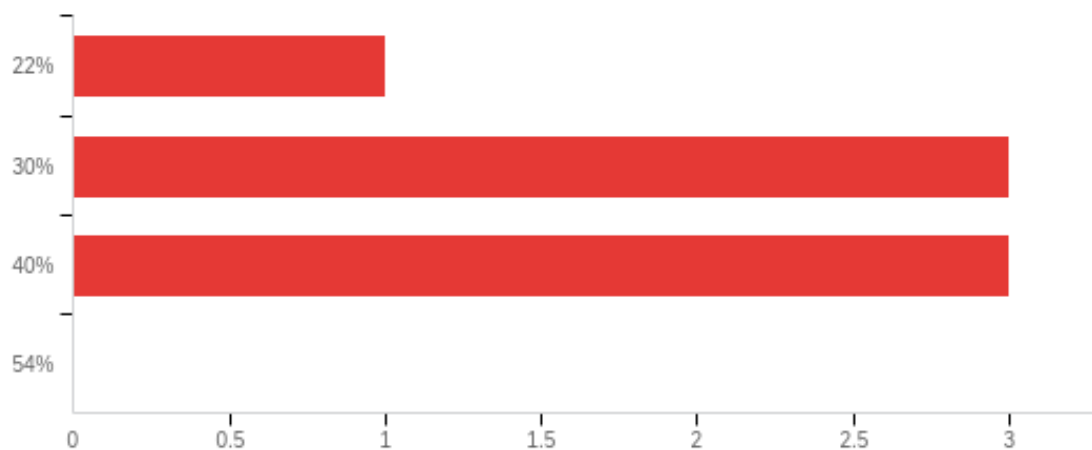
4. The majority of opioid abusers began their addictions from:



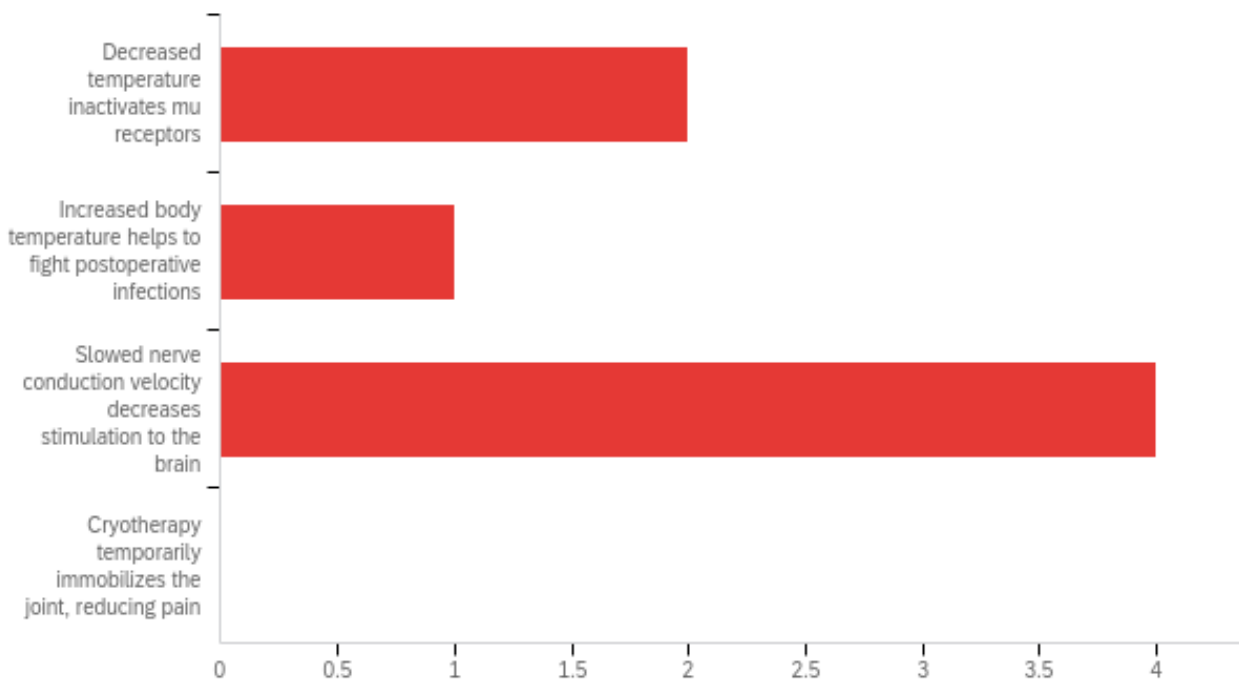
5. The procedures with the highest incidence of long-term postoperative opioid consumption are: (Select 2)



