

Improved Patient Satisfaction as the Result of Video-Based Education on
Neuraxial/Labor Analgesia for Labor Patients in Native Languages:
A Quality Improvement Program

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Abstract

Improvement of patient satisfaction as the result of video-based education on labor analgesia or epidurals/combined spinal-epidurals in primary-spoken languages was the focus of the Quality Improvement Program. The development of a culturally sensitive, patient-centered video on pain management was introduced for the intervention. The Randomized Control was conducted at a single teaching institution in a major metropolitan area of Florida. Subjects recruited included parturients ages 18 to 43, scheduled for induction or early labor, and admitted for vaginal delivery.

The Quality Improvement Program utilized two standardized videos on epidurals and combined spinal-epidurals in English or Spanish. The control group received the current practice to include the pre-anesthetic assessment with the verbal “in-person” presentation, and the intervention group received the educational video. Post-partum questionnaires for both the control group (PPAQ-6) and intervention group (PPAQ-7) utilized a 5-point Likert scale. The patients completed an anonymous survey postpartum for data collection and analysis.

The study comprised of two cohorts: primary English-speaking and primary Spanish-speaking labor patients. Patients were randomized to the control group (CG), or intervention group (IG). The results from the post-partum surveys were combined for analysis and resulted in a sample size of 52. The Mann-Whitney U Test was utilized to

analyze the data. At a confidence level of .05, the results revealed the distribution as approximately normal. The value of U is 308.5, z-score is 0.95215, *p*-value is .17106. Therefore, the result is not significant between the two educational methods. Despite the statistical analysis not demonstrating a significant difference, the combined survey results for Strongly Agree/Very Satisfied and Agree/Satisfied responses reveal satisfaction with the video (100% IG). No side effects were reported as the result of our educational only intervention.

In conclusion, video-based education is cost-effective and patient-centered for the improvement of the birth experience. Information provided improved health literacy, and satisfaction with both methods, evidenced by the survey results obtained from the CG and IG. The findings support the effectiveness of epidurals as a safe option for pain management and improved patient satisfaction. The video-based educational method is designed to augment current in-person methods, especially when precise translation is needed for different populations.

Keywords: Patient satisfaction, video-based education, labor/neuraxial analgesia, epidural

Introduction and Statement of the Problem

Problem identification: What is wrong with the current patient educational methods delivered by the anesthesia provider upon admission to the Department of Labor and Delivery? What interventions may be implemented to improve patient care, satisfaction, and outcomes?

Currently, pre-anesthetic assessment and pre-procedural teaching is performed personally by an anesthesia provider upon admission to the Department of Labor and Delivery. English speaking providers obtain translation with the assistance of translators, language lines or APPS for non-English speaking patients. The recent introduction of a translation program (VOYCE Global) with an IPAD was introduced for use in the Department of Labor & Delivery. The information provided during the anesthetic assessment includes an explanation of the procedure(s), risks, and benefits. Also, an opportunity for questions is offered during or at the end of the session and questions are encouraged.

Presently, the actual information imparted may vary slightly between providers. The information was standardized and culturally sensitive addressed secondary to the provision of video-based educational information in the patient's primary language (English and Spanish). The identification of a clinical problem and evidence-based interventions promote patient-centered care and the translation of the research findings into nursing practice. Patient education facilitates health literacy, informed decision making and is a component of patient-centered care. Video-based education is not the current standard, and implementation may improve health literacy, reduce anxiety,

increase patient satisfaction and positive outcomes (Dahodwala, et al. 2018). The standardization of information imparted ensured a comprehensive introduction and eliminated omission of facts and information imparted by individual providers. The beneficial interventions may be expanded to all demographics, non-English speaking, English-speaking labor patients and patients requiring increased health literacy (White, Dudley-Brown, & Terhaar, 2016).

Togioka et al., (2019) introduced a video and pamphlet explaining labor epidurals in the study “Education Program Regarding Labor Epidurals Increases Utilization by Hispanic Medicaid Beneficiaries: A Randomized Control Trial.” The final outcomes of increased epidural administration and decreased misconceptions regarding neuraxial analgesia supported the utility of the study for increasing patient satisfaction. The study is a randomized control study (Level I), published in *Anesthesiology*, a peer reviewed journal of the American Society of Anesthesiologists. The acceptance of the findings within the anesthesia community are revered as credible for implementation at the point-of-care and comparable to the project.

Literature Summary and Related Evidence

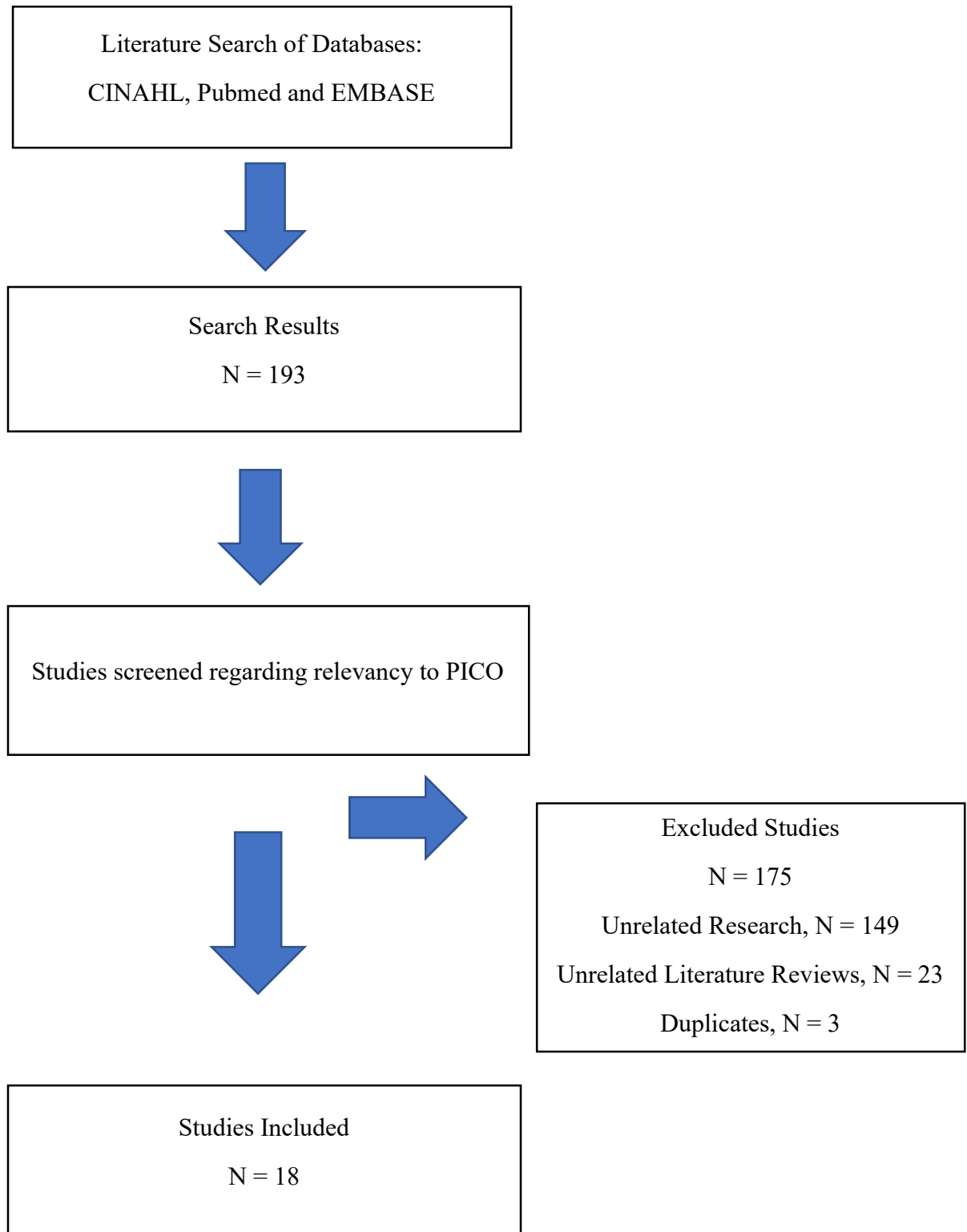
Literature Search

The literature search involved the identification of the keywords associated with the PICO question, “Improved patient satisfaction as the result of video-based educational methods in the patient’s native language on regional/neuraxial analgesia for labor patients.” Key words were utilized and Boolean search terms included for the literature review. Key words for search included: “video-based learning” or “patient

education” OR “health literacy” AND “patient satisfaction” AND “labor patient” OR “obstetrical patient” OR “parturient”; “video-based learning” or “patient education” AND “labor patient” OR “obstetrical patient”; “video-based learning” OR “health literacy” AND “labor patient” OR “obstetrical patient” OR “parturient”; “video-based learning” AND “Hispanic” OR “Spanish-Speak*”; “Obstetric analgesia” AND “labor experience” or “maternal experience, “systematic review on labor patients” OR “Parturients”; and “Systematic review” and “labor patients” OR “Parturients”; and “systematic review” AND “labor analgesia” and “labor patient” OR “parturient”,

Literature searches included Boolean/Phrase search terms, full text only, evidence limited to human subjects, pregnancy, English language, female sex, and recent publications (January 2015 until January 2020). Initial searches were performed on CINAHL (Cumulative Index to Nursing and Allied Health Literature) Plus with Full Text, PubMed, and the Cochrane Database of Systematic reviews. An extensive list of literature was obtained by the searches, but relevancy was limited. The searches including “systematic review” produced limited applicable research from over 190 articles on CINAHL and Pubmed. The availability of relevant scholarly articles and research related to my PICO question presented a limitation for my research. The most applicable systematic review from the Cochrane library exceeded 5 years, published in 2012. The gap in research can be realized by the latter and supports a need for more patient-centered studies targeting video-based education regarding labor analgesia and patient satisfaction (See Figure 1).

Figure 1



The identification of a systematic review supports the efficacy of regional anesthesia techniques for pain management during labor from the Cochrane Database of systematic reviews, “Pain management for women in labour: an overview of systematic reviews,” The systematic review was conducted greater than 5 years, but the study identified 15 Cochrane reviews, including 255 trials and 3 non-Cochrane reviews including 55 trials. The information revealed that epidural, combined spinal-epidural and inhalational analgesia provide adequate pain management in labor (Jones, et al., 2012). The discussion of the reference is to reinforce the need for the promotion of regional analgesia and possibly increase patient satisfaction post-partum for English-speaking, Spanish-speaking, and ultimately all women in labor. The investigation of the efficacy of regional anesthesia and improving patient satisfaction as the outcome of the PICO question was supported by the systematic review.

“Investigating determinants for patient satisfaction in women receiving epidural for labour pain” meets the criteria for Level III, and Good quality based on “reasonably consistent results, some control and sufficient sample size for the study design, and definitive conclusions” (Tan et al., 2018; Dang & Dearholt, 2018). The sample size was 10,146, adequate for the representation of the population and data analysis. The study revealed: 3230 (31.8%) were unsatisfied, 3646 (35.9%) were satisfied, and 3270 (32.2%) were very satisfied. According to Tan et al. (2018), the discussion addressed the patients experiencing lower satisfaction scores and contributing factors: patients experiencing higher post-epidural pain scores, instrumentation for vaginal delivery, epidural replacement, epidural placement at advanced cervical dilatation.

The previous study supports the development of quality improvement programs for increasing labor patient satisfaction. The factors contributing to lower satisfaction scores have limitations to interventions by healthcare providers. The one factor that may be influenced by patient education is epidural placement at advanced cervical dilatation. In my experience as a Certified Registered Nurse Anesthetist, the delay in acceptance of labor analgesia including epidural and CSE are secondary to preconceived fears and misconceptions associated with regional anesthetic techniques. According to the American Society of Anesthesiologists (2014), “Epidural myths may keep women from reliable pain management.” The acceptance of an epidural by the parturient may be at an earlier stage in the labor process before the escalation of discomfort becoming unbearable and increase patient satisfaction intra-partum and post-partum with patient centered video-based education intra-partum.

“The impact of the use of video-based educational interventions on patient outcomes in hospital settings: A scoping review,” supports the validity of utilizing video-based education as an effective medium for improving short-term health literacy goals (Dahodwala, et al. 2018). According to the American Hospital Association (2019), “Telehealth connects patients to vital health care services through videoconferencing, remote monitoring, electronic consults and wireless communications.” Telehealth allows providers to deliver the right care at the right place and the right time (AHA, 2019).

The scoping review database search produced 62 articles after exclusion criteria was met. The findings in 60% of the studies revealed significant improvement in outcomes for the intervention group. The introduction of video-based patient education

improved patient outcomes, increased knowledge, health literacy, allayed anxiety and improved patient satisfaction (Dahodwala, et al.). The scoping review is considered a type of research synthesis, identifying key concept, gaps in research and synthesizing research (Pham et al.). The article meets the criteria for Good quality. The qualitative study's sample size was adequate, results were reasonably consistent and meets criteria for Level III evidence (Dang & Dearholt, 2018).

The research project contributes to healthcare improvement goals, the *triple aim* identified by the Institute of Medicine. My PICO addresses the three aims directly or indirectly: population health, healthcare cost management, and patient satisfaction and quality of care (Marshall & Broome, 2017). The final outcomes from the intervention, video-based education in native language provided on Smart Tablet, provided the data to evaluate care and enable a continuous quality improvement program for providers (White, Dudley-Brown, & Terhaar, 2016). The translation of research into practice may improve health-literacy regarding pain management to include neuraxial/regional analgesia and maternal experience during labor.

