2014

Implementation of a Nurse-Initiated Topical Anesthesia Protocol

Jennifer Anderson
South Dakota State University, Jennifer.Anderson@avera.org

Implementation of a Nurse-Initiated Topical Anesthesia Protocol

Jennifer Anderson

A paper submitted in partial fulfillment of the requirements for the degree

Doctor of Nursing Practice

South Dakota State University

2014

Acknowledgements

I wish to express my sincere gratitude to my advisor, Cynthia Elverson for her patience, motivation, and guidance throughout this project. I would also like to thank the rest of my project committee: Gemechis Djira, Jo Voss, Jodi Jung, Lori Hendrickx, and Sheryl Marckstadt, for their encouragement and insightful comments.

Finally, I would like to thank my family for their support and encouragement as I completed this educational journey. My children Tucker, Harper, and Owen were always there with hugs and kisses of encouragement. My husband, Jake, has been my most enthusiastic cheerleader; my best friend; and an amazing husband and father.

Table of Contents

Page

Abstract

Although topical anesthetics are a safe, effective, and non-invasive alternative to infiltrated anesthesia for laceration repair, their availability to providers continues to limit their use. This practice innovation project developed a protocol for the nurse-initiated anesthesia for patients over one year of age presenting to a critical access hospital emergency department with lacerations. Pre and post implementation chart reviews were utilized to determine the effectiveness of the implementation of this protocol. This project has potential to impact patient pain levels, anxiety, restraint use, total treatment time, and patient satisfaction scores.

Keywords: laceration, anesthesia or anaesthesia, lidocaine, protocol, policy, guideline, and procedural pain.

List of Abbreviations

ADMH: Avera De Smet Memorial Hospital

CMS: Centers for Medicare and Medicaid Services

ED: Emergency Department

HCAHPS: Hospital Consumer Assessment of Healthcare Providers and Systems

LAT/LET: Lidocaine Adrenaline Tetracaine/ Lidocaine Epinephrine Tetracaine

List of Tables

List of Figures

Chapter 1: Development of the Clinical Question and Problem Identification

Introduction

Health care practice is shifting from an era where interventions were performed based upon tradition to evidence-based practice and pay for performance. Evidence-based practices result in improved health, safety, and cost outcomes (Melnyk & Fineout-Overholt, 2011). Although topical anesthetics have been available since the 1980s and have been recognized as providing effective analgesia for superficial procedures, including repair of dermal lacerations, their use is still limited in rural hospitals. Topical anesthesia is more likely to be used in an urban hospital than a rural hospital (Kleiber, Jennissen, McCarthy, & Ansley 2011). In order to provide patients in critical access and rural hospitals high quality, evidence based care; health care providers should be provided with evidence-based options for anesthesia. Providing topical anesthesia options that are less invasive than traditional infiltrated anesthesia leads to decreased patient pain with laceration repair (Eidelman et al., 2012; Howard et al., 2012). Little, Kelly, Jenkins, Murphy, and McCarron (2009) reviewed the literature, concluded that topical anesthesia provides effective pain relief, and proposed that providers may have greater ease in completion of laceration repair due to increased patient cooperation. The use of topical anesthetics for laceration repair significantly decreases the total treatment time for patients with lacerations (Priestley, Kelly, Chow, Powell, & Williams, 2003).

Significance of Problem

Lacerations account for a large number of emergency department (ED) visits. Unintentional cuts are the fifth leading cause of nonfatal injury in the United States (CDC, 2010). Pediatric laceration repair can be stressful for the patient, the child's

parents, and for the health care staff assisting with and completing the repair. Traditionally, laceration repair is completed after the administration of injectable lidocaine. While infiltration of lidocaine into the wound provides adequate analgesia for laceration repair, it is also associated with significant pain and discomfort upon infiltration, adding to the patient's pain and distress (Singer & Stark, 2000). Children have reported having a procedure that involved a needle as one of their most feared and painful experiences (Mcmurtry, 2013). The needle fear that patients have may cause such anxiety for patients that restraint or sedation is required to complete laceration repair (Eidelman et al., 2012; Howard et al., 2012; Little et al., 2009). An upset patient who is unable to remain still during laceration repair can make the procedure both technically and emotionally challenging for the provider. It can also result in restraint use to assist in positioning the patients in a way that limits their movement.

On October 1, 2012, the Centers for Medicare and Medicaid Services (CMS) Hospital Value-Based Purchasing Program Final Rule was implemented to help reform health care in the United States (CMS, 2011). This rule created a value-based incentive payment for acute care hospitals tying 30% of the incentive payment to patient satisfaction and the remaining 70% to disease specific quality measures (CMS, 2011). Patient satisfaction is measured using the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. Avera De Smet Memorial Hospital (ADMH) has proactively developed a HCAHPS team to review each question on the patient satisfaction survey and determine the best strategies to implement to improve survey scores. There are three questions on this survey pertaining to pain, "(1) Did you need medicine for pain? (2) How often was your pain well controlled? (3) How often did the

hospital staff do everything they could to help you with your pain?" (Lutz & Root, 2007, p. 56). During their discussions, the HCAHPS committee members determined that laceration repair in the emergency department was a frequent reason for patients to seek treatment with the potential for improved pain management. The HCAHPS committee researched and implemented many new strategies for laceration pain management, including: elevation, ice, and distraction techniques. These strategies were implemented in February 2012. The HCAHPS committee also discussed the possibility of implementing a less invasive means of anesthesia than their currently used method of lidocaine injection. It was determined that the barriers of time constraints, staffing, research, and implementation were too great for this committee.

The goal of topical anesthesia for the repair of lacerations is to provide anesthesia without causing the discomfort and distortion of the local anatomy associated with anesthesia infiltration (Trott, 2012). Prior to implementation, at the project setting, there was no standardized process related to the type, timing, or use of anesthesia for laceration repair. Also, topical anesthesia was not available for provider use. The only available option for anesthesia of lacerations was the infiltration of lidocaine with or without epinephrine.