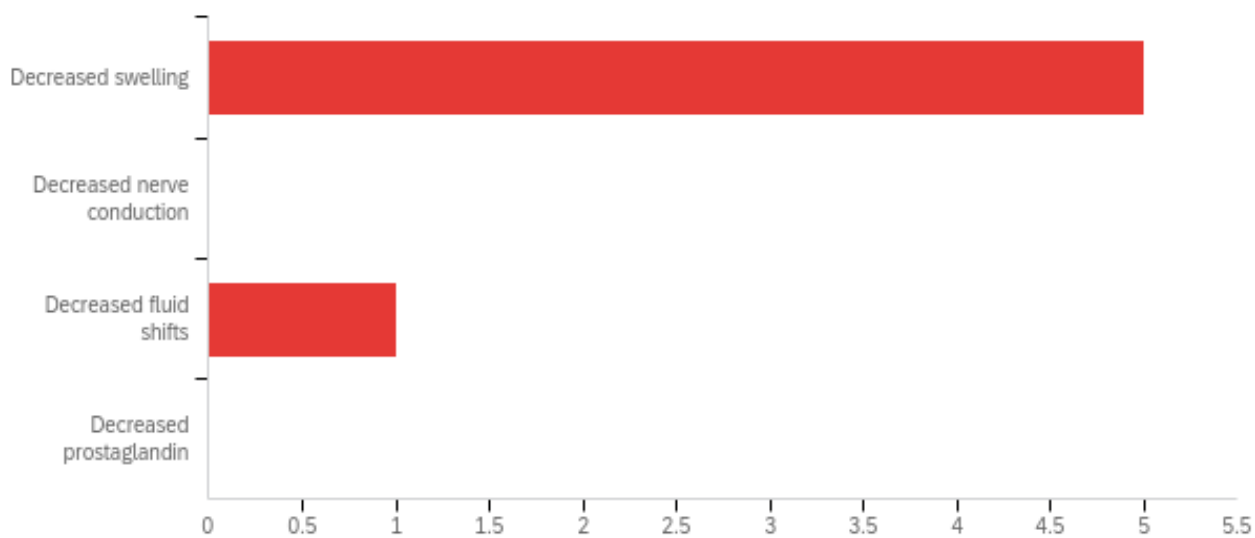
6. Opioid-related complications that occur postoperatively have been shown to increase the risk of hospital admission by what percentage?



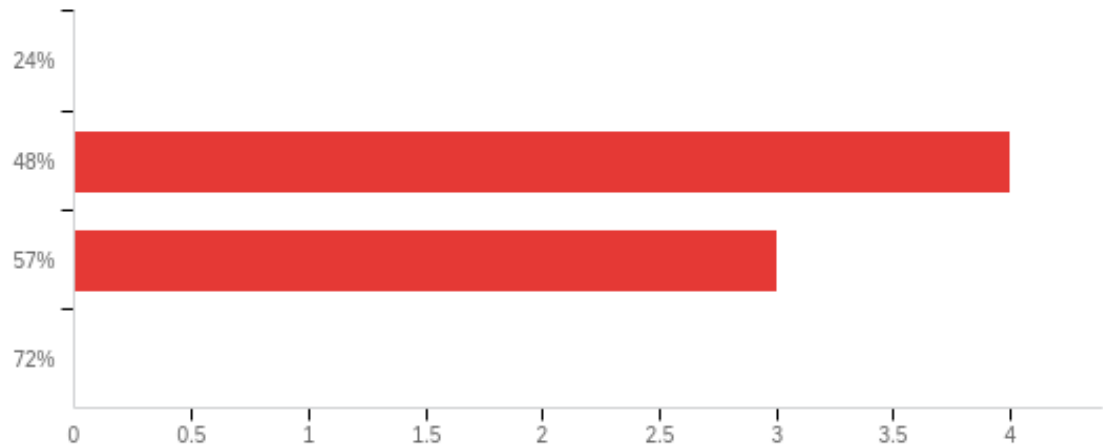
7. Which of these is believed to be one physiologic mechanism that accounts for the effectiveness of cryotherapy in limiting pain?