The literature search had some limitations with regards to search terms. The search results produced an adequate number of articles for review but limited relevancy to my topic, enforcing more awareness on the subject. The articles identified and discussed were scholarly efforts and evidence-based providing support for PICO question.

Literature Review

Will the implementation of video-based educational information on regional analgesia increase patient satisfaction scores for the parturient post-partum receiving regional techniques (epidural or combined spinal-epidural/CSE) for pain management during labor?

Regional analgesia/anesthesia or neuraxial administration for pain management during labor has advanced during the latter part of the 20th Century (Chestnut, 2014). According to Chestnut, the milestones transforming obstetric anesthesia and pain management in labor or “labor analgesia” included “the introduction of inhalational agents in 1847, the expanded use of opioids in the early decades of the twentieth century, and the refinement of regional anesthesia starting in the mid-twentieth century.” The evolution towards the routine placement of continuous epidural and combined spinal epidural for pain management in *labor* is presently the norm versus the exception. Insight is required to determine the obstacles to the acceptance of regional anesthesia, factors affecting satisfaction and improved outcomes associated with the acceptance and administration of regional analgesic techniques [epidural and combined spinal-epidural (CSE)] during the labor process.

The literature review presented highlights and examines the current literature addressing the understanding and administration of regional analgesia or neuraxial analgesia, video-based education, and patient satisfaction with the delivery of patient education and healthcare provided during labor. The culmination of reviews enlighten the strong indication for regional anesthesia to be utilized during labor, barring a medical

contraindication. The discussions refer to the technique as neuraxial analgesia with the understanding that regional analgesia is the same technique. The population of interest includes primary English speaking and primary Spanish speaking patients, the evidence provided includes studies not specifically focused on the population, but most findings may be associated with all demographics. Additional search parameters were added to include: “Systematic Reviews” And “Epidurals for Minorities,” and “Systematic review of epidural use and minorities.”

Benefits and Efficacy of Neuraxial Analgesia for Pain Management During Labor

The New England Journal of Medicine addressed the superiority of epidural analgesia (neuraxial analgesic techniques) for labor and delivery. The introduction presents a scenario describing a labor patient receiving intermittent administration of intravenous fentanyl and describes insufficient pain relief, inability to rest and nausea (Hawkins, 2010). The noxious and unwanted side-effects experienced secondary to alternative techniques, validate the efficacy and preference of regional analgesia for labor patients. According to Hawkins, good obstetrical care includes pain management, although every woman in labor does not receive or request analgesia during labor and delivery.

The options for pain management should be presented to all patients, providing an opportunity for informed decision making and informed consent regarding regional analgesia in a patient-centered and culturally sensitive manner. According to the American College of Obstetricians and Gynecologists (ACOG), both pharmacologic and non-pharmacologic methods addressing pain management require individualized or

patient centered care. The Committee opinion #295 in 2019 and enforces the belief that women requesting epidural analgesia should not be deprived of this service. Availability and the ability of the patient to access care as the result of patient education and health literacy were important components of the intervention to provide patient centered care (ACOG, 2019).

The study, “Investigating determinants for patient satisfaction in women receiving epidural for labour pain” revealed an association between higher post-epidural pain scores and epidural placement at advanced cervical dilatation contributing to lower patient satisfaction. Placement of an epidural during the labor process may be delayed secondary to misconceptions regarding neuraxial analgesia. The development of quality improvement programs to include patient education will promote acceptance of neuraxial analgesia at an earlier stage of cervical dilatation (Tan, et al., 2018). The final decision is the patient’s but may be influenced by health care providers, pre-natal classes, relatives, social contacts and the internet.

The literature review aims to confirm the administration of regional analgesia as an effective intervention for pain management during labor, identify disparities, obstacles, and gaps in practice preventing acceptance and receipt of labor analgesia for the non-English speaking Hispanic population. Anim-Somuah, et al. (2018) addressed the effectiveness of epidurals and revealed lower pain scores and increased satisfaction with pain relief for women receiving epidural versus women receiving opioids. The review included 40 trials with 11,000 women meeting the inclusion criteria, producing a large sample size. The authors utilized Grade and determined that the Quality of evidence

spanned moderate to low quality. The systematic review “Epidural versus non-epidural or no analgesia for pain management in labour” compared the benefits and side-effects. The side-effects including assisted birth, longer labor and lower blood pressure. The latter side-effects may be less than originally reported, secondary to lower concentrated epidural infusions are now administered to prevent profound motor block a contributing factor to the side-effects mentioned. A post hoc subgroup analysis determined that studies conducted after 2005 did not report the former findings. Therefore, the adverse effects of receiving an epidural may be outweighed by the benefits (Amin-Somuah et al., 2018).

The importance of pain management during labor and patient satisfaction affects the current state of being and impacts future perceptions and experiences of analgesia effectiveness and pain relief for future pregnancies and births (Czech, et al. 2018). Severe pain experienced during labor may contribute towards postpartum depression and post-traumatic stress disorder (Hawkins, 2010). The goal for safety, prevention of complications and improved outcomes should always be a priority for providers in healthcare.

The study, “Labor Analgesia as a predictor for Reduced Postpartum Depression Scores: A Retrospective Observational Study,” addressed the psychological effects of labor pain, administration of regional analgesia (epidural) for labor and postpartum depression. The sample size was adequate for the study design (n= 201), utilization of the Edinburgh Postnatal Depression Scale (EPDS) score 6 weeks postpartum provided standardization, results were consistent and generalizable with definitive conclusions. The criteria for Good quality and Level III evidence was achieved (Dang & Dearholt,

2018). Linear regression results demonstrated the correlation between higher patient improvement in pain (PIP) scores and lower EPDS scores ($r = 0.025$, $P = 0,002$). The prior history of postpartum depression is the number one indicator for reoccurrence, but the authors determined that a history of anxiety, depression, and/or psychiatric disorders were noncontributory to their findings (Lim, et al., 2018).

Effective pain management during labor is directly related to a decrease in postpartum depression symptoms and improved outcomes, warranting further investigation. The presence of physiological stress impacting psychological well-being was examined and the effects on patient satisfaction (Lim et al., 2018). The importance of effective labor analgesia and the reduction of post-partum depression is important for all labor patients, including non-English speaking Hispanic patients. The satisfactory relief of maternal pain that results from neuraxial analgesic techniques has been demonstrated, but the relationship between analgesia and postpartum depression needs further investigation (Farias de Arangao, et al., 2019). Interventions directed towards increased patient satisfaction and improved outcomes for the individual patient's perception of the birth experience and labor pain or discomfort may be considered for future guidelines (Lim, et al. 2018). The physiological impacts of pain and stress on the psychological well-being need to be considered to provide holistic care to all labor patients.

The study "Pharmacological and Non-Pharmacological Methods of Labor Pain Relief-Establishment of Effectiveness and Comparison" validated the efficacy of epidural analgesia/regional analgesia (n=42). Pain relief was obtained during all three stages of labor when compared to the alternative techniques. The alternative techniques included:

water immersion and birth (n=40), inhaled nitrous oxide gas (n=40), transcutaneous nerve stimulation (n=50), multiple management (n=42) and no intervention (n=44). During the first stage of labor, no difference was demonstrated regarding pain perception between the epidural and inhaled nitrous oxide group. As a result of evidence-based inquiry, the belief that regional analgesia [epidural and combined spinal epidural (CSE)] is the “gold standard” for pain management during labor was upheld. Although the findings support regional analgesia administration, the highest satisfaction was reported by participants experiencing water births (Czech, et al. 2018). The latter finding raises the question of what factors may contribute towards the greatest satisfaction in the water birth group and identifies a gap in the research, warranting further research.

Race Inequality in Epidural Use and Regional Anesthesia

Racial and ethnic disparities have been reported in birth outcomes, cesarean birth, labor induction and epidural acceptance and administration. The study, “Race inequality in epidural use and regional anesthesia failure in labor and birth: An examination of women’s experiences” is a qualitative study of race and the correlation between epidural use, availability of administration and failure of analgesia or anesthetic techniques (epidural or spinal) during labor and cesarean birth. The sample size was small (n=83) non-randomized and not generalizable. Important parameters measured in the study applicable to our research are epidural use, “pressure” to accept, and the initial intention to receive regional analgesia or epidural for pain management upon admission (Morris & Schulman, 2014).

Access to care was identified as an issue, in my experience I have not encountered the inability to receive regional analgesia based on race. The access to care and administration was equal for all patients presenting at the institution where I work and the institution where I trained. The barriers identified from my personal experience as a Certified Registered Nurse Anesthetist specializing in Obstetrical Analgesia are related to preferences to alternative modalities (Doula services, Lamaze, hypnobirthing), misconceptions or myths, and lack of patient education (Tan et al., 2018). I support the use of alternative modalities as a form of pain management and encourage all patients and practitioners to evaluate all the information available to promote positive outcomes. According to Alakeely, et al., (2018) the number of labor patients planning to receive epidurals increased as the result of educational materials presented by a health educator.

Pain management was received in 83% of laboring women in the United States as reported in the article dated 2014. Accounting for 62% of all techniques, the most common form of analgesia was labor epidural (Morris & Schulman, 2014). The rate of neuraxial analgesia has recently been reported to reach as high as 93% in one institution, above the national average (Toledo, et al., 2016). Labor patients experiencing vaginal delivery and rates of epidural administration are as follows: Non-Hispanic white women, 74%; African non-Hispanic, 63% and Hispanic, 69%. The gap between epidural/neuraxial analgesia administration has narrowed from earlier studies, demonstrating improvement in the delivery of services by providers. Educational components were not discussed as part of the study.

Another study cited in the article by Osterman and Martin examines 2008 birth certificate data for 27 states and found similar disparities, 68.6% of white women compared to 47.7% of Hispanic women. The data examined in this study is dated and did not address the cultural beliefs of different ethnic groups and their willingness to accept regional analgesia or intravenous medications for pain management. The study assumed that all women desired analgesia and subsequently the findings may not provide full representation of acceptance and patient satisfaction experienced today. The percentage of Hispanic parturients increased from 47.7% to 69%, decreasing the gap from 20.9% in 2008 to 5% in 2014 (Morris & Schulman, 2014; Toledo et al., 2016). The desired outcome for our project is to obliterate the disparity that exists today and improve patient satisfaction.

The qualitative study included a component of persuasion for receipt of the epidural and indicates a deficit regarding the educational component and health literacy among the patient population, and the right to informed consent. The feeling of persuasion by the labor patients may contribute towards dissatisfaction with care, but patient satisfaction was not directly measured. The sample size was small (n= 83) (Morris & Schulman, 2014). The objective for my research is to provide information in the primary language to facilitate patient-centered care and informed decision-making by labor patients. The Institute of Medicine reported on the “chasm” or gap between optimal care and actual healthcare received. Patient-centered care is 1 of the 6 domains of quality (Davis, et al., 2005). The intervention “Video-Based Education on Neuraxial/Labor

Analgesia for Labor Patients in Native Languages” narrows the information gap for our targeted population and possibly all labor patients.

Upon review of “Racial and Ethnic Disparities in Mode of Anesthesia for Cesarean Delivery,” a correlation exists with labor patients or parturients and labor analgesia (epidural or CSE). The study identified the national rates for Cesarean delivery (CD) were higher among African Americans (35.8%) and Hispanic women (32.2%). Disparities exist regarding an increased incidence of CD and an increased incidence of general anesthesia for both African Americans and Hispanic women. The final sample size for the study included 50,974. The sample comprised of Caucasians, 21,113 (41.4%), African Americans, 12,990 (25.5%), Hispanics 12,990 (25.5%) and remaining nationalities 2,533 (5%). The administration of general anesthesia was more prevalent for African American (11.3%) compared with Hispanics (5.8%) and Caucasians (5.2%) (Butwick et al., 2016). Therefore, the Cesarean Section rate was higher for minorities as compared to Caucasians and the incidence of GA was higher for minorities overall as compared to Caucasians. The rate for Hispanic women was only slightly higher than Caucasians, but video-based educational programs may be expanded to include all demographics and underserved populations upon successful implementation and improvement of patient satisfaction secondary to video-based education during labor.

The sample size of 50,974 was large, control and adequate outcomes were demonstrated. The findings were definitive, and recommendations were based on literature reviews. The criteria fulfilled the requirements for Good quality according to the Evidence Level and Quality Guide and Level III (Dang & Dearholt, 2018). Regional

anesthesia techniques include spinal anesthesia for Cesarean section and epidural or combined-spinal epidural for labor. The reasons for acceptance versus refusal of either technique for either route of delivery would be similar, therefore the findings from the study are applicable my research.

Barriers to Neuraxial Analgesia during Labor: Demographics and Health Literacy

The examination of state-level variation and use of neuraxial analgesia revealed a twofold difference between the lowest prevalence in Maine (36.6%) and the highest in Nevada (80.1%). Patient level factors were considered and the statewide variation attributable to the state was 5.4%, therefore narrowing the difference. The patient level factors considered based on previous findings are race/ethnicity, insurance type, and level of education (Butwick, et al., 2018). The underlying factors of race/ethnicity and level of education that may contribute towards health literacy appear to be a reoccurring theme for the acceptance of neuraxial analgesia for pain management in labor, but many other contributing factors exist such as access to care. Therefore, from the multiple barriers presented, our original center of attention was drawn towards ethnic/race inequality. Based on this knowledge, our focus may include all labor patients presenting for delivery that meet our criteria for inclusion. Therefore, future insight to all obstacles for acceptance of regional analgesia and satisfaction will enable providers to develop interventions and programs to improve delivery of healthcare.