Clinical Question

P: Population of interest: In emergency department (ED) patients greater than one year of age with simple lacerations

I: Intervention of interest: Will a practice innovation project, implementing a protocol for the use of topical anesthesia

C: Comparison of interest: Compared to current practice (infiltration of lidocaine)

O: Outcome of interest: Increase the use of topical anesthetics for laceration repair, decrease total treatment time, and decrease pain associated with laceration repair?

Long-Term Outcome

A long-term outcome, related to the outcomes of interest is patient satisfaction. This outcome will be contained in the literature review, but not included in the measures of this project due to the short duration of this project.

Purpose of the Project

Practice improvement is key to improving the quality of patients' experiences and care. This project was designed to assess and improve the delivery of anesthesia for laceration repair. The purpose of this evidence-based practice innovation project was to bring the research evidence for the use of topical anesthesia for laceration repair into clinical practice in the ED of a critical access hospital. The goal of this project was to create, implement, and evaluate a protocol for the use of topical anesthesia in simple laceration repair to advance the quality of pain management during the laceration repair process.

Definitions

Adult is defined as patient 18 years of age or older.

Child is defined as patient less than 18 years of age (< 1 year old contraindicated for nurse-initiated topical anesthesia protocol).

Pain, as defined by the International Association for the Study of Pain (2012), is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage" (p. 209).

Providers is defined as nurse practitioners, physicians, and physicians' assistants.

Simple laceration is defined as a repair that includes superficial, single-layer closure with local anesthesia; excluding lacerations that require multiple-layer closure, extensive cleaning, and debridement (Forsch, 2008).

Treatment time is defined as the period of time from admission to discharge.

Topical anesthesia is defined as "local anesthesia induced by the application of an anesthetic directly to the surface of the area to be anesthetized (Trott, 2012, p. 147)."

Value-based purchasing program is an incentive payment made to hospitals that meet performance standards with respect to a performance period (CMS, 2011).

Chapter 2: Review of Literature and Model of Evidence-Based Care

Introduction

This chapter includes the review of literature, which investigated the state of the evidence pertaining to the translation of a topical anesthesia protocol for pediatric laceration repair into the clinical setting. The model of evidence-based practice and nursing theory that guided the project are described.

The review of the literature was completed using the search engines PubMed, Cochrane Database, CINAHL, and an internet search through Google Scholar and the National Guideline Clearinghouse for clinical practice guidelines (See Appendix A). The following organizations' websites were searched for guidelines or position statements regarding the topic: American Academy of Pediatrics, American Society of Plastic Surgeons, American Association of Plastic Surgeons, American Academy of Cosmetic Surgery, American Academy of Dermatology, American Dermatological Association, Association of Emergency Physicians, American Academy of Emergency Medicine, Emergency Nurses Association, and American College of Emergency Physicians. The initial search was performed in June 2013 with the assistance of the medical librarian at the Wegner Health Sciences Center. The search was restricted to meta-analysis, systematic reviews, clinical trials, randomized controlled trials, and guidelines published from January 2005 to present. January 2005 was selected as the earliest date for inclusion due to the lack of more recent systematic reviews on the subject. Additional restrictions to the search were human population and English language. The PICO question served as a guide for the literature search. Search terms included: *laceration, anesthesia or anaesthesia, lidocaine, protocol, policy, guideline, management,*

procedural pain, and a combination of these terms. Inclusion criteria were meta-analysis, experimental or quasi-experimental design, and guidelines. Articles were excluded if the lacerations were not dermal in origin.

There were ten articles identified through the literature search. The articles include two systematic reviews of randomized control trials (Eidelman et al, 2012; Eidelman, Weiss, Enue, Lau, & Carr, 2005), three randomized controlled trials (Priestley et al., 2003; Singer & Stark, 2000; Harman, Zemek, Duncan, Ying, & Petrcich, 2013), two quasi-experimental designs (Crocker, Higginbotham, King, Taylor, & Milling, 2012; Taylor, Taylor, Jao, Goh, & Ward, 2013), and three practice guidelines (Fein, Zempsky, & Cravero, 2012; Howard et al., 2012; Royal Australasian College of Physicians, 2006). Each article was critically appraised and given a level of evidence using the Johns Hopkins Nursing Evidence-based Practice rating scale. Few guidelines, policy statements, and expert opinions on the topic were discovered. In an effort to include only the best evidence to guide this project, all guidelines were screened using the AGREE instrument and only those that scored favorably were incorporated in to the literature review (Appendix B). Two sets of guidelines (Howard et al., 2012; Royal Australasian College of Physicians, 2006) utilized a broad range of professional groups as their stakeholders, used systematic methods for development, explicitly stated their criteria, and provided supporting evidence for their recommendations. However, the two highest quality guidelines were developed in Australia and Great Britain, and may not apply to provision of care in the United States. Therefore, despite the lower quality rating with the AGREE instrument, recommendations of the American Academy of Pediatrics (Fein et al., 2012) were also included as evidence for this project. Those practice guidelines

eliminated merely contained a sentence stating topical anesthetics could be used and did not provide any supporting evidence.

Literature Review

The literature review included three sets of guidelines for managing procedural pain in children and adolescents. The three guidelines (Fein et al., 2012; Howard et al., 2012; Royal Australasian College of Physicians, 2006) were consistent in the following recommendations:

- topical anesthetic is preferred to infiltrated anesthetics, as they are less painful to apply;
- cocaine-free topical anesthetics are preferred because of their equivalent efficacy and superior safety profile;
- pre-treatment with topical anesthetics reduces the pain of infiltrated lidocaine, if it is needed.