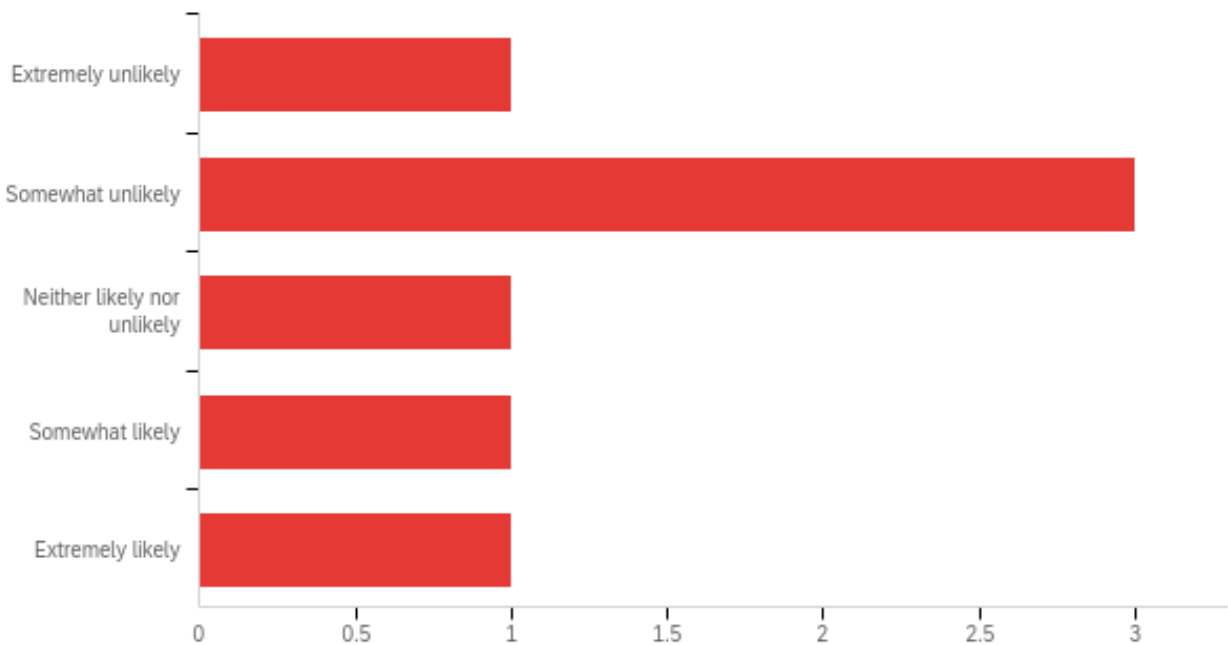
8. The cooling of synovial fluid is believed to have what direct effect on limiting pain?



9. In randomized control trials, cryotherapy has been shown to reduce postoperative opioid consumption by as much as:



10. How likely are you to consider using cryotherapy for postoperative pain management in your anesthetic plan for orthopedic surgery cases?