The retrospective cross-sectional study included 2,625,950 women experiencing labor before birth includes a very large population. Comparing Non-Hispanic whites (n= 1,409,509) 1,081, 556 or 76% women received neuraxial analgesia and Hispanic (n =

613, 435) 401, 407 or 65% received neuraxial analgesia. The Hispanic sample was not identified as English or non-English speaking. Reduced rates of neuraxial analgesia during delivery are associated with the following Sociodemographic factors: older maternal age, nonwhite race and Hispanic ethnicity, no private insurance or no insurance, late or no pre-natal care and less than high school education (Butwick, et al., 2018). Further investigation is warranted with more specific criteria for the possible barriers and satisfaction with healthcare and pain management.

The study did not determine why the variation exists among states, but the correlation between rural populations and low neuraxial administration rates were realized in Maine, Arkansas, Vermont, and Mississippi. (Butwick, et al., 2018). Access to healthcare in rural communities including obstetrical and anesthesia services resulted from hospital closures, workforce shortages and social determinants of health. Thus, contributing to decreased maternal health care access for rural labor patients, including minorities (CMS.gov, n.d.). The correlation between the number of providers (anesthesiologists or Certified Registered Nurse Anesthetists) per 1000 births was not revealed as part of the study (Butwick, et al., 2018). Access to care for some labor patients may result in seeking care outside of their communities for delivery, presenting challenges for providers in urban communities, including South Florida. Non-English-speaking migrant workers will be provided delivery services without pre-natal care and lacking health literacy. The responsibility of providers is to provide patient-centered care and education, despite the multiple contributory factors obstructing access to quality healthcare.

Neuraxial Labor Analgesia Use

The study, “Education Program Regarding Labor Epidurals Increases Utilization by Hispanic Medicaid Beneficiaries: A Randomized Controlled Trial” (Togioka, et al. 2019), meets the criteria for Level I secondary to the randomization of subjects for experimental studies (Dang & Dearholt, 2018). The sample size (200) was adequate for the study design. Results were presented clearly, recommendations consistent and supported by a comprehensive and current literature review, supporting High quality evidence. The Johns Hopkins Evidence-Based Practice Research Evidence Appraisal Tool guided the appraisal of evidence (Dang & Dearholt, 2018). An increase in the frequency of epidural administration was 33% higher (40 out of 50) in the treatment group of Hispanic patients receiving the education program compared to the routine care or control (30 out of 50). Results obtained from the study support the hypothesis that an increase in epidural acceptance for analgesia was increased secondary to the educational program intervention and the elimination of misconceptions. The Hispanic group was primarily Mexican and not a heterogeneous group of Hispanic or Latino descent (Togioka, et al. 2019). The publication of the article supports further investigation and the implementation of video-based education, epidural acceptance, improving patient satisfaction and positive outcomes as final goals of the intervention.

In the study, “The effect of epidural education on Primigravid Women’s decision to request epidural analgesia: a cross-sectional study,” the number of pregnant women planning to receive epidurals increased after patient specific educational materials were presented by a health educator during labor, (before education, 2.12+/- 0.578 vs after

education 2.27 \pm 0.592). The study is a qualitative study and Level III and good quality. The sample size was adequate, some control and results were reasonably consistent (Dang & Dearholt, 2018). The findings were not comparable with previous studies, demonstrating older age, partner preference and higher socio-economic status as predictors for requesting epidural analgesia. The demographics in Saudi Arabia are not as diverse as compared to other countries, including the United States. The provision of healthcare is provided by their government for all citizens. The necessity for continued exploration of the clinical issue was reinforced by the positive impact fostered secondary to the initiation of a formalized educational program initiated as a part of the study (Alakeely, et al. 2018).

The study, “Primary Spoken Language and Neuraxial Labor Analgesia Use Among Hispanic Medicaid Recipients” is a 3-year retrospective, cross-sectional study conducted at a single institution. Nulliparous Hispanic women self-identified as primary Spanish-speaking were included in the study and the sample size (n=182) were included from 932 Hispanic women identified. The population studied is similar to the current study on video-based education conducted at our institution. I can regularly identify women presenting at my institution that have delivered without regional analgesia in their native countries and otherwise will meet the inclusion criteria. The problem identified by the authors is the utilization of regional analgesia is less among Hispanic women compared to non-Hispanic Caucasian women. The study is the first to address both the intention to receive regional/neuraxial analgesia upon admission and actual administration during labor. Non-English speaking Hispanic women anticipated receipt

of neuraxial analgesia 30% less and administered 12% less than English-speaking Hispanic labor patients. Language based disparities have been identified in healthcare and the intent of the research is to identify the determinants of the language-based disparities (Toledo, et al., 2016).

The data collection was from a large urban center (894 inpatient beds), Northwestern Memorial Hospital (Northwestern Medicine, n.d.). Labor patients admitted to the hospital are met by a member of the anesthesia department, provided regional/neuraxial analgesia counseling and interpreter services are available 24/7 by telephone. Therefore, the rate for the receipt of regional/neuraxial analgesia at the institution is 93%, reported to be “much” higher than the national average. Although 96% of patients requesting regional/neuraxial analgesia or epidurals were administered during labor (Toledo, et al. 2016). Although our hospital (672 beds) and the labor and delivery department delivery volume is lower, the Department of Anesthesia utilizes the same interventions and additionally provides translation from a member of the anesthesia care team or nursing staff when available.

The results observed were consistent and revealed a lower incidence regarding the anticipated and actual utilization of neuraxial analgesia for pain management among non-English speaking Hispanic patients. The limitations included in the report acknowledged that the access to information and health literacy regarding neuraxial analgesia was unknown for the population during the decision-making process to receive or not receive the intervention during labor. The only independent factor decreasing the anticipated or actual receipt of neuraxial analgesia was care managed by a midwife (Toledo, et al.,

2016). The practice model at our institution is a physician driven practice with Board Certified OB/GYN's and residents. Midwives are not routinely involved with care provided to our patients unless the patient was transferred from a birthing center or home as the result of failed delivery attempt. Our service welcomes doulas for the support of the patient desiring alternative delivery methods, but the OB/GYN will perform the birth of the neonate at time of the delivery.

The pain interventions utilized by midwives include psychological care, sacral massage and deep breathing. Many midwives view labor pain as normal and the support for the utilization of neuraxial analgesia by midwives is not promoted as the front-line intervention for pain management (Aziato, et al., 2017). The national survey of the members of the American College of Nurse-Midwives conducted in 1998 revealed, “the majority (53%) of respondents had a negative attitude towards the increase use of neuraxial analgesia in midwifery practice and 53% of respondents agreed that experiencing labor pain was a valuable experience for most women.” (Toledo, et al., 2018). The survey was completed in 1998 and may reflect older views of practice. The American College of Nurse-Midwives website was accessed. The site included a position statement to eliminate racism and racial bias, the Joint Statement with ACOG regarding collaborative practice management, epidural use for pain management and epidurals in the 2nd stage of labor. No official statement regarding neuraxial analgesia was observed and alternative pain measures were promoted (American College of Nurse Midwives, 2018).

Pain management and resultant patient satisfaction are important aspects for the delivery of patient-centered care. Pain is subjective and perceptions are both physiological and psychological necessitating intervention (pharmacologic and/or nonpharmacologic). Labor pain is recognized as intense pain and likely to be considered as the “worst” pain experienced. Pharmacological (neuraxial and opioid administration, intravenous or intramuscular) and non-pharmacological methods should be options and the risks and benefits addressed by the provider(s) for informed decision making by the patient. According to Thompson et al., (2019), effective pain relief does not always correlate to patient satisfaction during labor. “Women’s experiences of pharmacological and non-pharmacological pain relief methods for labour and childbirth: a qualitative systemic review” identified twenty-four good quality studies (instrument developed by Walsh and Downe and modified by Downe, Walsh, Simpson & Steen) for review and the GRADE-CERQual tool was used (Thompson et al., 2019).

The data collected followed the PRISMA reporting for systematic reviews and identified the following studies for inclusion: epidural (n=12), opioids (n=3), relaxation (n=8) and massage (n=4) and (n= 1507) women in total. Their experiences were compared regarding the similarities and differences between all methods. Five elemental themes predisposing to the decision for choosing pharmacological or nonpharmacological techniques materialized:

1. Desire for pain relief, rationales for both pharmacological and non-pharmacological methods
2. Impact on pain, the method’s effectiveness

3. Influence and experience of support, positive and/or negative experiences with support from providers or partners/ family/friends
4. Factors influencing capabilities
5. Effects on health and wellbeing (Thompson et al., 2019).

The latter study was conducted to support the guidelines on pain relief for the World Health Organization (WHO) recommendations for positive experiences during labor and patient centered care (Thompson et al., 2019). According to the WHO, “Epidural analgesia is recommended for healthy pregnant women requesting pain relief during labour, depending on a woman’s preference.” The WHO recommendation on labor epidural analgesia for pain management was based on 43 trials. Seven trials (n= 897) women comparing epidural with no epidural or placebo did not demonstrate whether epidural compared to no epidural reduced pain scores, but a single study produced low certainty evidence that epidural analgesia may increase satisfaction with pain management during labor. Qualitative studies revealed the receipt of information for decision making, opportunity to decide, and the resultant benefit of effective epidural analgesia promotes a positive birth experience (WHO, 2018).

The understanding of the dynamics that occur during labor both physically and psychologically to all populations of women are paramount and promote the basis for their study (Thompson et al., 2019). The five *themes* were considered and addressed for our educational program. Interventions for improved patient-centered care and patient satisfaction were the focus of the study on the effectiveness of video-based educational information on regional analgesia for pain management during labor. The population for

the study includes primary English speaking and primary Spanish speaking parturients, but the evidence may reveal improved outcomes for expansion to all demographics and eliminate disparities in care.

Patient Education and Improved Satisfaction

The nursing professional may fulfill their role of providing quality cost-effective healthcare through the utilization of technology including video-based education for patient education, increase access to care and satisfaction with care (Hassmiller, 2010). Mastrian & McGonigle (2017), define telehealth as a technology “to deliver health-related services or to connect patients and healthcare providers to maximize patients’ health status.” The increasing demands for access to care may be met by the implementation of telehealth applications to our population, especially regarding language barriers as an obstacle to care. The ability to provide educational information in the patient’s native language without the need for extensive translation by a translator or language line will promote operational efficiency and cost-effectiveness (Mastrian & McGonigle, 2017).

The study “Investigating determinants for patient satisfaction in women receiving epidural analgesia for labour pain: a retrospective cohort study” included a large population (n = 10,146) of parturients. The study revealed, 31.8% (n= 3230) of the patients were unsatisfied with their experience. Dissatisfaction was related to higher post-epidural pain scores, instrumentation for vaginal delivery, epidural replacement at advanced cervical dilatation. According to Tan et al., (2018), coping mechanisms and pain perceptions influenced by cultural differences may precipitate dissatisfaction as

evidenced by Chinese parturients 48.7% (n=1573) were not satisfied compared to Malay parturients 23.5% (n=760). Patients with dissatisfaction may be more reluctant to receive neuraxial analgesia for future pregnancies. The proposal for future research suggestions included further study of predictive models for risk factors and precautionary time-sensitive interventions (Tan et al., 2018). The study did not address patient education as an intervention to improve understanding for expectations as a result of neuraxial analgesia and/or increasing patient satisfaction

Upon review of “Telehealth and patient satisfaction: a systematic review and narrative analysis,” 44 studies were identified from the Cochrane Library meeting the criteria for satisfaction, effective and efficient. Patient views on effectiveness (24), patient satisfaction (14) and both (14) were identified. The authors concluded that patient satisfaction can be associated with telehealth, findings for effectiveness and efficiency were varied. The study acknowledged benefits of telehealth included: ease of use for patients and providers, increased communication, high quality service, access to care, and good educational modality.

The studies included for a relevant systematic review included various modalities for telehealth and the focus was broad. In addition to the scoping review “The impact of the use of video-based educational interventions on patient outcomes in hospital settings” (Dahodwala, et al., 2018), the information generally supports technology as a modality for patient education, improving satisfaction, health literacy and outcomes. The population of interest, non-English-speaking Hispanic parturients was not specifically addressed, but long-term goals are to include women across all demographics. The

necessity for further research for possible barriers to care and satisfaction was demonstrated (Dahodwala, 2018).

The study, “Preoperative patient education: can we improve satisfaction and reduce anxiety?” implemented an educational handout in English and Spanish. The findings included higher satisfaction with understanding of the type of anesthesia (4.15 vs. 4.45, $p = 0.0028$), options for pain management (3.98 vs. 4.33, $p = 0.0027$), and sum of the information regarding was higher (4.31 vs. 4.60, $p = 0.0038$) for English and Spanish participants. Increased patient satisfaction was realized but no significant difference seen for the reduction of anxiety associated with surgery (Ortiz, et al., 2013). This study provides a foundation for the efficacy of video-based educational materials in the patient’s native language improving health literacy and patient satisfaction and supports video-based education for all English and non-English speaking populations.