Effectiveness. A wide variety of topical anesthetics are available and give equivalent analgesia to infiltrated local anesthetics (Fein et al., 2012; Royal Australasian College of Physicians, 2006; Eidelman et al., 2012). Due to methodological heterogeneity, Eidelman et al. (2012) was limited to a narrative review with no calculation of an overall effect size. Three of the three trials included in the Eidelman et al. (2012) systematic review, comparing patient reported VAS pain scores, found no significant difference between the anesthetic efficacy of cocaine-free anesthetics that were either infiltrated or applied topically prior to laceration repair. While studies consistently reveal equivalent efficacy of topical and infiltrated anesthetics, the required time to produce an effective response is significantly different. Topical agents require

approximately 20 to 60 minutes of direct skin contact to produce effectiveness; while infiltrated agents generally require less than two minutes to produce the same effect (Hsu, 2013). Topical anesthetics have the advantage of a painless application and a reduction in pain of subsequent anesthetic infiltration (Howard et al., 2012; Royal College of Australasian Physicians, 2006; Singer & Stark, 2000).

One study included outcomes on wound hemostasis and pain with tissue adhesive application (Harman et al., 2013). It found that physicians more frequently rated wound hemostasis as complete with LET gel than placebo, $p < .008$; and children receiving LET gel reported no pain more frequently than those receiving placebo, with 51.6% and 28.3% reporting no pain respectively. One study examined the effect of a topical lidocaine and epinephrine solution on patient experiences and found that those who received the topical anesthetic were more likely than those receiving infiltrated lidocaine to rate their experience as excellent (Gaufberg, Walta, & Workman, 2007).

Safety. Two studies found no difficulty with wound healing or infection (Gaufberg et al., 2007; Singer & Stark, 2000). There have been no reports of toxicity or acute adverse events with cocaine-free topical anesthetic agents (Royal Australasian College of Physicians, 2006; Eidelman et al., 2012). Trials enrolling 1,686 patients, reviewed by Eidelman et al. (2012), assessed and reported nature and incidence of topical anesthetic related acute adverse effects. Of these 1,686 patients, only one adverse event was reported. This event involved the development of a large indurated, erythematous reaction one day post application of a topical cocaine-containing anesthetic, which completely resolved following administration of an antihistamine and warm compress. However, five randomized controlled trials in the Eidelman et al. (2012) review

compared only cocaine-free topical anesthetics and reported no toxicity or adverse effects in their combined 358 patients. Therefore, the investigaor recommended the use of cocaine-free topical anesthetics rather than those that contain cocaine.

Treatment time. Topical anesthetics can reduce the total treatment time in patients with simple lacerations. A prospective, randomized controlled trial was conducted in an urban pediatric ED, with a sample size of 161 patients and revealed a decrease in total treatment time for patients receiving topical anesthetic. This study examined the treatment of all lacerations that met inclusion criteria, regardless of the exact treatment rendered (suture, glue, steristrips, or no closure). The median treatment time was 77 minutes compared with 108 minutes for the control group, for an effect size of 31 minutes (Priestley et al., 2003). This is the only study found that specifically looked at treatment time. This study was double-blinded and found a statistically significant reduction in treatment time. Although more study in this area is needed, reductions in treatment time can equate to substantial cost savings by decreasing staff time; therefore this was an important outcome measurement to include in the proposed project.

Rural disparity. Kleiber et al. (2011) surveyed 259 providers and nurses working in 118 EDs in the state of Iowa regarding evidence-based pediatric pain management. They found significant ($p < .001$) disparity in anesthesia for lacerations among urban, rural, and critical access hospitals. Providers and nurses in urban EDs reported using a topical anesthesia 50 to 75% of the time and providers and nurses in rural and critical access EDs reported using topical anesthesia 25 to 50% of the time.

Protocol implementation. A protocol for management of laceration repair pain would provide nursing staff with a systematic guide for managing laceration repair. Based on the following two studies, the investigator recommended implementing a nurse-initiated protocol for the application of topical anesthesia. Crocker et al. (2012) showed that the implementation of a pain management protocol in an urban pediatric ED reduced patients' pain during visits, with a 5.07 pain rating in the pre-protocol group and a 4.01 pain rating in the protocol group ($p < .001$). All patients with a pain score of greater than 1 were to receive topical anesthesia provided by the nurse prior to assessment by a provider. However, their pain management protocol was multifaceted, including non-pharmacologic methods, topical anesthesia, oral analgesics, intranasal analgesic, IV analgesic, and use of a child life specialist.

A pre- and post-intervention trial evaluated the impact of a nurse-initiated analgesia pathway for pediatric patients in an urban ED (Taylor et al., 2013). Although their pathway encompassed guidelines for all types of pain, it also allowed nurses to administer topical anesthesia for lacerations prior to being assessed by the provider. Fifty-one children were enrolled in both the pre- and post-intervention periods. They found that more patients received nurse-initiated analgesia, $p < .001$; the median time to analgesia was reduced, $p < .001$; and more patients received adequate analgesia post-intervention, $p < .001$. Although not statistically significant, there was a trend upwards in the proportion of parents who were very satisfied with their child's overall pain management, 41.2% pre-implementations and 72.5% post-implementation. It is also important to note that no adverse events were observed during either period. Based on

these two studies, the investigator recommended implementing a nurse-initiated protocol for the application of topical anesthetics.

Comparison of cocaine-free topical agents. Topical agents containing cocaine will not be considered for use in this project due to safety and storage concerns. Of the cocaine-free topical anesthetics, those containing lidocaine and epinephrine/adrenaline with and without tetracaine are the most commonly studied for pain intensity, adequacy of anesthesia, wound hemostasis, and wound healing/infection. Seven sources in my evidence search specifically recommended the use of LET/LAT (Singer & Stark, 2000; Harman, et al., 2013; Eidelman et al., 2005; Crocker et al., 2012; Taylor et al., 2013; Howard et al., 2012; Royal Australiasian College of Physicians, 2005).