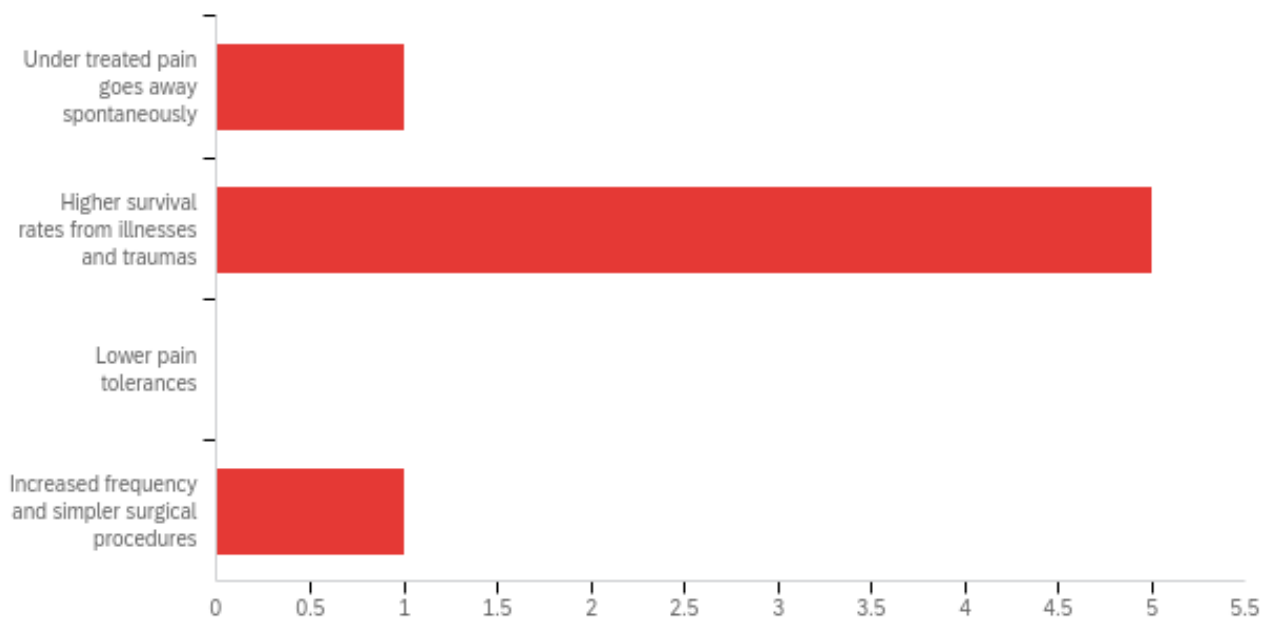


Appendix J

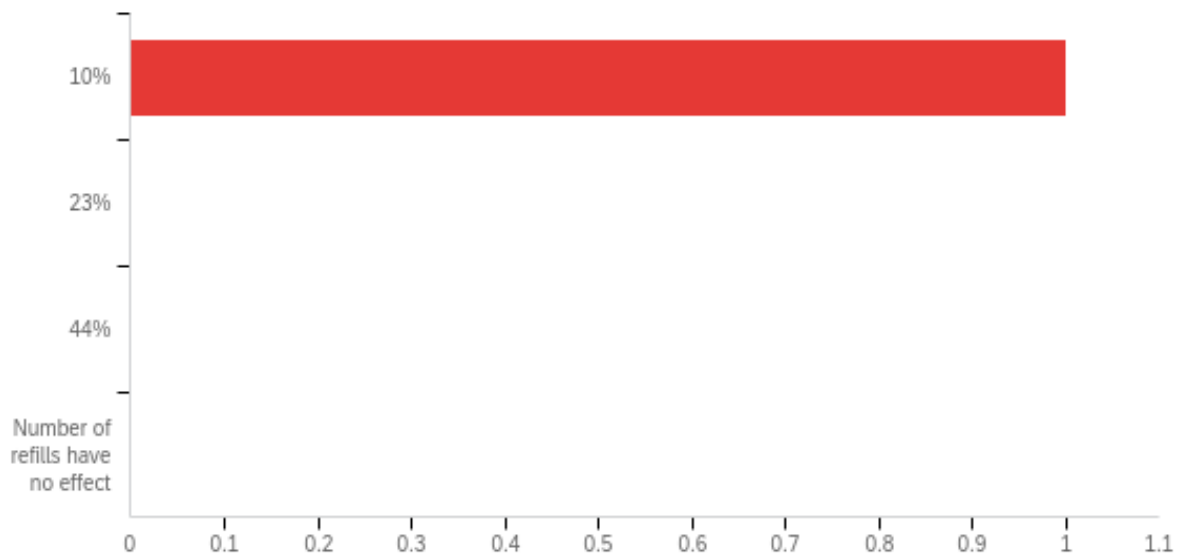
Posttest Results Report

Posttest Report

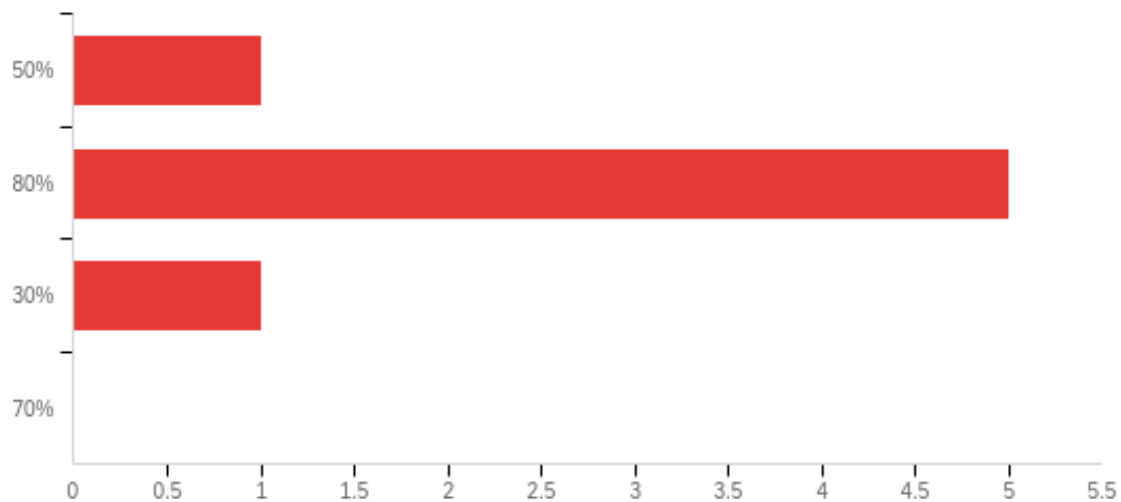
1. Which of these factors contributes to the complexity of modern day pain management?



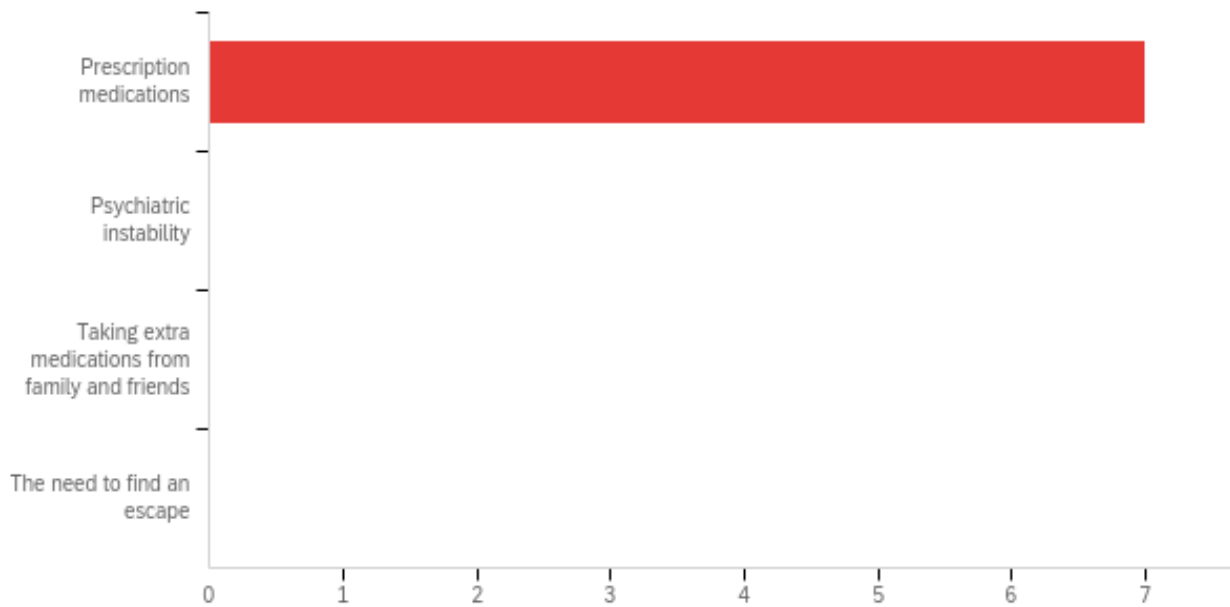
2. Each time a patient refills an opioid prescription after surgery, the rate of opioid misuse increases by:



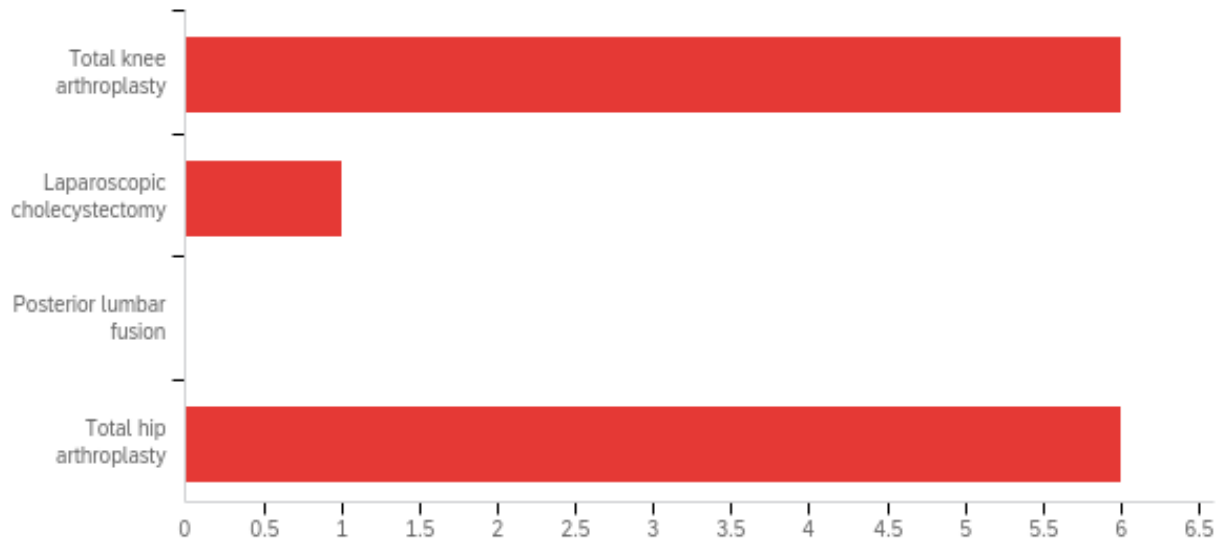
3. The United States is responsible for what percentage of the world's opioid use?



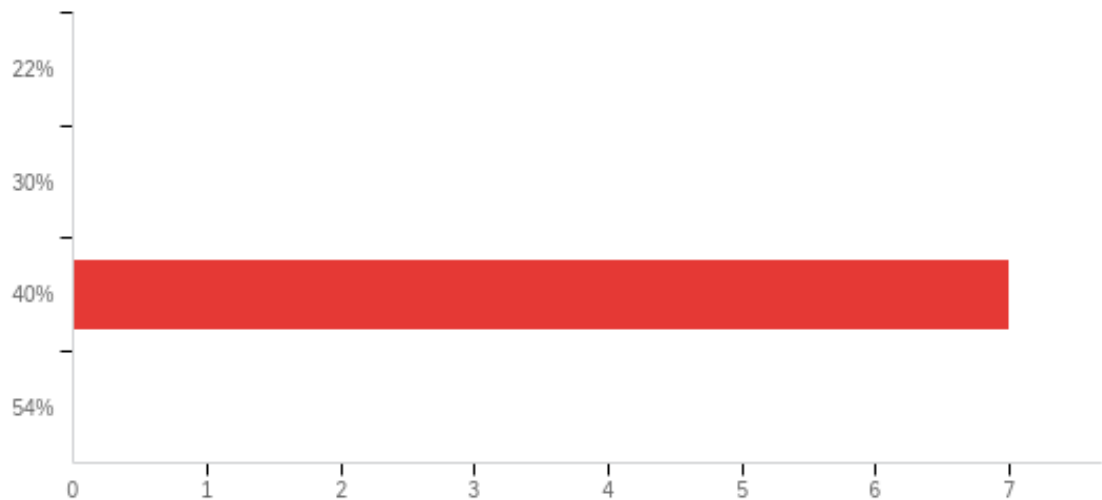
4. The majority of opioid abusers began their addictions from:



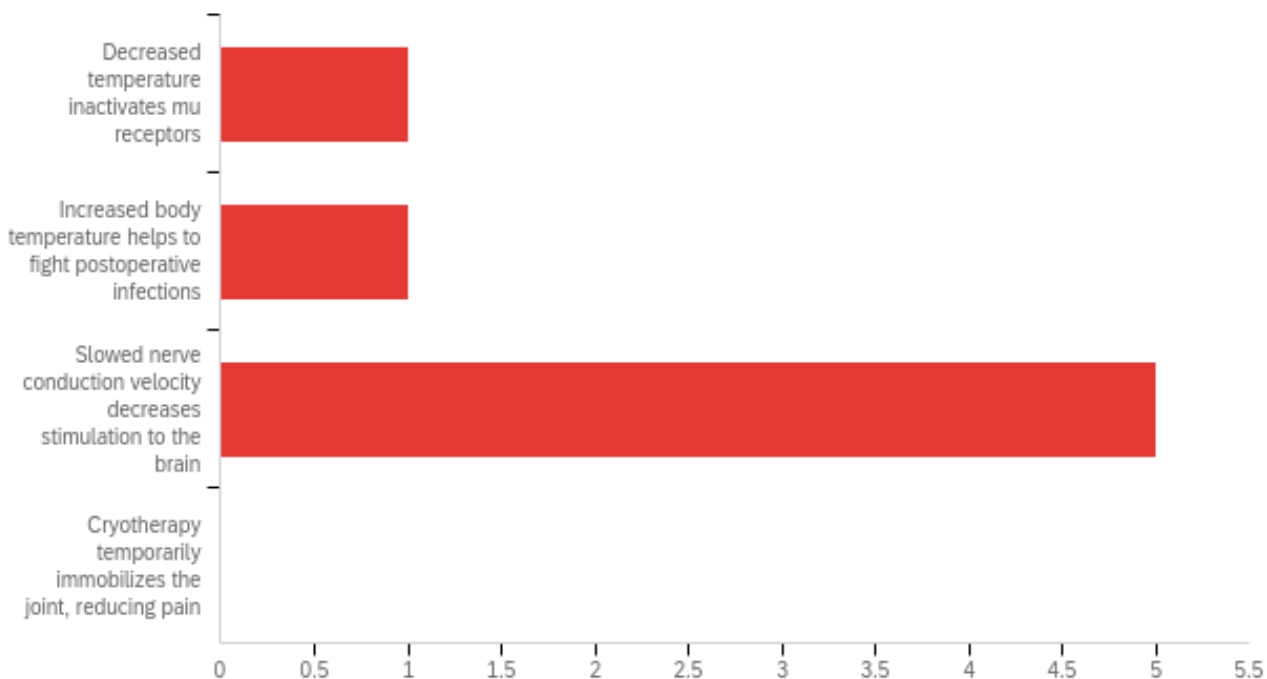
5. The procedures with the highest postoperative opioid consumption are:
(Select 2)



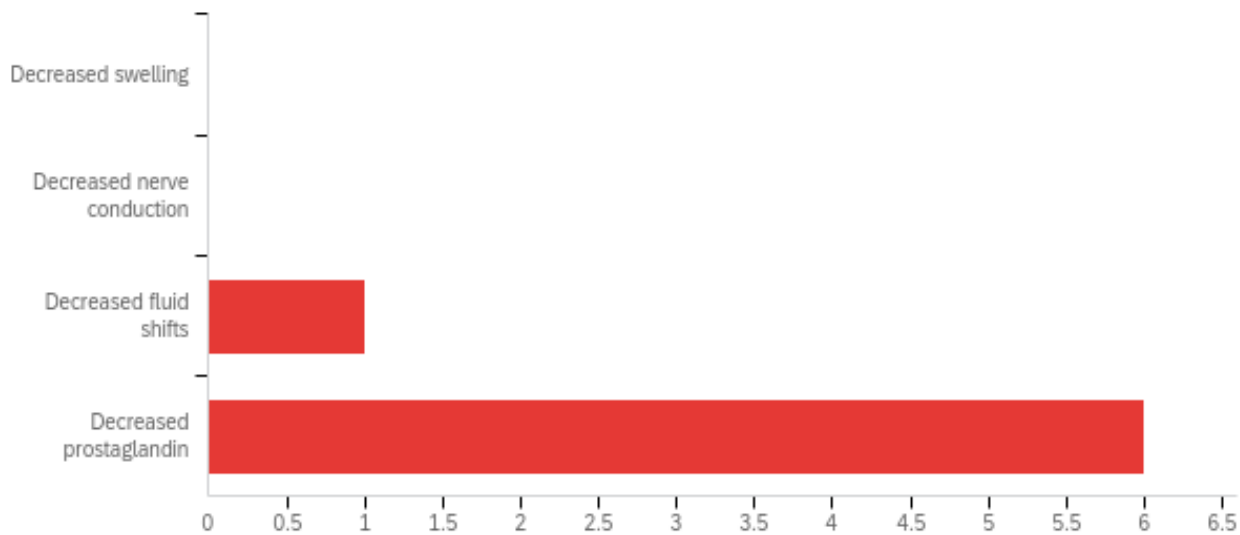
6. Opioid-related complications that occur postoperatively have been shown to increase the risk of hospital admission by what percentage?