Upon review of the study, “Education Program Regarding Labor Epidurals Increases Utilization by Hispanic Medicaid Beneficiaries: A Randomized Controlled Trial” the population and interventions provide a foundation for the study of video-base education and effectiveness on patient satisfaction for non-English speaking Hispanic labor patients. The authors revealed a 33% increase regarding epidural administration comparing the control group and intervention group during labor. Results obtained from the study support the hypothesis that an increase in epidural acceptance for analgesia was increased secondary to the educational program intervention. The Hispanic group was primarily Mexican and not a heterogeneous group of Hispanic or Latino descent (Togioka, et al. 2019). The publication of the article supports further investigation and the

implementation of video-based education, epidural acceptance, improving patient satisfaction and outcomes as final goals of the intervention.

The effectiveness of video-based education on the perceptions of surgery among obese and diabetic patients demonstrated an improved patient's perception secondary to the introduction of an educational video. The study, "Efficacy of video-based education program in improving metabolic surgery perception among patients with obesity and diabetes" is a prospective interventional study utilizing the video-based educational program to increase health literacy and reduce fears regarding the efficacy and safety of metabolic surgery. The results were an increase from 22.5% to 53.1% ($P < .01$) regarding positive impression of the surgical procedure and 41.7% to 51% increase for interest in surgical consultation. Barriers for the remaining individuals were revealed: fear of surgery (31.4%), safety of surgery (27.5%) and cost (27.5%) (Juo, et al., 2018). The findings may be applied to different populations of patients presenting for procedures including labor patients presenting for epidural or combined spinal-epidural for pain management.

Misconceptions surround healthcare delivery in general and the specialty of Obstetrics is no exception. Toledo et al., (2016) reported that 75% of women concerned about back pain with epidural analgesia were Hispanic and language barriers may predispose to decreased health literacy. The concern of neuraxial analgesia or epidural placement in early labor may predispose to the need for cesarean delivery is voiced by patients and the reported information is related to findings from observational studies. Studies referenced may be dated, but the information is published on websites and

internet blogs. Randomized control trials (3) and A Cochrane review of 20 trials agree that the risk was non-contributory or low (Hawkins, 2010). The updated Cochrane review conducted in April 2017(40 trials versus 20 trials) confirmed “little or no difference” in cesarean delivery, chronic back disorders, and side-effects on newborns (Anim-Somuah et al., 2018). Side-effects of the procedure are explained and addressed routinely during the anesthesia pre-operative assessment phase.

The retrospective study, “Preferred spoken language mediates differences in neuraxial labor analgesia utilization among racial and ethnic groups” (n=3129), supports quality improvement projects targeting native language, health literacy and patient satisfaction as evidenced by their findings. Neuraxial labor utilization was reduced for Hispanic ethnicity (0.77, 95% CI 0,61-0,98) and multiparous patients (0.59, 95% CI 0.51-0.69) without a dependent association. The reductions in receipt of neuraxial analgesia were not a factor with rate of administration after the “preferred” (native) language was controlled. The data was retrospective and compared the utilization of neuraxial analgesia (epidural or combined-spinal epidural) with self-reported Hispanic patients identified as English or non-English speaking (Caballero, et al., 2013). The study gives support for the introduction of preferred or native language health information in all settings. The study introduced a video in the native language and measured the effects on patient satisfaction post-partum. Our intervention translated evidence-based research into practice.

Video-based education using a smart pad for patients receiving bone marrow biopsies demonstrated an improvement in educational satisfaction and reduced uncertainty among the patients. The findings, increased satisfaction with the experimental

group (34.09) and the control group (30.70) was statistically significant ($t = -3.08$, $p = .003$). The study, “Effects of Video-Based Information Provision Using a Smart Pad on Patients Undergoing Bone Marrow Biopsy” reports that patient-centered or individualized care is attained through the ability to provide specific educational materials through a medium conducive to repeated viewings secondary to the availability of the video on the smart pad. The interventions for the randomized control study on patient satisfaction included a Smart Tablet. The need for effective and accessible health education for patients receiving care in a time sensitive manner allowed the findings from the bone marrow patients to be generalized to our population, parturients or labor patients.

Video-based education in Native Languages provided on Smart Tablet and verbal explanation of regional anesthetic techniques provided the data to evaluate care and enable a continuous quality improvement program for providers (White, et al., 2016). As a result of the review of the literature, the population for future study may be expanded to include all labor patients presenting for labor. The development of future educational videos may include several languages: English, Creole/French, Portuguese, Russian, and sub-titled for the hearing impaired. The scope of future projects will require further analysis of all cultures presenting to our service to determine need. The implementation of video-based educational information on regional anesthesia will increase labor patient satisfaction scores receiving regional/neuraxial analgesia for labor pain. The intervention was intended to improve patient understanding of neuraxial analgesia, satisfaction with care and outcomes.

PICO Clinical Question

P - Women presenting for labor induction and vaginal delivery are candidates for the receipt of regional /neuraxial anesthetic techniques (epidural or combined epidural-spinal)

I - Video based education in native languages on neuraxial/labor analgesia provided on Smart Tablet, accessed at the completion of the anesthesia providers' pre-operative assessment and subsequent verbal clarification of regional anesthetic techniques

C - Current Practice, (interview and in-person patient education during anesthetic assessment)

O - Increased patient satisfaction and outcomes as the result of video-based educational Information provided in native language (English and Spanish)

Primary DNP Project Goal

The Primary DNP Project Goal was to provide patient centered care and improve patient satisfaction with the development of a video-based educational program on neuraxial/regional analgesia for the labor patient. A standardized multimodal approach allowed accurate information on the subject to be reviewed by the patient and promoted understanding and health literacy for informed decision-making. The focus of the program and video included the specific advantages and disadvantages of neuraxial/regional analgesia. A summary of alternative methods included full disclosure of options for pain management. Improved patient outcomes, increased health literacy, decreased anxiety and increased patient satisfaction were demonstrated as the result of video-based education in 60% of the studies reviewed in the study, "The impact of the

use of video-based educational interventions on patients in hospital settings: A scoping review” (Dahodwala, et. al. 2018), therefore supporting the goal.

The gap between the translation of evidence-based practice and delivery of care has been addressed by the Institute of Medicine’s “Crossing the Quality Chasm: A New Health System for the 21st Century. The deficiencies and inefficiency of care may contribute to costly, harmful and ineffective care. (White, et al., 2016). The ability to improve communication through technological advancements (video-based education) facilitates and enhances the dissemination of information in a timely and cost-effective manner. The delivery of health information in native languages promotes health literacy in our population of women presenting for labor.

A definition of health literacy provided by the U.S. Department of Health and Human Services (HHS) includes the ability of individuals to make health decisions as the result of the receipt and comprehension of basic health related information. The basic elements identified are the receipt of written health related information, accurate interpretation of information and patient-provider communication (Healthypeople.gov, n.d.). The project advances the current practice from verbal and/or written information as the primary method for patient education and translates the utilization of video-based education at the point-of-care.

Health literacy is essential for patient engagement and participation. Patient participation and mutual goal setting with healthcare providers for analgesia is a component of patient-centered care. The middle-range theoretical framework “Pain: A

Balance Between Analgesia and Side Effects” provides insight into the dynamics surrounding labor analgesia and patient satisfaction. The discussion is presented below.

Objectives

SMART represents specific, measurable, attainable, realistic and timely objectives. The attainment of the objectives should ultimately support the progression towards your goal(s). The desired outcome may involve more than one goal and the identification of objectives for advancement of your goals may require prioritization (Zaccagnini & White, 2014).

Specific – The PICO states the explicit improvement process, population, and setting.

Measurable – Addition of questions to existing format for post-procedural rounds will be implemented after approval by the Internal Review Board (IRB) and the Department of Anesthesia. Data will be collectable and retrievable through EPIC.

Attainable and Realistic – The project is feasible secondary to the availability of staff to perform intervention as part of the existing assessment and patient education process. The facility is a research/teaching institution and recruitment of Student Registered Nurse Anesthetists (SRNAs) and anesthesia residents will facilitate data collection. The intervention will provide patient centered care and promote increased patient satisfaction with pain management.

Timely – The project will be accomplished in the time allotted, continued as the method of patient education and possible adoption as a guideline.

Definition of Terms

Labor: physical activities involved during the birth process, including dilatation of the cervix and contraction of the uterus. The process of delivering the baby and placenta (Merriam-Webster, 2020).

Parturient/Labor Patient: a pregnant woman, a woman in labor and ready to give birth

Pain Management: the delivery of medical care that relieves or reduces the intensity of pain or discomfort (Shiel, 2018).

Labor Analgesia/Anesthesia: pain relief options for labor, ranging from pain medications or narcotics to nerve blocks, including epidural, combined spinal-epidural, and spinal anesthesia

Obstetrical Analgesia/Anesthesia: same as labor analgesia

Neuraxial Analgesia/Anesthesia: Epidural, combined spinal-epidural, spinal anesthesia

Regional Analgesia/Anesthesia: same as neuraxial analgesia

Epidural Analgesia: a reduction in pain as the result of the injection of a local anesthetic with or without a narcotic into the epidural space. The blocking of nerve impulses from spinal segments creates less sensation or numbness from the site of injection and caudad or below the level of injection.

Combined Spinal – Epidural Analgesia: the introduction of a spinal needle through the epidural needle during epidural placement and the injection of a spinal dose of local anesthetic to create a shorter onset of analgesia.

Patient Satisfaction: the level of happiness with healthcare and effectiveness of care (Heath, 2016).

Video-based Education: use of audio-visual recordings and technology for the expansion of knowledge (IGI Global, n.d.).

Health Literacy: the ability of individuals to access, understand and utilize health information to make informed decisions for health promotion (WHO, n.d.)

Native-Language: the language that someone speaks primarily or the language spoken in the country of birth (Collins Dictionary, 2020)

Healthcare Disparities: preventable differences or opportunities to attain optimal health and health outcomes experienced by individuals or populations secondary to social disadvantages, including race and ethnicity (CDC, 2017).

Healthcare Utilization: access and use of services for disease prevention, health promotion and treatment of health-related conditions (Carrasquillo, 2013).

Race: a family, tribe, people or nation belonging to the same stock, sharing certain physical traits (Merriam-Webster, 2020)

Ethnicity: specific ethnic affiliation or group, ethnic quality (Merriam-Webster, 2020)

Conceptual Underpinning and Theoretical Framework

The AGREE II tool was utilized to determine the quality of the evidence and guideline formulation for translation of the findings into the clinical setting. The appraisal process included 2-4 appraisers to review the final guideline, identify limitations and implement quality guideline(s). The Agree II tool contains 6 quality domains (scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability and editorial independence) with 23 items addressing practice guideline quality. The manual, reporting checklist and training videos are available online (AGREE II, n.d.). The appraisers reviewed the AGREE II Manual and utilized the AGREE II checklist, a link was provided at the team member orientation and discussed at the subsequent meeting.

The middle range theoretical framework, “Pain: A Balance Between Analgesia and Side Effects” guided our efforts to demonstrate increased patient satisfaction as the result of understanding non-pharmacological and pharmacological options for pain management. The purpose of the study is to increase health-literacy to provide knowledge, promoting patient engagement and informed healthcare decision-making. The three principles of acute pain management or prescriptive propositions are incorporated as the existing standard of care for patients presenting with acute labor pain, including attentive care, multimodal interventions, and patient participation. The balance between analgesia and side-effects is the goal or desired outcome achieved secondary to the three prescriptive propositions or principles outlined by the theory (Peterson & Bredow, 2017).

The assumptions of the theory, the balance between analgesia and side-effects were considered during our study. The assumptions included:

1. Acute pain management is a collaboration between providers (nurses, obstetricians, anesthesia providers and doulas)
2. Intravenous opioid analgesics or epidural opioids/local anesthetics administered p.r.n.
3. Side-effects are treated with appropriate medications
4. The majority of our patient population is comprised of the adult learner (occasionally we have a younger patient, and our teaching may be tailored accordingly). As the result of health literacy, the increased capacity to communicate, learn and set health care goals are facilitated.
5. The Nursing Staff and healthcare providers are knowledgeable regarding pain management techniques, pharmacological and non-pharmacological (Peterson & Bredow, 2017).

Studies have demonstrated the superiority of neuraxial/labor analgesia but the correlation between patient satisfaction and adequate analgesia during labor have not always been demonstrated. The study, “Investigating determinants for patient satisfaction in women receiving epidural for Labour pain” demonstrated lower satisfaction scores as the result of instrumentation for vaginal delivery and epidural placement at advanced cervical dilatation. The introduction of an educational component may alleviate patient dissatisfaction as a result of increased knowledge and health literacy regarding alternatives for pain management, timing of pain management techniques, and

expectations during the labor and delivery process. Interventions were not be limited to the two experiences reported in the previous study. The study “Improved patient satisfaction as the result of video-based education on neuraxial/labor analgesia in native languages for labor patients” addressed the identified *gap* in nursing practice, created a guideline and improved clinical practice.