Four studies indicated that topical anesthesia was incomplete at times and required supplemental infiltrated lidocaine (Krief, Sadock, Tunik, & Manikian, 2002; Adler, Dubinsky, & Ersen, 1998; Resch, Schilling, Borchert, Klatzko, & Uden, 1998; Blackburn, Butler, Hughes, Clark, & Riker 1995). However, there were limited comparisons of the effectiveness of solution versus gel preparations in providing complete analgesia. The percentage of patients that required supplemental infiltrated lidocaine after LAT/LET solution ranged from 43% (Adler et al., 1998) to 24% (Resch et al., 1998). Gel formulations of LET were slightly more effective with 23% (Krief et al., 2002) and 15% (Resch et al., 1998) requiring supplemental infiltrated anesthesia. Adler et al. (1998) found that patients who received LAT solution rated their pain with needle stick significantly less than those in the placebo group, $p < .05$. Therefore, the protocol needs to include patient education that despite the use of a topical anesthetic, the provider will at times also use an infiltrated anesthetic. Due to the significant body of evidence

supporting the use of lidocaine containing topical anesthetics, the investigator recommended their use in the implementation of this protocol.

Summary of the Evidence

Topical anesthetics have anesthesia effectiveness equivalent to infiltrated local anesthetics, although they require more time to become effective (Eidelman et al., 2012; Howard et al, 2012; Hsu, 2013; Royal Australasian College of Physicians, 2006). There have been no adverse events reported with cocaine-free containing topical anesthetic agents, although there is a theoretical risk of tissue ischemia in end arteriolar sites (Eidelman et al., 2012; Royal Australasian College of Physicians, 2006). Topical anesthetics may have the potential to reduce treatment time and improve patient experience, although more study in these areas is needed (Priestley et al., 2003). While comparative effectiveness studies of the many different topical anesthetics are lacking, gel preparations resulted in slightly better anesthesia than solutions (Resch et al., 1998). The implementation of nursing-initiated pain management protocols have improved pain management by increasing the number of patients receiving adequate analgesia (Crocker et al., 2012; Taylor et al., 2013) and decreasing the time to initiation of pain relief (Taylor et al., 2013).

Gaps in the Evidence

The literature search and critical review process identified a gap in evidence for some areas of the project. While there has been much research regarding painful procedures in infancy and painful needle stick procedures, such as vaccinations and insertion of intravenous catheters, which were not reviewed for this project; there is little current research specifically regarding pain management during laceration repair. This is

concerning, since lacerations are such a common reason for patients to seek emergency care. There is also a lack of head to head studies comparing the efficacy of cocaine-free topical anesthetics. While the evidence supports the use of topical anesthesia, it appears there has been limited publication of efforts made to translate this research into practice, specifically in rural or critical access hospitals.

Recommendations for Practice

The recommendations for practice were to develop a nurse-initiated protocol for the administration of topical anesthesia for laceration repair in the ED; because topical anesthesia has been found to be a safe, non-invasive, effective alternative to infiltrated lidocaine for laceration repair (Eidelman et al., 2012). The availability of cocaine-free preparations has eliminated the previous safety, storage, and cost concerns of topical anesthesia (Howard et al., 2012; Royal Australasian College of Physicians, 2006). Additionally, the investigator recommended that this protocol be designed in a way that would allow nursing staff to apply the topical anesthetic prior to provider assessment of the laceration. This helped to alleviate the barrier of the relatively long time to onset of action of topical anesthetics. Due to the number of studies that included LAT/LET or LE, the investigator recommended further exploring the possibility of implementation of one of these agents with the staff pharmacist. The pharmacist will also assist in making the decision between using solution or gel based topical anesthesia, based on availability and shelf-life.

Model of Evidence-Based Care

The Model for Evidence-Based Practice Change, as revised by Rosswurm and Larrabee, was used to guide this practice change (Appendix D). This model was

designed to lead nurses in research utilization and quality improvement (Rosswurm & Larrabee, 1999). The first step was to assess a need for a change in practice by including stakeholders, collecting internal data about current practice, and identifying the problem. The second step is to link the problem, intervention, and outcomes. Potential interventions, activities, and outcomes were identified and clearly stated in the methods section of this paper. A synthesis of the best evidence, step three, was conducted. Step four was the process of designing the practice change. Implementation and evaluation is the fifth step in the process. The final step in the change process is integrating and maintaining the change.

Nursing Model

The theoretical framework that guided this practice improvement project was the Theory of Symptom Management (Appendix E). This theory uses a symptomatic approach to determine intervention strategies, including how and when an intervention is delivered, and key issues in the management of the painful experience of laceration repair. Appendix E depicts the interrelations of the domains of nursing and the three dimensions of this model: symptom experience, management strategies, and outcomes. The three domains of nursing (person, health/illness, and environment) affect and modify all three dimensions of the Symptom Management Model. Symptom experience includes a patient's perception of a symptom, evaluation and meaning of a symptom, and response to a symptom (Dodd et al., 2010). In the case of painful laceration, a patient makes judgments about the severity, cause, treatability and effects that this pain will have on his or her life. The management of laceration pain using a topical anesthesia protocol pertains most directly to the symptom management strategies domain of this theory. This

domain includes the specifications of what, when, where, why, how much, to whom, and how laceration pain management should occur. This project developed a protocol for the use of topical anesthesia (what), during laceration repair (when), in the emergency department (where), to provide non-invasive anesthesia (why), to patients presenting to the emergency department with lacerations (whom). The how much, or dose was determined in collaboration with the staff pharmacist. The implementation of this protocol directly affected the third domain, outcomes. This includes the patient's functional and emotional status, the status of the symptom (elimination of pain), quality of life, mortality, and morbidity.

Chapter 3: Project Design and Methodology

Introduction

Melnyk and Fineout-Overholt (2011) define evidence-based practice as "a paradigm and life-long problem solving approach to clinical decision-making that involves the conscientious use of the best available evidence with one's own clinical expertise and patient values and preferences to improve outcomes" (p. 257). This project was based on the available research, which included systematic reviews of randomized control trials, quasi-experimental studies, and clinical practice guidelines. This chapter describes the evidence-based project design and methodology which corresponds to Step 4 in the Rosswurm and Larrabee model (Appendix D).