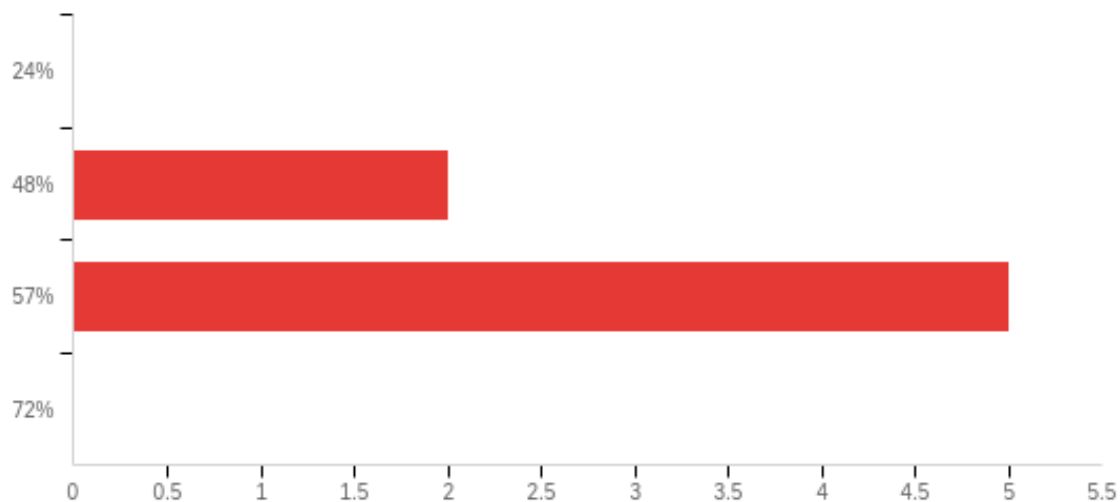
7. Which of these is believed to be one physiologic mechanism that accounts for the effectiveness of cryotherapy in limiting pain?



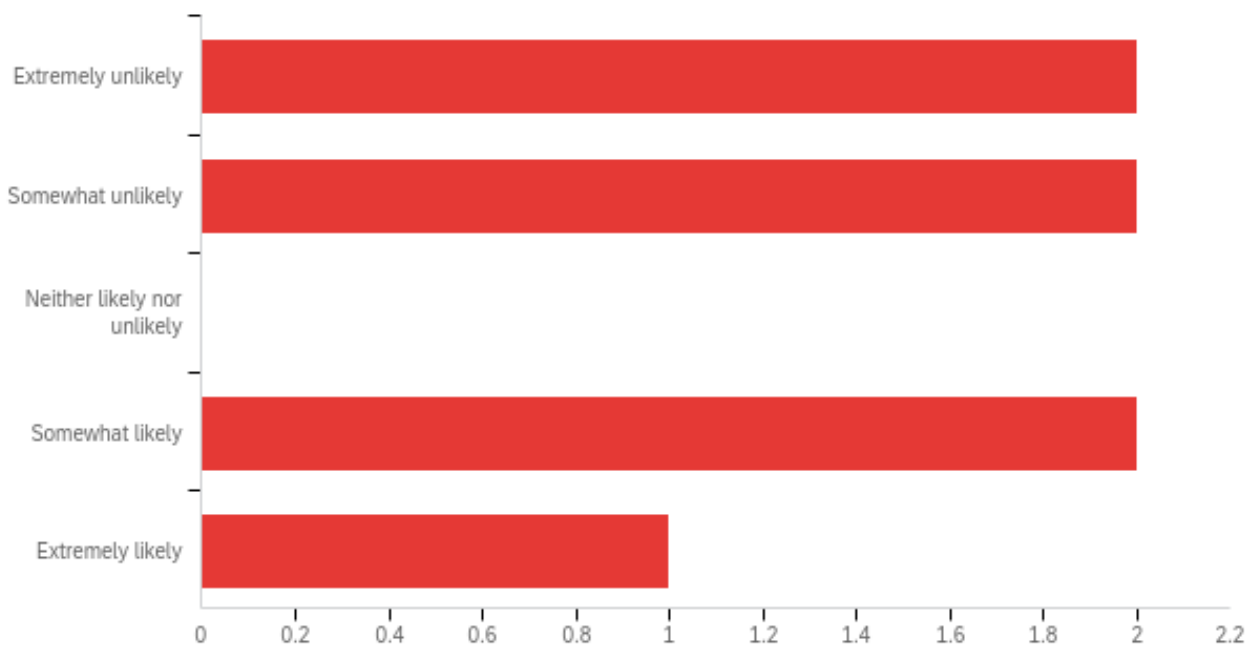
8. The cooling of synovial fluid is believed to have what direct effect on limiting pain?