Methodology

Setting, Participants, and Project Procedures

The prospective randomized control study was conducted at a single institution in the Department of Labor and Delivery and postpartum unit for a 10-week period. Implementation and data collection included labor patients anticipating a vaginal delivery, based on their plan of care outlined by their Obstetrician and agreed upon by themselves. Included for the study were the scheduled inductions and parturients experiencing early labor with pain rated <4 out of 10 on a numeric pain scale. Patients testing positive to COVID-19, experiencing the onset of labor before induction and individuals refusing to participate were excluded from the study.

Data collection included age, gravida/para status, and patient satisfaction with educational method and epidural administration for pain management. Recruitment was performed by one of the team members upon admission to the Department of Labor and Delivery. Consent was obtained by the co-investigators, whereby the consent and HIPAA forms were presented and explained. The video-based intervention and data collection was performed by the CRNA, Anesthesiologist, Student Registered Nurse Anesthetist and Anesthesia Resident assigned to labor and delivery for the shift. Patients self-

identified the preferred language with the registered nurse upon admission to the department. The identification of the preferred language is part of the patient admission questions and did not create a documentation burden for the nurses. The anesthesia provider confirmed with the registered nurse and patient the preferred language and preferred or anticipated pain management techniques during the anesthetic assessment phase. The findings were documented in EPIC in the patient history section to determine which video to be presented for the intervention group.

The program structure utilized a team approach for the roles, responsibilities, and tasks. The coordinator was be mentored by a Doctoral prepared faculty member and a board-certified physician at the clinical site. The coordinator met weekly with both mentors to review interventions and progress of the study during the first month of implementation. Subsequently, the meetings were reduced to bi-monthly secondary to satisfactory review by the mentors. Videos produced in native languages (English and Spanish) to promote health literacy and increased patient satisfaction were utilized. The videos were downloaded onto an Amazon FIRE tablet for viewing. A long-term goal is the hospital administration approval of future patient access to the program through the hospital channel or website.

Anesthesia providers participated in the study as part of the execution of the routine care of the parturient including: pre-operative assessment, patient education and post-procedural rounds. The intervention was a non burdensome addendum to the existing work flow of the anesthesia provider. The providers included the Certified

Registered Nurse Anesthetists (CRNAs), Board-Certified Anesthesiologists, SRNAs and anesthesia residents assigned to Labor & Delivery.

Preliminary meetings with the Chief Anesthesiologist for Labor & Delivery and Clinical Coordinator were held and support for the project was positive, pending approval by the IRB. Orientation was provided to the SRNA and resident once a month. The orientation for team members and in-service program for the nursing staff on both shifts were conducted before the program launch. The coordinator performed rounds with each team member obtaining data on their first day to ensure accuracy of results. Data collection was performed by team members and data entry for analysis by the coordinator with oversight by the mentors.

SWOT Analysis

The SWOT analysis was utilized to provide a systematic guide for identification of systems for development or improvement and allocation of personal, physical and intellectual resources within healthcare organizations and business establishments (Blayney, 2008). Quality improvement directed towards educational programs improving patient satisfaction may be accomplished secondary to the introduction of video-based platforms. The acronym “SWOT” is defined as: Strengths, weaknesses, obstacles and threats and the analysis proved beneficial to project guidance (Zaccagini & White, 2014).

The Department of Labor and Delivery coordinates care between several departments to provide care for expectant mothers, newborns, and women post-partum until transfer. The departments include anesthesia, nursery, postpartum and emergency. Anesthesia providers are assigned to labor and delivery on a 24/7 basis, with multiple

providers on the dayshift and one CRNA on nightshift and weekends. As a result, a cohesive relationship has developed between the providers and may be viewed as the major strength. The department is not large and comprises 12 labor rooms, 2 antepartum rooms and 3 operating rooms. Access to participants were onsite and the size and volume of patients were manageable for our study.

The team members and nursing management were experienced, knowledgeable, approachable and supportive for improvement of patient care. The introduction of the project required enlistment, recruitment and retention of subjects and personnel. The identified stakeholders with interests in the outcome were the patients, IRB, Chief Anesthesiologist, Director of Labor & Delivery, Clinical Coordinator, anesthesia and nursing staff and respective professional organizations (Moran et al., 2020). Strengths were realized with early stakeholder enlistment, and weakness resulted from time constraints and availability of personnel during the delivery of care. The dedication and willingness of patients and providers to embrace new methods was realized upon implementation and completion of the project. The SWOT analysis is outlined in Table 1 for review:

TABLE 1

Internal Factors	
<p style="text-align: center;">Strengths</p> <ul style="list-style-type: none"> • Research/teaching hospital • Affiliation with FIU • Doctoral prepared faculty • Dedicated, experienced leadership • Departmental/staff involvement & support, stakeholders enlisted early during planning phases • Coordinator & team members employed at clinical site • Optimizes resources to enhance patient centered care 	<p style="text-align: center;">Weaknesses</p> <ul style="list-style-type: none"> • New quality improvement project requiring approval and implementation • Internal Review Board approval necessary for implementation • Recruitment of participants/patients • Recruitment and retention of team members for study • Inability to control all variables
External Factors	
<p style="text-align: center;">Opportunities</p> <ul style="list-style-type: none"> • Subjects/participants onsite • Team members onsite for implementation of interventions and data collection • Data collection may be introduced as an addendum to an existing protocol: post-procedural rounds • Supportive management, team members, nursing staff and physicians • The incentive for providers to increase knowledge, health literacy and patient satisfaction 	<p style="text-align: center;">Threats</p> <ul style="list-style-type: none"> • Budget constraints and funding • Access to technological support • Competition for time/services of available personnel to support project. Introduction of video-based education and data collection • Acceptance of method by staff and patients • Sustainability of the project after implementation <p>(White et al. 2016)</p>

Protection of Human Subjects

The project met the stringent human research protection standards established by the U.S. Department of Health and Human Services Office for Human Research Protections at 45 CFR Part 46 by qualifying as exempt research under §46.104, where certain basic protections as contained in the project were met. Human subject research is exempt from complying with all provisions of this regulation if one of the following conditions is met:

(2) 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) if at least one of the following criteria is met:

- (i) 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;
- (ii) 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 subjects' financial standing, employability, educational advancement, or reputation; ...

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

- (A) 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;
- (B) 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 subjects' financial standing, employability, educational advancement, or reputation; ...

As explained in the Data Management discussion, no personal information was divulged regarding identities of the participants or individuals refusing to participate in the study. The consent provided reassurance to individuals that all treatment would not be affected by their participation or non-participation.

The patient benefited by being better informed of options available.

The nature of the study posed no risk to the patient.

The Data Management discussed data safety, and individual identities were not maintained because the surveys were placed into a plain white envelope to ensure confidentiality and anonymity. The study was approved by the IRB at Mount Sinai Medical Center, Miami Beach, Florida, and at Florida International University, Miami, FL.

Data Collection

The collection of data was obtained from the pre-operative assessment and the survey performed post-partum utilizing the 5-point Likert scale. The survey was anonymous and disclosed in the document without any identifying patient information attached after completion. The Mann-Whitney U test was utilized to compare patient satisfaction of the intervention group versus the control group.

The patient-centered survey questionnaire was completed by the patient during post-procedural anesthesia rounds routinely performed by members of the anesthesia care team. The assessment of mobility, absence of side effects and complications was currently assessed at that time and the additional introduction of survey questions was

facilitated secondary to the routine visit inherent to the present workflow of anesthesia providers. The anesthesia care team member collected the survey at the end of the rounding process allowing an opportunity for the patient to answer the survey and ask questions upon retrieval. The patient placed the survey into a plain white envelope to ensure confidentiality. The envelopes were placed in a locked mailbox in a secure locked office. The coordinator and principle investigators performed data entry and analysis.

The survey questions were formulated to assess the perception of the patient's understanding of pain management, including neuraxial analgesia or epidural/combined spinal-epidural and multiple aspects of patient satisfaction. The questionnaires were translated from English to Spanish for the primary Spanish-speaking subjects. Patient satisfaction was assessed utilizing the providers' delivery and quality of information for deduction, decision-making, epidural placement, and satisfaction with the introduction of the native-language video-based program for the intervention group. The questions were reviewed by lay mothers and healthcare providers specializing in obstetrical nursing and obstetrical anesthesia. The attempt to obtain relevant information in a concise format resulted in 6 questions for the control group (Table 2) and 7 questions for the intervention group (Table 3).

TABLE 2

 POSTPARTUM PATIENT SATISFACTION QUESTIONNAIRE
 (PPAQ-6)

The following questions are part of the study to determine the effectiveness and improve care provided to women during labor. No side-effects or harm will result from receiving or not receiving the intervention. Your participation in the survey is voluntary and anonymous. Our only interest is how you feel about your experience with pain management during your labor, there are no right or wrong answers. We appreciate your input and completion of the survey is your consent to participate. Congratulations on your new addition to the family!

Did you feel knowledgeable about pain control upon arrival to the hospital?	1-Strongly Agree	2-Agree	3-Neutral	4-Somewhat Disagree	5-Disagree
The anesthesia provider explained the options for pain control well.	1-Strongly Agree	2-Agree	3-Neutral	4-Somewhat Disagree	5-Disagree
The information received allowed me to make a better informed decision for pain control techniques.	1-Strongly Agree	2-Agree	3-Neutral	4-Somewhat Disagree	5-Disagree
I am satisfied with the information I received regarding pain control from the anesthesia team representative.	1-Very Satisfied	2-Satisfied	3-Neutral	4-Somewhat Dissatisfied	5-Dissatisfied
The epidural was helpful and Improved my experience during labor.	1-Strongly Agree	2-Agree	3-Neutral	4-Somewhat Disagree	5-Disagree
I would use an epidural for pain control for future deliveries.	1-Strongly Agree	2-Agree	3-Neutral	4-Somewhat Disagree	5-Disagree

TABLE 3

POSTPARTUM PATIENT SATISFACTION QUESTIONNAIRE (PPAQ-7)

The following questions are part of the study to determine the effectiveness and improve care provided to women during labor. No side-effects or harm will result from receiving or not receiving the intervention. Your participation in the survey is voluntary and anonymous. Our only interest is how you feel about your experience with pain management during your labor, there are no right or wrong answers. We appreciate your input and completion of the survey is your consent to participate. Congratulations on your new addition to the family!

Did you feel knowledgeable about pain control upon arrival to the hospital?	1-Strongly Agree	2-Agree	3-Neutral	4-Somewhat Disagree	5-Disagree
The anesthesia provider explained the options for Pain control well.	1-Strongly Agree	2-Agree	3-Neutral	4-Somewhat Disagree	5-Disagree
The information received allowed me to make a better informed decision for pain control techniques.	1-Strongly Agree	2-Agree	3-Neutral	4-Somewhat Disagree	5-Disagree
I am satisfied with the information I received regarding pain control from the anesthesia team representative.	1-Very Satisfied	2-Satisfied	3-Neutral	4-Somewhat Dissatisfied	5-Dissatisfied
I am satisfied with the information from the video on epidurals and pain control.	1-Very Satisfied	2-Satisfied	3-Neutral	4-Somewhat Dissatisfied	5-Dissatisfied
The epidural was helpful and Improved my experience during labor.	1-Strongly Agree	2-Agree	3-Neutral	4-Somewhat Disagree	5-Disagree
I would use an epidural for pain control for future deliveries.	1-Strongly Agree	2-Agree	3-Neutral	4-Somewhat Disagree	5-Disagree

Data Management

The data collection including age, gravida and para status was recorded at the time of consent. The review of the surveys completed and collected by a member of the anesthesia care team during the post-partum visit was completed weekly. The patient questionnaire was placed in a white self-sealing envelope and collected from the patient by team members. All team members attended meetings before implementation and a printed guideline was available for review. The coordinator accompanied each team member during the first encounter of postpartum visits and supervised weekly. The data was compiled in a file on one password protected computer by the coordinator.

Written consents and HIPAA forms were obtained and are stored in a locked file in a locked anesthesia office within the Department of Labor and Delivery for 5 years. Final data collection is stored on one computer by the coordinator and secured with password access, the information was not linked to the patient's identity secondary to the utilization of anonymous surveys. Statistical analysis was performed by the principle investigator after the completion of data collection by the team members. No personal information will be divulged regarding identities of the participants or individuals refusing to participate in the study. The consent and HIPAA form included the latter disclosure to provide reassurance to individuals that all treatments would not be affected by their participation or non-participation.

Discussion

Limitations

Execution of the SWOT Analysis before the onset of the study helped identify some of the obstacles encountered during the implementation. Initiation of the project was impacted by the delayed production of the videos (English and Spanish), approval by the Internal Review Boards, and funding. Recruitment of subjects was affected by the retention of team members for consenting of subjects, reduction of the census from prior years, and timing of the study during a pandemic. All factors contributed to the small sample size and were beyond our control.

The approval of our project by the Internal Review Boards at the University, and the clinical site was arduous. Despite early submission, approval was received in July 2020 from the clinical site and August 2020 from the University. The project length was proposed to be 4-5 months and the study period was reduced to 10 weeks. Thus, our sample size was reduced by at least 50% or half of our target. Despite enlisting stakeholders and meeting with research colleagues, the inexperience of a novice researcher will impact the navigation of the process for project approval and implementation, especially when seeking approval by two entities and recruitment strategies.