Population

The focus population for this project included all patients greater than one year of age presenting to this rural emergency department with simple lacerations. Patients with lacerations in anatomical end artery locations were excluded, due to the theoretical risk of tissue necrosis with epinephrine application to these sites.

Environmental and Organizational Context

This practice innovation project was implemented at Avera De Smet Memorial Hospital (ADMH), a small rural critical access hospital. ADMH's ED serves the needs of the local and surrounding communities. The providers in this facility had identified a need for a less painful means of anesthesia for laceration repair.

The hospital employs 15 registered nurses, two local physicians, two local nurse practitioners, and one physician assistant. In addition to ED coverage by the employed providers, locum providers cover ED call. The hospital staffs two nurses for each 12-

hour shift covering all hospital patients with a provider available to respond to the emergency department within 20 minutes. Locums staff either stay on-site or at the local motel. Prior to this project, ADMH utilized lidocaine injection anesthetic for all laceration repairs. There were no topical anesthetics available for the providers to use prior to the implementation of this project. The development of a topical anesthesia protocol for laceration repair allowed nursing staff to initiate anesthesia prior to provider arrival. This was ideal, since topical anesthetics can take 20 or more minutes to reach peak effectiveness (Hsu, 2013), which coincides with the 20 minute response time for ED providers.

Design

Hospitals in the surrounding area were contacted to determine practices for utilizing topical anesthesia across the region. The other facilities were surveyed to determine which topical anesthetics are used, how they are compounded and if their compounded topical anesthetics can be sent via courier system to ADMH, and any protocols for use (Table 1). Findings were discussed with the ADMH pharmacist and medical staff and the knowledge obtained was used to determine which topical anesthetic would be used in the protocol and determining where it will be compounded. Safety, effectiveness, availability, and cost were other factors considered in determining which agent would be used. The solution recommended for use was LAT solution. This solution was already being compounded in a regional pharmacy and would be able to be sent via courier to the facility for use.

Table 1

Topical Anesthesia Use of Regional Hospitals

Hospital	Critical Access	Topical Anesthesia	Protocol	Ability to Courier
A	x	none		
B	x	none		
C	x	none		
D		LAT solution	x	x

A retrospective chart review was conducted by hospital staff by electronic data extraction on all laceration patients greater than one year of age that were seen in the emergency department the seven months preceding the implementation of the topical anesthesia protocol and the three months post implementation using the data collection chart found in Appendix F. De-identified data was given to the investigator.

Protocol development occurred in collaboration with the director of nursing and pharmacist, who are responsible for the development of all nursing and provider protocols that include medications. The investigator presented the protocol to the Hospital Consumer Assessment of Health Plans Survey (HCAHPS) committee for their input and the medical staff for approval. The investigator provided education to the providers and nursing staff at their monthly meeting the month prior to implementation of the protocol. Education included identification of indications for use, contraindications, equipment, procedure for application, and documentation procedures. A competency based checklist was given to nurses prior to implementation to ensure competence (Appendix G). This checklist was provided in an interactive manner, while walking through the steps of the protocol. Time was provided for questions about the process. An email was sent to all staff the week prior to implementation to provide additional

education regarding the implementation of the protocol (Appendix H). A copy of the protocol was placed in each emergency room for quick reference. Four locums providers were informed about the protocol upon arrival for their shift by the investigator and the educated nursing staff.

Investigation of Problem

Stakeholders in this project included the hospital administrator, director of nursing, pharmacist, providers, HCAHPS committee, and nursing staff. The investigator engaged with pre-identified stakeholders to select the topical anesthesia to be used, develop the protocol, and educate the staff. In addition, the hospital administrator was instrumental in the protocol approval process.

The principal barrier to implementation was determining how the topical anesthesia would be compounded or obtained. Most topical anesthetics need to be compounded and are not commercially made. ADMH only has a pharmacist on staff five hours per week and is not able to compound the anesthetic at the hospital. Another potential barrier was the relatively long onset of topical anesthesia. Depending on the specific topical anesthetic used, onset of action can be between 20 and 60 minutes (Hsu, 2013). This could affect the applicability of topical anesthesia to the fast pace of the emergency room setting. This barrier was addressed by creating a nurse-initiated protocol, which allowed the topical anesthetic to reach effectiveness upon arrival of the provider.

My affiliation with the facility helped to facilitate this project. The investigator has been employed at ADMH for seven years and has developed positive working relationships with the key stakeholders in this project. Also, the administrator of this

facility has been looking for nursing staff to become evidence-based care champions and implement best practices into our current patient care processes. It was easy to get buy in from nursing staff and providers for this project. Some providers had requested the use of topical anesthesia, but due to the compounding issue, the request had been tabled in the past. Since laceration repair is common, staff members were able to think of a time when topical anesthesia would have been desirable if it had been available.

Protection of Human Subjects

A letter of support for the proposed project was obtained from the ADMH administrator (Appendix G). The investigator completed the institutional review board process with both Avera and South Dakota State University to ensure protection of the population (Appendix I and J).

Projected Evaluation and Analysis

The Rosswurm and Larrabee model was used to guide implementation and evaluation of the project. Process was evaluated with the following.

Use of topical anesthesia. The utilization of the protocol was measured through post-implementation chart review of the use of topical anesthesia. Utilization of the protocol was narratively described. A focus group was conducted with nursing staff and providers to assess their attitudes and beliefs about the success of the project. This focus group was led by a member of the HCAHPS committee, who was not associated with the project, to encourage the free expression of ideas. The information learned through this project implementation will be used in the future to address barriers to implementation of evidence-based processes at this hospital.