9. In randomized control trials, cryotherapy has been shown to reduce postoperative opioid consumption by as much as:

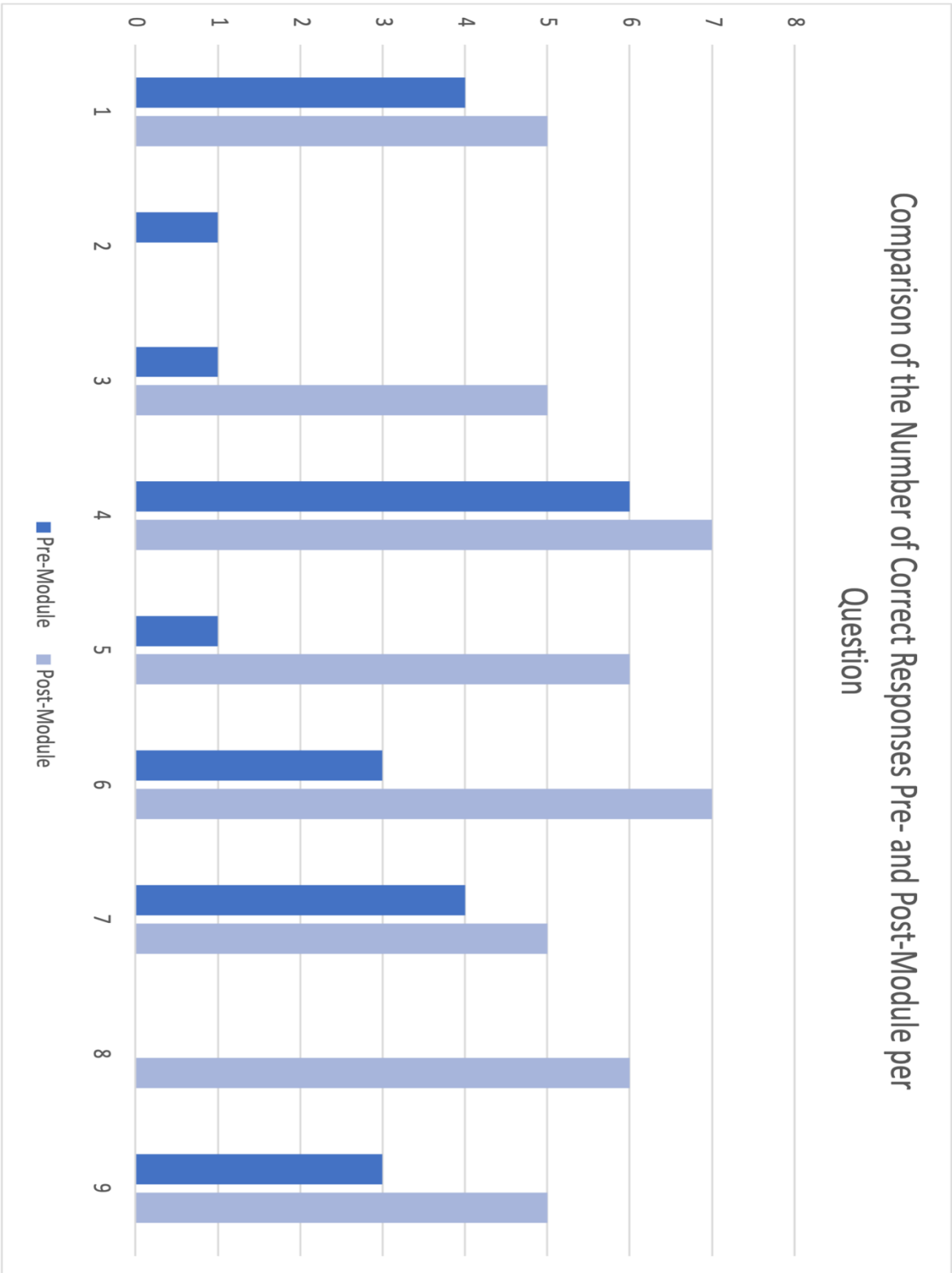


10. How likely are you to consider using cryotherapy for postoperative pain management in your anesthetic plan for orthopedic surgery cases?



Appendix K

Combined Pre- and Post-Module Results



Appendix L CITI Certificates



Completion Date 07-Jan-2022
 Expiration Date 06-Jan-2025
 Record ID 46304923

Not valid for renewal of certification through CME.

CITI
 Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wcb83a9a9-b507-4117-a0ed-cea607d7f13b-46304923



Completion Date 08-Feb-2020
Expiration Date 07-Feb-2023
Record ID 35312850

This is to certify that:

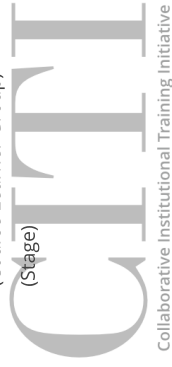
Valerie Diaz

Has completed the following CITI Program course:

Basic/Refresher Course - Human Subjects Research (Curriculum Group)
Biomedical Human Research Course (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

Florida International University



Verify at www.citiprogram.org/verify/?w4e8a4763-3494-44c6-9857-91f65cf90d0b-35312850