After exhaustive research revealed the difficulty to produce a video without hiring a professional service, the alternative concept was to introduce a PowerPoint for the video-based educational intervention. The PowerPoint was presented to stakeholders and staff. The PowerPoint Presentation and review of the Research Proposal by the Chairman of

the Department of Anesthesia, anesthesia providers and nurses contributed to additional support of the project. As a result of the renewed interest, the video was produced by an anesthesiologist and anesthesia providers as actors. The video production delayed the start of the research project, but the quality of the video surpassed that of the PowerPoint. The video production was delayed secondary to staffing schedules for filming onsite. The COVID-19 pandemic impacted work schedules with the reduction of hours for anesthesia providers, and therefore their availability for filming of video. We coordinated filming after completion of scheduled shifts, the availability of the Producer/Director (anesthesiologist), and staff when patient care was not required.

Survey completion by subjects recruited cannot be controlled, based on the patient's desire or willingness to complete. The anonymous written survey distributed postpartum was not always retrieved by the anesthesia providers on duty and reduced the retention of participants by 21%, number of participants recruited (n=66), number of surveys retrieved (n= 52). The retention of credentialed team members was reduced by 50% as the result of the CRNA scheduled on dayshift being replaced by an Anesthesia Resident rotating through the Department of Labor and Delivery. The sample size (N=52) was ultimately affected by the duration of the study, access to participants, retention of recruiters, and participation of participants for data analysis.

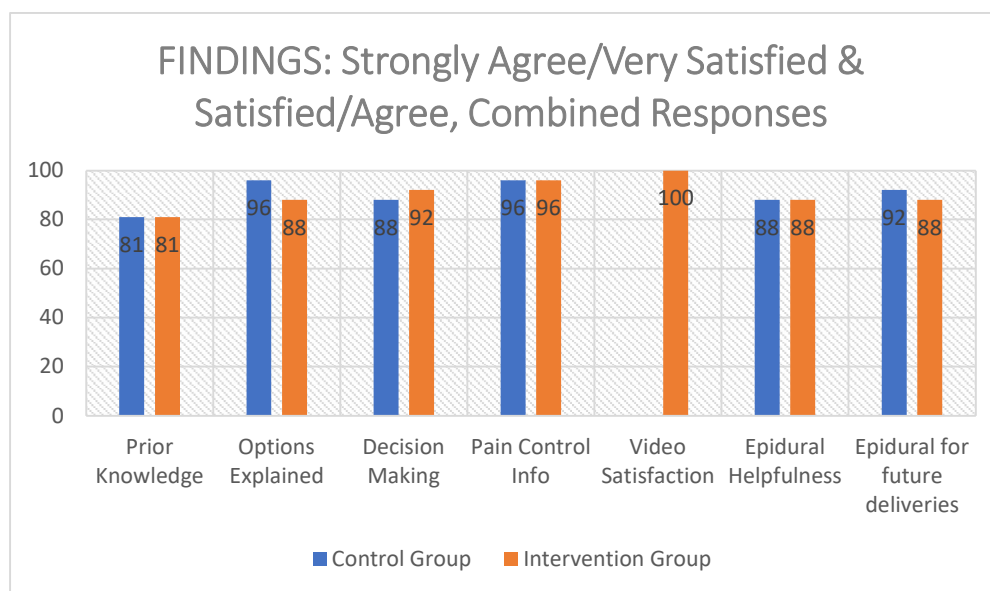
The project was funded privately limiting resources and recruitment of additional populations. The cost to translate consents by certified translators for the study and translators to produce videos in different languages were identified during the planning phase. The majority of patients cared for at our institution include English-speaking and

Spanish-speaking patients and are the sampled populations. Secondary to the video production limitations, the efforts produced a cost-effective educational tool in English and Spanish, providing standardized and accurate information on regional/neuraxial analgesia for labor patients. The study may be expanded for future studies across additional populations of labor patients and patient centered education to include but not limited to: Creole, Portuguese, Russian, Yiddish, Turkish, Chinese, Arabic and subtitled versions for the hearing-impaired labor patients.

Findings

The combined English and Spanish Cohorts sample size produced: n=26 (50%) Control Group and n=26 (50%) Intervention Group. The survey results (PPAQ-6 &7) for Strongly Agree/Very Satisfied and Agree/Satisfied (Figure 2) reveal: prior knowledge of pain control (81% CG versus 81% IG); Options for pain management explained well (96% CG versus 88% IG); Promotion of informed decision-making (88% CG versus 92% IG); Information regarding pain control from provider, (96% CG versus 96% IG); satisfaction with video (100% IG); Satisfaction with epidural and improvement of experience (88% CG versus 88% IG)and Epidural acceptance for future deliveries (92% CG versus 88% IG).

Figure 2



Advanced Nursing Practice Implications

Patient satisfaction reflects perceived aspects of patient care quality. Every individual will interpret their experience in a subjective manner. The ability to educate individuals regarding their care and increase health literacy may increase the patient's comprehension, acceptance, compliance and promote realistic expectations and improved outcomes. The study incorporated Donabedian's framework for the evaluation of health care quality utilizing structure, process, and outcomes. The structure included resources, staff, and finance. Our setting provided the resources and staff. The funding of the project was minimal secondary to the basic structure inherent to our team approach and anesthetic practice model at a single health care organization (Zaccagnini & White, 2014).

The process for our research was comprised of the delivery of information during the pre-anesthetic assessment. Upon completion of the history and physical, the

subsequent educational components included the verbal explanation of neuraxial/regional analgesia, or video-based education program. During the post-partum follow-up visit, an anonymous survey was presented to the subject to measure our outcomes. Our goal was to provide information, improve outcomes, and satisfaction with their experience during labor including pain management. In addition to the latter, the avoidance of using intravenous or systemic opioids for pain relief complies with the National Institute of Health's response to the opioid crisis through the advancement of pain management with access to high-quality evidenced based pain management alternatives, including epidurals and combined spinal-epidurals. Overall, establishment of standards of care and guidelines promote quality care evidenced by improved patient outcomes as the result of patient education and increased health literacy (Zaccagnini & White, 2014).

The Quality Improvement Project "Improved Patient Satisfaction as the Result of Video-Based Education for Regional/Epidural Analgesia in Native Languages for Labor Patients" addresses the "gap" in care and provides an opportunity to improve outcomes. Through interprofessional and intraprofessional collaboration of the anesthesia team members, obstetricians, and nurses, the data driven project provided evidence for improved nursing practice and outcomes. The findings from the research will facilitate the translation of the findings for improved practice guidelines (Moran et al., 2020). As providers we strive to deliver the best care possible secondary to the resources available. The video-based platform promotes the "Triple Aim" developed by the Institute for Healthcare Improvement (improved patient care experience, improved health of populations, and cost reduction of quality healthcare) and the Institute of Medicine's six

dimensions for patient experiences (safe, effective, patient-centered, timely, efficient, and equitable) (Lewis, 2014).

An attempt to “Cross the Quality Chasm” and translate evidence-based research into practice to provide effective and efficient care was demonstrated by our efforts (White, et al., 2016). It is a reward within itself to improve patient-centered care. The betterment of population health is often taken for granted and ignored. All providers and individuals are responsible for each other’s well-being and moving forward to cost-effective healthcare for all, and my initiative will set a precedent for providers envisioning to join the movement towards healthcare reform.

The dissemination of information will ultimately include submission to a professional journal for publication. The incorporation of video-based education on pain management may be introduced as a practice guideline to improve patient education as an adjunct to current practices, especially for minority populations when options for translation may be limited.

Conclusions

A reduction for the necessity to use translators, translation devices, and APPS may save time and reduce discrepancies related to information delivered. Standardized information for evidence-based care provided to patients by providers across the board with video-based education effectively fulfills patient educational needs. Videos in native language promote health-literacy and promote informed decision-making and patient-centered care. Video(s) accessible 24/7 allow for review before, during and after the labor process. Improved patient satisfaction, and video-based education can be expanded to

include all languages for culturally sensitive, patient centered care within the Department of Labor and Delivery.

The sample size may not reveal a statistical difference regarding improved patient satisfaction between the two groups. The feedback from patients, staff, and physicians was extremely positive regarding our intervention, validating video-based education. The PPAQ-7 survey results obtained from the intervention group revealed that 100% of patients were “Very Satisfied” or “Satisfied” regarding information from the video on epidurals and pain control. The study supports the use of native language instructional videos as part of the pre-anesthetic interview and education process for patients upon admission to the Department of Labor and Delivery and contributes to evidenced based practice. Development of a “Welcome Packet” with video access prior to hospital arrival and availability during prenatal visits with the obstetrician will provide additional information in a non-threatening manner. The videos are informative and culturally sensitive, creating an effective educational platform for patient-centered delivery of care.

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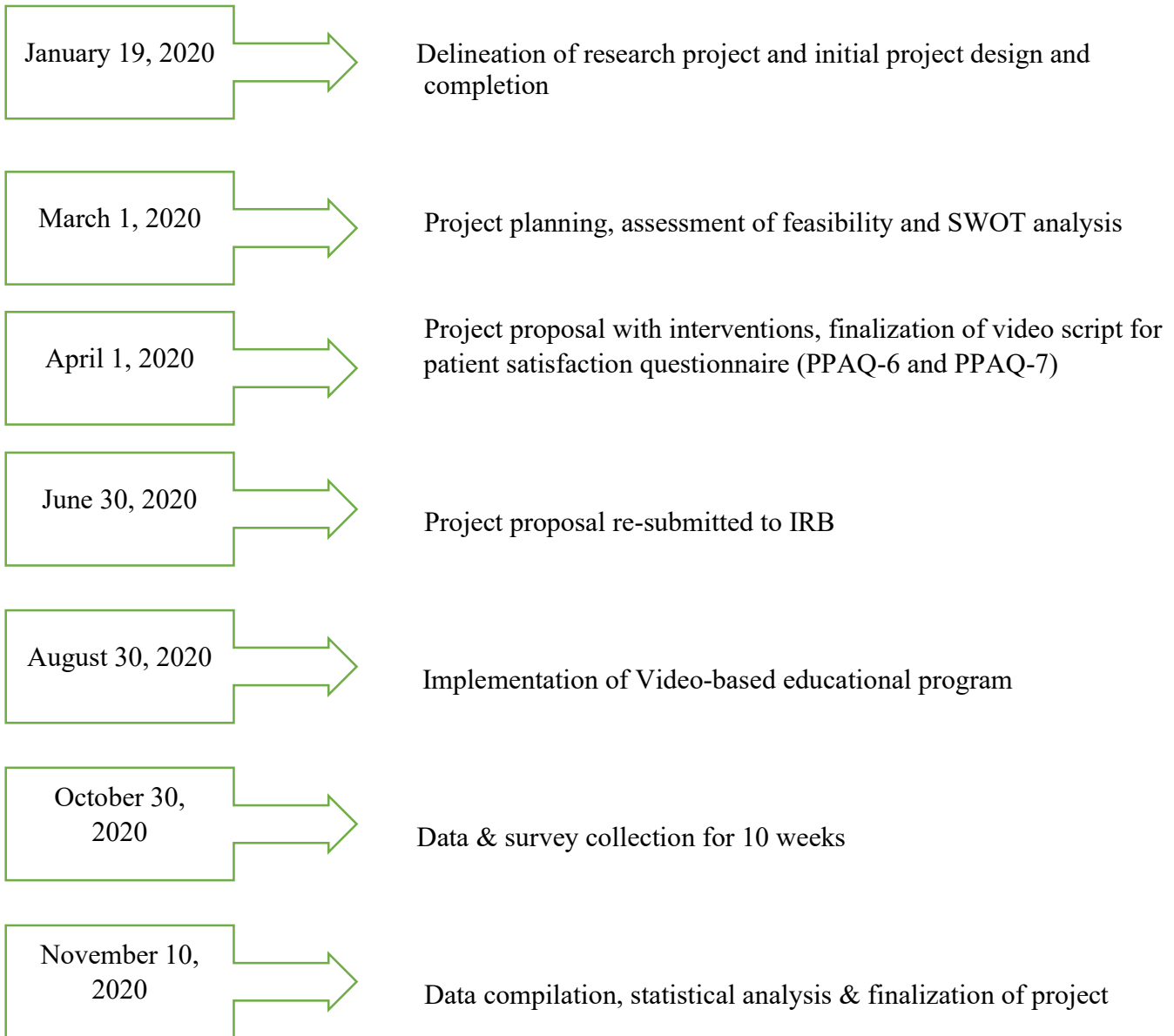
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Appendix A

TIMELINE



Appendix B

**DATA COLLECTION TOOL FOR DNP PROJECT ON VIDEO-BASED
EDUCATION FOR LABOR PATIENTS**

Patient Identification No. _____

1. Age _____

2. Gravida _____ Para _____

3. Primary / Native Language: English Spanish

4. Patient Satisfaction Score Obtained
from Questionnaire and Likert Scale _____

Data Collector Title: CRNA Anesthesiologist

Initials _____

Mount Sinai

MEDICAL CENTER

July 10, 2020

Howard Goldman, M.D./
Pablo Fumero, M.D.
Anesthesiology
Mount Sinai Medical Center

RE: Protocol No. 20-20-H-07: "Improved Patient Satisfaction as the Result of Video-Based Education on Neuraxial/Labor Analgesia in Native Languages for Labor Patients"

Dear Drs. Goldman and Fumero:

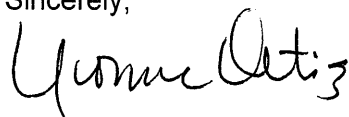
The above referenced protocol and informed consent form have been given an initial expedited review and approved as submitted on 7/9/2020 by Jose A. Adams, M.D., Chairman of the Institutional Review Board of Mount Sinai Medical Center. The date for continuing review is 7/8/2021, unless closed before that date. You are now authorized to proceed with your research study. The Federalwide Assurance Number is FWA00000176.