Treatment time. Total treatment time was measured through chart review of

admission and discharge time. The small number of patients in the post-implementation group resulted in a population without normal distribution. Therefore, a Mann-Whitney *U* test was used to compare the pre and post implementation groups. A run chart was used to compare treatment time from month to month.

Pain. Pain associated with laceration repair was measured through chart review of pain level on admission and discharge. Pain was assessed using a verbal 0-10 scale and FACES Pain Scale with word descriptions (Appendix J).

Patient satisfaction. A long-term outcome, the impact of this project on the patient satisfaction survey results was not evaluated due to the low emergency department volume in this setting. It would take up to a year or more to see an impact on the patient satisfaction survey.

Chapter 4: Outcomes and Impact

Introduction

The short-term outcomes that were measured were total treatment time, pain with laceration repair, and utilization of the protocol. A focus group was conducted to help ascertain clinical significance and staff acceptance of the protocol. Ultimately, this project has the potential to impact patient satisfaction, which was not measured for the purposes of this project due to time constraints.

Process Evaluation

Use of topical anesthesia. Records of laceration patients were reviewed for the seven months prior to implementation for type of anesthesia used, treatment time, and pain associated with laceration repair. There were 35 total lacerations during the surveyed pre-implementation period. The pre-implementation data included lacerations for patients greater than one year of age, lacerations seven centimeters in length or less, and included lacerations that were located in areas of end areteriolar circulation. Of these, six were children and 23 received anesthetic by injection. No topical anesthesia was used in the pre-implementation period, as it was not available.

Post-implementation data was collected for the 12 weeks following the implementation of the topical anesthesia protocol. During this period, there were a total of 13 lacerations. Six of these were excluded from this study due to end arteriolar location, which is a contraindication to the use of topical anesthesia. All seven of the lacerations that met inclusion criteria received topical anesthesia. Five cases also received a subsequent injection of anesthesia. Only one of the included cases was a child.

A focus group was conducted by the HCHAPS committee to evaluate for potential clinical significance and staff attitudes about the utilization of the protocol. The focus group included six staff members: four nurses, one local provider, and one locum provider. Two of the participants had not had an opportunity to utilize the protocol, while the other four had utilized it at least one time. The nursing staff reported that the education they received was adequate and they felt confident in their ability to determine if topical anesthetic would be indicated or contraindicated. Several of the participants reported an increase in patient satisfaction, citing that their patients were relieved that something could be done to prevent them from feeling the stinging of the infiltrated anesthesia and needle insertion. Two nurses and one provider stated that they felt they were able to clean the wound with better patient tolerance after application of topical anesthesia. All four of the participants who were able to utilize the protocol during the study period reported that using topical anesthesia appeared to result in a decrease in pain and increase tolerance of infiltrated anesthesia. Two participants reported that topical anesthesia seemed to have increasing effectiveness the smaller the wound is in size. The participants who utilized the protocol verbalized their desire to continue using it. The participants who did not utilize the protocol stated that they were looking forward to the opportunity to use it and had heard only positive feedback from other staff.

Outcome Evaluation

Treatment time. The median total treatment time for the pre-implementation group was 79 minutes. The median total treatment time for the post-implementation group was 65minutes. Pre and post-implementation groups were compared using a

Mann-Whitney *U* test, finding no statistically significant difference in treatment time. However, the mean treatment time was trending downward (Figure 1).

Table 2

Results

Outcome	Pre/Post Innovation	Mean	SD	Median
Treatment Time (min.)	Pre (n=35)	82.31	31.34	79.00
	Post (n=7)	62.57	21.37	65.00
Pain on Admit	Pre (n=35)	3.34	3.10	4.00
	Post (n=7)	1.00	1.41	0.00
Pain on Discharge	Pre (n=35)	1.29	1.60	0.00
	Post (n=7)	*Pain at discharge was 0 for all post-implementation patients		

Pain. The pre and post implementation groups were compared using a nonparametric Mann-Whitney *U* test for the distribution of pain at admit and pain at discharge. There was no statistically significant difference in pain at admit. Although this was not a direct reflection of an outcome, it is an important finding. This finding shows that pre and post-implementation groups were similar in pain level prior to treatment. Pain at discharge was statistically significantly decreased in the post-implementation group, compared to the pre-implementation group ($p = 0.024$). This indicates that the addition of topical anesthesia influenced patients' perception of pain.

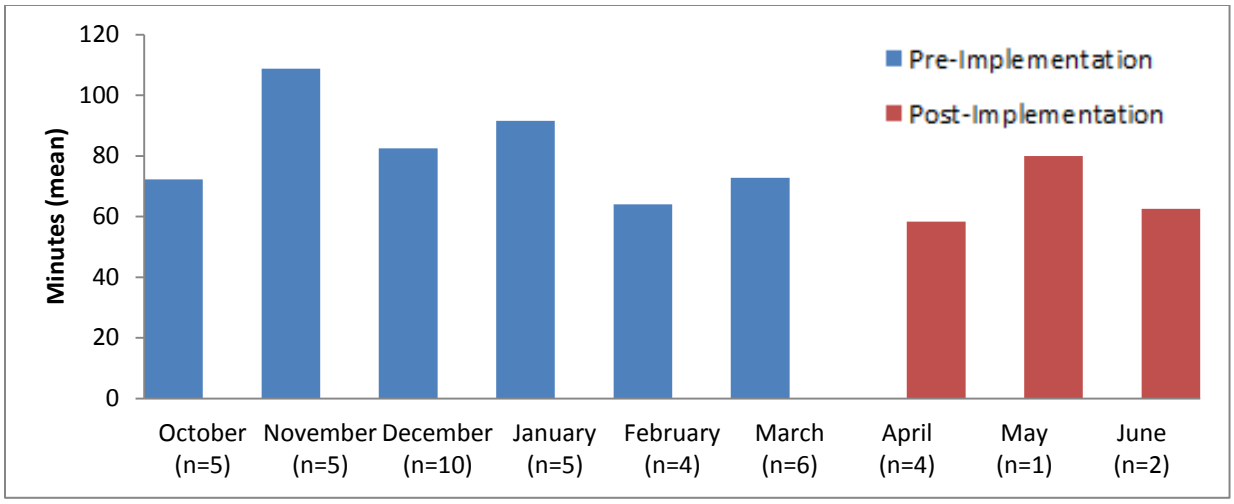


Figure 1. Treatment Time

Patient satisfaction. The long-term impact of this intervention on patient satisfaction was not measured due to the short time period this study was conducted. The HCHAPS committee at the hospital is planning on trending the patient satisfaction surveys over a longer period of time to determine if this project impacted patient satisfaction.

Chapter 5: Summary

Quality improvement projects integrating evidence based practice into health care are critical for improving the quality of health care. This project was able to integrate the current evidence related to topical anesthesia into practice by making topical anesthesia available for use in laceration repair. The investigator's affiliation with the implementation site allowed identification of the need for an improvement in the practice of laceration care. Although the literature has shown topical anesthesia to be effective in managing pain associated with laceration repair, the availability of these products continues to be limited in rural areas.

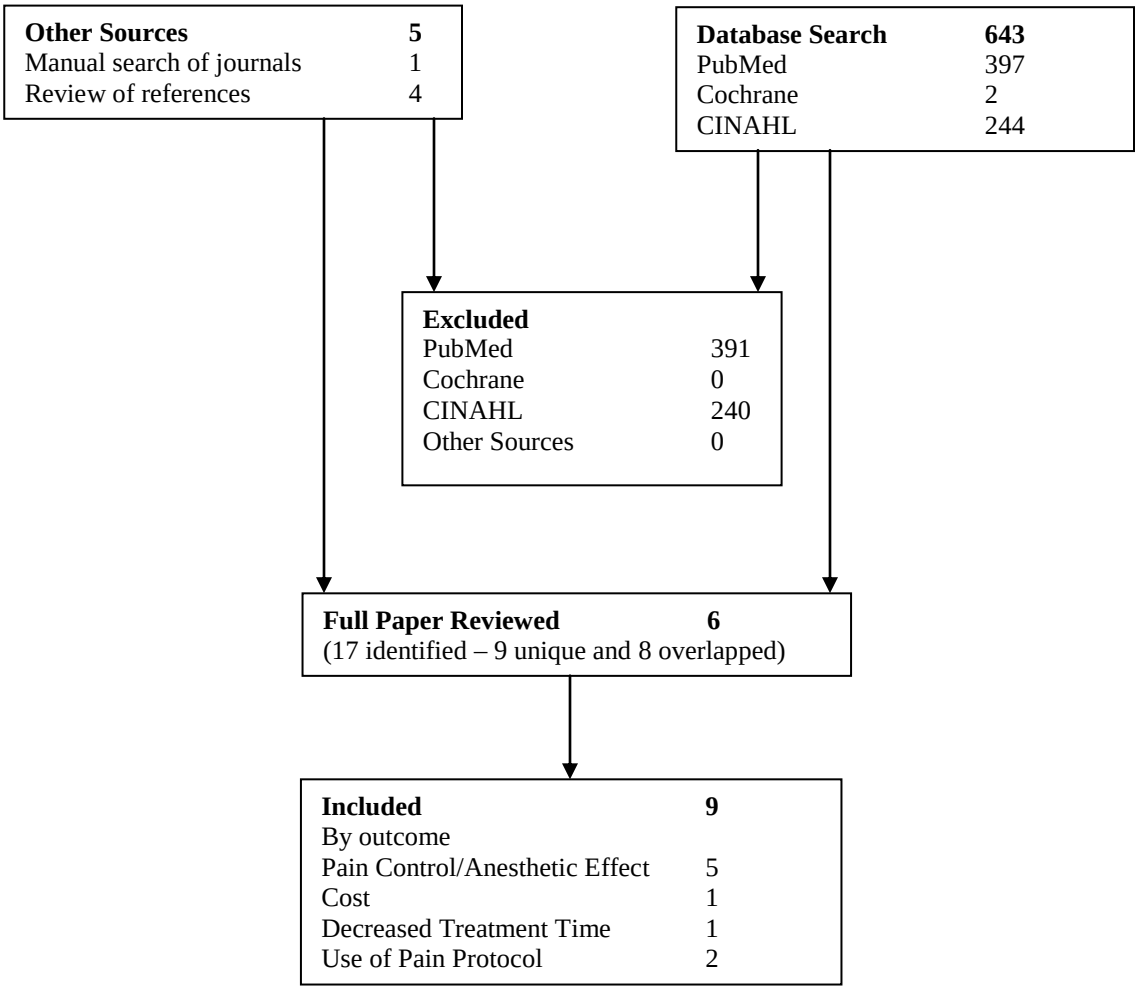
Overall, this project was successful. There was a statistically significant decrease in discharge pain. However, due to the small number of patients who qualified for this nurse-initiated protocol, this outcome needs further confirmation. The clinical impact of the project is significant. The focus group information revealed that the providers and nursing staff thought that there were significant impacts on patient satisfaction and tolerance to wound cleaning and infiltration of anesthesia. These impacts were significant enough to the staff that they are willing to continue integrating this protocol into their work flow without any modifications.

Limitations of the project included the small sample size, short time period studied for this project, and the inclusion in the pre-implementation group of some patients with lacerations (e.g., ears or digits) that would not have qualified for the nurse-initiated protocol. Further study is warranted to determine if topical anesthesia has a statistically significant impact on treatment time or patient satisfaction. Additional study

is needed in the rural setting to evaluate the impact of topical anesthesia and other evidence based interventions.