Signed informed consent for each patient involved in this study must be kept on file for future reference for at least five years after completion of the study.

Should any changes be made in your procedures, or if any new risks, reactions, injuries, or deaths of persons as subjects are encountered, please notify the Committee immediately.

Thank you for your cooperation.

Sincerely,



Yvonne Ortiz
IRB Coordinator

Mount Sinai Primary & Specialty Care

- Aventura
- Coral Gables
- Hialeah
- Hialeah-Miami Lakes
- Key Biscayne
- Miami Shores
- Midtown
- Skylake
- Sunny Isles Beach
- Mount Sinai Cardiology of the Florida Keys

**Mount Sinai Free-Standing
Emergency Departments**

- Aventura
- Hialeah



Appendix D
Mount Sinai
MEDICAL CENTER

EXPIRES

JUL 08 2021

INFORMED CONSENT FORM

Education on epidural, combined spinal-epidural or neuraxial/labor analgesia for pain relief

YOU ARE ASKED TO READ THE FOLLOWING FORM TO MAKE SURE THAT YOU COMPLETELY UNDERSTAND WHAT WILL HAPPEN IF YOU AGREE TO TAKE PART IN THIS RESEARCH STUDY. THIS INFORMED CONSENT FORM MAY CONTAIN WORDS THAT YOU DO NOT UNDERSTAND. PLEASE ASK THE STUDY STAFF TO EXPLAIN ANY WORDS OR INFORMATION THAT YOU DO NOT CLEARLY UNDERSTAND. A VERBAL AGREEMENT TO PARTICIPATE AND THE COMPLETION OF A SURVEY AFTERWARD MEANS THAT THE STUDY HAS BEEN EXPLAINED TO YOU AND THAT YOU GIVE YOUR PERMISSION TO TAKE PART. THE FEDERAL GOVERNMENT REQUIRES YOUR APPROVAL BEFORE YOU TAKE PART IN ANY RESEARCH STUDY. IT IS IMPORTANT THAT YOU KNOW WHAT WILL TAKE PLACE AND WHAT RISKS ARE INVOLVED BEFORE YOU DECIDE WHETHER OR NOT TO TAKE PART IN THIS STUDY.

1. RESEARCH PURPOSE AND DURATION

This is a clinical trial (a type of research study). You are being asked to take part in this study because you are a woman being induced for labor. The purpose of the study is to improve educational methods used by the anesthesia care team for labor patients. The study involves only educational methods used to provide information to you on epidurals and combined spinal epidurals, your satisfaction will be measured with a survey post-partum. About 100-200 women will take part in this study and your participation is limited to this hospital admission. The study period will be 3-4 months.

2. PROCEDURES

If you agree to take part in this study, you will be “randomized” into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have a 50% chance of being placed in any group. Which group you are put in is determined at the time you are admitted. Each patient will alternate being enrolled into the group getting the intervention or treatment. Neither you nor the researcher will choose what group you will be in. You will receive patient education during the anesthesia assessment upon admission to the Department of Labor and Delivery. A question and answer session will then be provided. During the postpartum follow-up we will provide you with a survey to complete to determine your satisfaction with the patient education you received. The survey you complete will then be placed in a self-sealing plain white envelope to maintain that your answers are confidential.

If you take part in this study, during your hospital admission you will receive all the standard care, provided health information to make informed patient-centered care decisions. Procedures that are part of your regular care will be done even if you do not join the study.

3. RISKS OR DISCOMFORTS

There are no risks or discomforts associated with your participation in this study as you will only receive education and will complete surveys.

Subject's Initials: _____

Mount Sinai Medical Center
4300 Alton Road
Miami Beach, FL 33140
Phone: 305.674.2121
msmc.com

Mount Sinai Primary & Specialty Care
• Aventura • Hialeah-Miami Lakes • Skylake
• Coral Gables • Key Biscayne • Sunny Isles Beach
• Hialeah • Miami Shores • Mount Sinai Cardiology
• Midtown of the Florida Keys

**Mount Sinai Free-Standing
Emergency Departments**
• Aventura
• Hialeah

**Mount Sinai
Comprehensive Cancer Center**
4306 Alton Road
Miami Beach, FL 33140
Phone: 305.674.9100
msccc.com

EXPIRES
JUL 08 2021

4. **BENEFIT(S) TO YOU**

If you agree to take part in this study, there may or may not be direct benefit to you now. We hope information learned from this study will benefit you for any future deliveries and future patients.

5. **ALTERNATIVE PROCEDURES OR FORMS OF THERAPY**

Your alternative would be to not take part in the study.

6. **COST TO YOU FOR TAKING PART IN RESEARCH STUDY**

There will be no cost to you for taking part in this research study.

7. **PAYMENT FOR TAKING PART IN RESEARCH STUDY**

You will not be paid for taking part in this research study.

8. **CONFIDENTIALITY**

Your role in this research study and any information collected about you in this study, including your medical records (known as Protected Health Information, or "PHI") will be protected as required by state and federal laws (including HIPAA) that govern the confidentiality and privacy of medical, personal and genetic information. If your PHI is being used in this research study, you will be asked to sign a specific permission form called an "Authorization" which explains who can see this information and how it can be used. Without your authorization, we may also use or disclose information related to your medical, personal or genetic condition if any information that could identify you has first been removed or a waiver (of Authorization) is approved by the IRB. Whether your PHI is being collected, or not, the following parties may look at and/or copy your study related records for research, quality assurance, and data analysis:

- (A) Government agencies or agents authorized by the federal government, including the Food and Drug Administration and the Office for Human Research Protections at the Department of Health and Human Services
- (B) Other persons set forth in MSMC's Notice of Privacy Practices if permitted or required by law.
- (C) The Investigators and persons working with the Investigators to oversee the study.

9. **RESEARCH-RELATED INJURY**

There is not a physical component or part, only educational content. No injury should result. Therefore, there are no plans to provide financial compensation for research-related injury or loss of wages.

10. **WHOM TO CONTACT FOR ANSWERS**

If you do not understand anything related to this study or problem related to your taking part in this study, please contact Paula Schultz, Principal Investigator @ 305-308-5157 at once.



Subject's Initials: _____

EXPIRES**JUL 08 2021**

3

For questions about your rights as a research participant, contact the Coordinator of the Mount Sinai Medical Center Institutional Review Board (which is a group of people who review the research to protect your rights) at (305) 674-2790.

11. PARTICIPATION IS VOLUNTARY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. This will not affect your continued medical care and treatment by your doctor. Your doctor may ask you to leave this study if he/she feels it is appropriate or necessary and will notify you. This in no way will affect your continued medical care and treatment by your physician.

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

12. I HAVE READ THIS INFORMED CONSENT FORM AND HAVE BEEN GIVEN THE OPPORTUNITY TO DISCUSS AND ASK QUESTIONS ABOUT THIS RESEARCH STUDY. I HAVE ALSO RECEIVED A COPY OF THIS INFORMED CONSENT FORM AND AGREE TO PARTICIPATE.

Printed Name, Address & Telephone No of Participant:

Signature of Participant Date

Printed Name of Person Obtaining Consent Date

Signature of Person Obtaining Consent Date



*I attest that the person who explained the study to the subject is qualified and properly delegated for that task.

*Signature of Principal Investigator

Subject's Initials: _____

EXPIRES

JUL 08 2021

Appendix E

Mount Sinai
MEDICAL CENTER



FORMULARIO DE CONSENTIMIENTO INFORMADO

Educación sobre la analgesia epidural, combinada espinal-epidural o neuroaxial / laboral para el alivio del dolor.

SE LE SOLICITA LEER EL SIGUIENTE FORMULARIO PARA ASEGURARSE DE QUE COMPRENDE COMPLETAMENTE LO QUE OCURRIRÁ SI ACEPTA PARTICIPAR EN ESTE ESTUDIO DE INVESTIGACIÓN. ESTE FORMULARIO DE CONSENTIMIENTO INFORMADO PUEDE CONTENER PALABRAS QUE USTED NO ENTIENDA. POR FAVOR PIDA AL PERSONAL DEL ESTUDIO QUE EXPLIQUE CUALQUIER PALABRA O INFORMACIÓN QUE NO ENTIENDA CLARAMENTE. UN ACUERDO VERBAL PARA PARTICIPAR Y LA REALIZACIÓN DE UNA ENCUESTA POSTERIOR SIGNIFICA QUE SE LE HA EXPLICADO A USTED EL ESTUDIO Y QUE USTED OTORGA SU PERMISO PARA PARTICIPAR. EL GOBIERNO FEDERAL REQUIERE SU APROBACIÓN ANTES DE PARTICIPAR EN CUALQUIER ESTUDIO DE INVESTIGACIÓN. ES IMPORTANTE SABER QUÉ OCURRIRÁ Y QUÉ RIESGOS ESTÁN INVOLUCRADOS ANTES DE DECIDIR SI PARTICIPAR EN ESTE ESTUDIO.

1. PROPÓSITO DE LA INVESTIGACIÓN Y DURACIÓN

Este es un ensayo clínico (un tipo de estudio de investigación). Se le pide que usted participe en este estudio porque es una mujer inducida para el parto. El propósito del estudio es mejorar los métodos educativos utilizados por el equipo de atención de anestesia para pacientes de parto. El estudio involucra solo métodos educativos utilizados para proporcionarle información sobre epidurales y epidurales espinales combinadas, su satisfacción se medirá con una encuesta posparto. Aproximadamente 100-200 mujeres participarán en este estudio y su participación se limita a esta admisión hospitalaria. El período de estudio será de 3 a 4 meses.

2. PROCEDIMIENTOS

Si usted acepta participar en este estudio, será "aleatorizado" en uno de los grupos de estudio que se describen a continuación. La aleatorización significa que le ponen en un grupo por casualidad. Es como lanzar una moneda. Tendrá un 50% de posibilidades de ser colocado en cualquier grupo. El grupo en el que se encuentre se determina en el momento de su admisión. Cada paciente alternará su inscripción en el grupo que recibe la intervención o el tratamiento. Ni usted ni el investigador elegirán en qué grupo estarán. Usted recibirá educación para pacientes durante la evaluación de la anestesia al ingresar al Departamento de Trabajo y Parto. Luego se proporcionará una sesión de preguntas y respuestas. Durante el seguimiento posparto, le proporcionaremos una encuesta que debe completar para determinar su satisfacción con la educación de pacientes que recibió. La encuesta que complete se colocará en un sobre blanco liso autoadhesivo para asegurar que sus respuestas sean confidenciales.

Si usted forma parte de este estudio, durante la admisión a su hospital, recibirá todo el cuidado estándar, y se le proporcionará información de salud para tomar decisiones informadas de atención centrada en el paciente. Los procedimientos que formen parte de su atención habitual se realizarán incluso si usted no se une al estudio.

3. RIESGOS O MOLESTIAS

No existen riesgos ni molestias asociados con su participación en este estudio, ya que solo recibirá educación y completará encuestas.

Iniciales del Sujeto: _____

4. **BENEFICIO(S) PARA USTED**

Si usted acepta participar en este estudio, puede haber o no un beneficio directo para usted ahora. Esperamos que la información obtenida de este estudio le beneficie para futuros partos y futuros pacientes.

5. **PROCEDIMIENTOS ALTERNATIVOS O FORMAS DE TERAPIA**

Su alternativa sería no participar en el estudio.

6. **COSTO PARA USTED POR PARTICIPAR EN EL ESTUDIO DE INVESTIGACIÓN**

No habrá ningún costo para usted por participar en este estudio de investigación.

7. **PAGO POR PARTICIPAR EN EL ESTUDIO DE INVESTIGACIÓN**

No se le pagará por participar en este estudio de investigación.

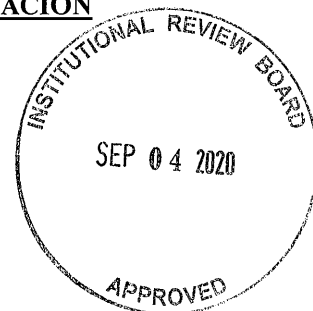
8. **CONFIDENCIALIDAD**

Su papel en este estudio de investigación y cualquier información recopilada sobre usted en este estudio, incluidos sus registros médicos (conocida como Información de salud protegida o "PHI") estarán protegidos según lo exijan las leyes estatales y federales (incluida HIPAA) que rigen la confidencialidad y privacidad de la información médica, personal y genética. Si su PHI se está utilizando en este estudio de investigación, se le solicitará que firme un formulario de permiso específico llamado "Autorización" que explica quién puede ver esta información y cómo se puede utilizar. Sin su autorización, también podríamos usar o divulgar información relacionada con su afección médica, personal o genética si cualquier información que pudiera identificarle fue eliminada por primera vez o el IRB aprueba una exención (de autorización). Ya sea que se recopile su PHI o no, las siguientes partes pueden ver y/o copiar sus registros relacionados con el estudio para investigación, control de calidad y análisis de datos:

- (A) Agencias o agentes gubernamentales autorizados por el gobierno federal, incluida la Administración de Alimentos y Medicamentos y la Oficina de Protección de la Investigación Humana del Departamento de Salud y Servicios Humanos
- (B) Otras personas establecidas en el Aviso de prácticas de privacidad de MSMC si la ley lo permite o lo exige.
- (C) Los investigadores y las personas que trabajan con los investigadores para supervisar el estudio.

9. **LESIONES RELACIONADAS CON LA INVESTIGACIÓN**

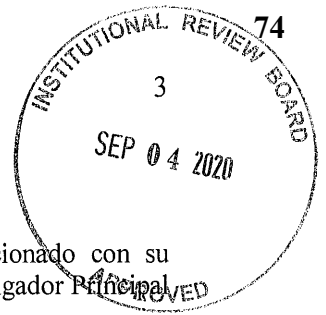
No existe un componente o parte física, solo contenido educativo. No debería producirse ninguna lesión. Por lo tanto, no hay planes para proporcionar una compensación financiera por lesiones relacionadas con la investigación o pérdida de salarios.



EXPIRES

JUL 08 2021

Iniciales del Sujeto: _____



10. A QUIÉN CONTACTAR PARA RESPUESTAS

Si no comprende algo relacionado con este estudio o tiene un problema relacionado con su participación en este estudio, por favor contacte de inmediato a Paula Schultz, Investigador Principal al 305-308-5157.

Para preguntas sobre sus derechos como participante de la investigación, comuníquese con el Coordinador de la Junta de Revisión Institucional del Centro Médico Mount Sinai (que es un grupo de personas que revisan la investigación para proteger sus derechos) al (305) 674-2790.

11. LA PARTICIPACIÓN ES VOLUNTARIA

Participar en este estudio es voluntario. Usted puede elegir no participar o puede abandonar el estudio en cualquier momento. Abandonar el estudio no dará lugar a ninguna sanción o pérdida de beneficios a los que tiene derecho. Esto no afectará su atención y tratamiento médico continuo por parte de su médico. Su médico puede pedirle que abandone este estudio si lo considera apropiado o necesario y se lo notificará. Esto de ninguna manera afectará su atención y tratamiento médico continuo por parte de su médico.

Una Junta de Seguridad y Monitoreo de Datos, un grupo independiente de expertos, revisará los datos de esta investigación a lo largo del estudio. Le informaremos sobre la nueva información de este u otros estudios que puedan afectar su salud, bienestar o disposición para permanecer en este estudio.

12. HE LEÍDO ESTE FORMULARIO DE CONSENTIMIENTO INFORMADO Y HE TENIDO LA OPORTUNIDAD DE DISCUTIR Y HACER PREGUNTAS SOBRE ESTE ESTUDIO DE INVESTIGACIÓN. TAMBIÉN HE RECIBIDO UNA COPIA DE ESTE FORMULARIO DE CONSENTIMIENTO INFORMADO Y ACEPTO PARTICIPAR.

Nombre Impreso, Dirección y Teléfono del Participante:

Firma del Participante

Fecha

Nombre de la Persona que Obtiene Consentimiento Fecha

Nombre de la Persona que Obtiene Consentimiento Fecha

* Doy fe de que la persona que explicó el estudio al sujeto está calificada y debidamente delegada para esa tarea.

*Firma del Investigador Principal

EXPIRES
JUL 08 2021

Iniciales del Sujeto: _____

**Authorization (Permission) to Use or Disclose (Release) Identifiable Health Information for Research****Protocol Title: Improved Patient Satisfaction as the Result of Video-Based Education On Epidurals for Labor Patients in Native Languages****Principal Investigator:** Dr. Howard Goldman & Dr. Pablo Fumero**Participant's Name:** _____**Birth Date:** _____**1. What is the purpose of this form?**

Miami Beach Anesthesiology Associates (MBAA) is an organization that does research to improve education on epidurals. Researchers would like to use your health information for research. This information may include data that identifies you. Please carefully review the information below. You should have been provided with a copy of the "Notice of Privacy Practices", which describes Mount Sinai Medical Center's ("Medical Center") privacy practices. If you have not yet received a copy, please ask the researcher for a copy. If you agree that researchers can use your personal health information, you must sign and date this form to give them your permission.

2. What personal health information do the researchers want to use?

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter the MBAA research study, information that will be used and/or released may include the following:

- Your name, for the consent and follow-up visit and survey postpartum, but it will not be published.
- Age
- specific information about the treatments you received or desired, including the epidural.

The research involves the education on pain management, including the epidural and combined spinal epidural for labor. After delivery, during post-partum rounds we will ask you to complete a one page survey.

You may request a blank copy of the data forms from the study doctor or his/her research staff to learn what information will be shared.

3. *Why do the researchers want my personal health information?*

Mount Sinai Medical center will collect your health information and share it with the Florida International University if you enter a cooperative group research study. Miami Beach Anesthesiology Associates will use your information in their research study.

We are attempting to improve our educational methods regarding the information we provide on pain relief during labor, including the epidural and combined spinal epidural

4. *Who will be able to use my personal health information?*

Mount Sinai Medical Center, Florida International University and MBAA will use your health information for research. As part of this research, they may give your information to the following groups taking part in the research. Mount Sinai Medical Center may also permit these groups to come in to review your original records that are kept by Mount Sinai Medical Center so that they can monitor their research study.

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator's study team.
- The Mount Sinai Medical Center Institutional Review Board (the committee charged with overseeing research on human subjects)
- The Mount Sinai Medical Center Office of Research Administration (the office which monitors research studies)
- Authorized members of the Medical Center workforce who may need to access your information in the performance of their duties (for example: to provide treatment and to ensure integrity of the research)
- The Sponsor that is Supporting the Study: Miami Beach Anesthesiology Associates.
- Other collaborating academic research centers: Florida International University
- Public Health agencies and other government agencies (including non-U.S.) as authorized or required by law; ClinicalTrials.GOV.

5. *How will information about me be kept private?*

Mount Sinai Medical Center will keep all patient information private to the extent possible. Only researchers working with Miami Beach Anesthesiology Associates will have access to your information. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

6. *What happens if I do not sign this permission form?*

If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered.

7. If I sign this form, will I automatically be entered into the research study?

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form.

8. What happens if I want to withdraw my permission?

You can change your mind at any time and withdraw your permission to allow your personal health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.

To withdraw your permission, please contact the person below. He/she will make sure your written request to withdraw your permission is processed correctly.

Paula Schultz@ pschu004@fiu.edu /Phone:305-308-5157

9. How long will this permission last?

If you agree by signing this form that researchers can use your personal health information, this permission has no expiration date. You can change your mind and withdraw your permission at any time.

10. What are my rights regarding access to my personal health information?

You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your personal health information kept by **Mount Sinai Medical Center**. You do not have the right to review and/or copy records kept by **Miami Beach Anesthesiology Associates** or other researchers associated with the research study.

Signatures

I agree that my personal health information may be used for the research purposes described in this form.

Signature of Research Subject _____ Date: _____

Signature of Person Obtaining Permission: _____ Date: _____

Printed Name of Person Obtaining Permission: _____



Autorización (permiso) para usar o divulgar información de salud identificable para investigación

Título del protocolo: Mejora de la satisfacción del paciente como resultado de la educación basada en video sobre epidurales para pacientes de parto en lenguas nativas

Investigador principal: Dr. Howard Goldman & Dr. Pablo Fumero

Nombre del participante: _____

Fecha de nacimiento: _____

1. ¿Cuál es el propósito de este formulario?

Miami Beach Anesthesiology Associates (MBAA) es una organización que investiga para mejorar la educación sobre epidurales. Los investigadores desean utilizar su información de salud para la investigación. Esta información puede incluir datos que lo identifiquen. Por favor revise cuidadosamente la información a continuación. Debería haber recibido una copia del "Aviso de prácticas de privacidad", que describe Mount Sinai Medical Center's ("Medical Center") prácticas de privacidad. Si aún no ha recibido una copia, solicite una copia al investigador. Si acepta que los investigadores pueden usar su información personal de salud, debe firmar y fechar este formulario para darles su permiso.

2. ¿Qué información personal de salud quieren usar los investigadores?

Los investigadores quieren copiar y usar las partes de su registro médico que necesitarán para su investigación. Si ingresa al estudio de investigación MBAA, la información que se utilizará y / o divulgará puede incluir lo siguiente::

- Su nombre, para el consentimiento y la visita de seguimiento y la encuesta posparto, pero no se publicará.
- Años
- información específica sobre los tratamientos que recibió o desea, incluida la epidural.

La investigación involucra la educación sobre el manejo del dolor, incluyendo la epidural epidural y combinada para el trabajo de parto. Después del parto, durante las rondas posteriores al parto, le pediremos que complete una encuesta de una página.

Puede solicitar una copia en blanco de los formularios de datos al médico del estudio o al personal de investigación para conocer qué información se compartirá.

3. ¿Por qué los investigadores quieren mi información personal de salud?

Mount Sinai Medical Center recopilará su información de salud y la compartirá con la Florida International University si ingresa a un estudio de investigación grupal cooperativo. Miami Beach Anesthesiology Associates utilizará su información en su estudio de investigación.

Estamos tratando de mejorar nuestros métodos educativos con respecto a la información que proporcionamos sobre el alivio del dolor durante el parto, incluida la epidural epidural y combinada.

4. *¿Quién podrá usar mi información personal de salud?*

Mount Sinai Medical Center, Florida International University y MBAA utilizarán su información de salud para la investigación. Como parte de esta investigación, pueden brindar su información a los siguientes grupos que participan en la investigación. Mount Sinai Medical Center también puede permitir que estos grupos entren para revisar sus registros originales que mantiene Mount Sinai Medical Center para que puedan monitorear su estudio de investigación.

Las siguientes personas y organizaciones pueden usar o divulgar su información personal de salud para este proyecto de investigación:

- El investigador principal y el equipo de estudio del investigador.
- La Junta de Revisión Institucional del Centro Médico Mount Sinai (el comité encargado de supervisar la investigación sobre sujetos humanos)
- La Oficina de Administración de Investigación del Centro Médico Mount Sinai (la oficina que monitorea los estudios de investigación)
- Miembros autorizados de la fuerza laboral del Centro Médico que pueden necesitar acceder a su información en el desempeño de sus funciones (por ejemplo: para proporcionar tratamiento y garantizar la integridad de la investigación)
- El patrocinador que apoya el estudio: Miami Beach Anesthesiology Associates.
- Otros centros de investigación académica colaboradores: Florida International University
- Agencias de salud pública y otras agencias gubernamentales (incluidas las no estadounidenses) según lo autorizado o requerido por la ley; ClinicalTrials.GOV.

5. *¿Cómo se mantendrá privada la información sobre mí?*

Mount Sinai Medical Center mantendrá la privacidad de toda la información del paciente en la medida de lo posible. Solo los investigadores que trabajan con Miami Beach Anesthesiology Associates tendrán acceso a su información. Es posible que las leyes federales de privacidad (como la Regla de privacidad) no exijan a las personas que reciben su información de salud que la protejan y pueden compartir su información con otros sin su permiso, si así lo permiten las leyes que los rigen.

6. *¿Qué sucede si no firmo este formulario de permiso?*

Si no firma este formulario de permiso, no podrá participar en el estudio de investigación para el que está siendo considerado.

7. Si firmo este formulario, ¿ingresaré automáticamente al estudio de investigación?

No, no puede ingresar a ningún estudio de investigación sin más discusión y consentimiento por separado. Después de la discusión, puede decidir participar en el estudio de investigación. En ese momento, se le pedirá que firme un formulario de consentimiento de investigación específico.

8. ¿Qué sucede si quiero retirar mi permiso?

Puede cambiar de opinión en cualquier momento y retirar su permiso para permitir que su información de salud personal se use en la investigación. Si esto sucede, debe retirar su permiso por escrito. A partir de la fecha en que retire su permiso, no se utilizará ninguna nueva información personal de salud para la investigación. Sin embargo, los investigadores pueden continuar utilizando la información de salud que se proporcionó antes de que retirara su permiso.

Si firma este formulario e ingresa al estudio de investigación, pero luego cambia de opinión y retira su permiso, será eliminado del estudio de investigación en ese momento.

Para retirar su permiso, comuníquese con la persona a continuación. Él / ella se asegurará de que su solicitud por escrito para retirar su permiso se procese correctamente.

Paula Schultz@ pschu004@fiu.edu / Teléfono: 305-308-5157

9. ¿Cuánto tiempo durará este permiso?

Si acepta al firmar este formulario que los investigadores pueden usar su información personal de salud, este permiso no tiene fecha de vencimiento. Puede cambiar de opinión y retirar su permiso en cualquier momento.

10. ¿Cuáles son mis derechos con respecto al acceso a mi información personal de salud?

Tiene derecho a negarse a firmar este formulario de permiso. Tiene derecho a revisar y / o copiar registros de su información personal de salud mantenida por el Centro Médico Mount Sinai. No tiene derecho a revisar y / o copiar registros guardados por Miami Beach Anesthesiology Associates u otros investigadores asociados con el estudio de investigación.

Firmas

Estoy de acuerdo en que mi información personal de salud se pueda usar para los fines de investigación descritos en este formulario.

Firma del sujeto de investigación _____ Fecha: _____

Firma de la persona que obtiene el permiso: _____ Fecha: _____

Nombre impreso de la persona que obtiene el permiso _____