Appendix A

Search Flow Diagram



Appendix B

Authors, Year, Location, Title, and Design	**Purpose, Intervention, Sample Size, Setting**	**Intervention Period, Outcome Measures, Follow-up, or Agree Domains**	**Author Findings and Conclusions**	**Study Strengths and Limitations**
Authors: Eidelman, Weiss, Baldwin, Enu, McNicol, & Carr **Year:** 2012 **Title:** Topical anesthetics for repair of dermal laceration **Design:** Descriptive Systematic Review of RCTs **Level of Evidence: IB**	**Purpose:** To compare the efficacy and safety of infiltrated local anesthetics with those of topical local anesthetics for repair of dermal lacerations with sutures or staples. **Intervention:** Topical local anesthetics, 18 different topical anesthetics **Sample Size:** 23 RCTs involving 3128 adult and pediatric patients	**Outcome Measure:** To compare the efficacy of infiltrated local anesthetics and topically applied local anesthetics. Compare efficacy of single or multi-component topical anesthetics. Identify cocaine-free, topical anesthetics that are as efficacious as cocaine-containing topical anesthetics.	**Findings and Conclusions:** • 3/3 RCTs (406 patients) showed no statistical significance between cocaine-free topical anesthetics and infiltrated local anesthetic in patient reported VAS pain scores. • 5 RCTs studying 10 different cocaine-free topical anesthetics found no significant difference between patient reported VAS pain scores between groups. • No serious complications with the use of topical anesthesia. Based on 11 studies and 1686 participants.	**Strengths:** -Review of RCTs -Each RCT was critically reviewed with GRADE. -Comprehensive search **Limitations:** -Most of the comparisons between specific anesthetic agents were confined to a single trial. -Due to methodological heterogeneity unable to do meta-analysis. -GRADE scores of low to a few moderate due to risk of bias in most trials and lack of blinding,

Authors: Priestley, Kelly, Chow, Powell, & Williams **Year:** 2003 **Title:** Application of topical local anesthetic at triage reduces treatment time for children with lacerations: a randomized control trial. **Setting:** Australian urban ED. **Design:** RCT **Level of Evidence: IB**	**Purpose:** To determine whether the application of topical local anesthetic at triage reduces total treatment time for children with simple lacerations **Intervention:** Topical anesthesia ALA solution, also known as LET. **Sample Size:** 161 patients age 1 to 10 years.	**Outcome Measure:** Total treatment time and sedation rate	**Findings and Conclusions:** • Median treatment time for topical anesthetic group was 77 minutes compared to 108 for the control group. Effect size 31 minutes • No difference in requirement for sedation between groups. • No observed complications relating to prolonged periods of anesthesia contact with wounds (20 to 125 minutes).	**Strengths:** -Double-blinded **Limitations:** -The control group was given the placebo of adrenaline 1:1000, not an infiltrated anesthetic which is the usual care. -Staff failed to screen 13% of lacerations for inclusion.
Authors: Singer & Stark **Year:** 2000 **Title:** Pretreatment of lacerations with lidocaine, epinephrine, and tetracaine at triage: A randomized double-blind trial. **Setting:** Emergency	**Purpose:** To compare the levels of pain of lidocaine injection and the proportion of adequately anesthetized wounds after topical application of LET or placebo at time of triage. **Intervention:** Topical application of LET solution or placebo	**Outcome Measure:** Pain of application, adequate anesthesia, pain of injection, and rate of infection.	**Findings and Conclusions:** • No difference between LET and placebo for pain of application. • Those who received LET were more likely to be	**Strengths:** -Double-blinded. **Limitations:** -Pain for patients under age 8 was reported by guardian. -Only ½ the patients returned to the emergency department for follow-up, therefore ½ the determination of infection

department of urban tertiary care center. **Design:** RCT **Level of Evidence: IB**	(epinephrine) applied by nurses prior to provider assessment, for those lacerations the nurse judged as needing closure. **Sample Size:** 43 patients (22 LET and 21 placebo) age 1 to 69 years.		completely anesthetized, $p = .03$. • Those who received LET experienced less pain with injection of lidocaine, $p = .02$ • No infections were reported in either group.	was based on whether patients had received an antibiotic to treat infection
Authors: Harman, Zemek, Duncan, Ying, & Petrcich **Year:** 2013 **Title:** Efficacy of pain control with topical lidocaine-epinephrine-tetracaine during laceration repair with tissue adhesive in children: a RCT. **Setting:** Tertiary-care, academic, pediatric emergency department.. **Design:** RCT **Level of Evidence: IB**	**Purpose:** To investigate whether pre-applying lidocaine-epinephrine-tetracaine would decrease pain in children during minor laceration repair using tissue adhesive. **Intervention:** Topical application of LET gel or placebo gel applied by nurses prior to provider assessment.. **Sample Size:** 221 patients (113 LET and 108 placebo) age 3 months to 17 years.	**Outcome Measure:** Amount of pain reported during application of tissue adhesive. Physician rating of difficulty of repair and wound hemostasis achieved before repair.	**Findings and Conclusions:** • Children receiving LET reported less pain (51.6% receiving LET vs. 28.3% receiving placebo reported no pain with application of tissue adhesive). • Physicians more frequently rated wound hemostasis as complete in the treatment group (78.2%) than the placebo group	**Strengths:** -RCT **Limitations:** -Physicians were able to guess 73% of the time whether the analgesic or placebo was applied, were they truly blinded. -Patient's younger than 7 pain was rated by guardian.

			(59.3%), $p < .008$. • No significant difference in physicians rating of difficulty of repair.	
Authors: Eidelman, Weiss, Enu, Lau, & Carr **Year:** 2005 **Title:** Comparative efficacy and costs of various topical anesthetics for repair of dermal lacerations: a systematic review of randomized controlled trials. **Setting:** University-affiliated hospital. **Design:** Systematic Review of RCTs **Level of Evidence: IIB**	**Purpose:** To compare the efficacy of infiltrated local anesthesia with topical anesthesia for dermal laceration to identify less costly and equally efficacious topical anesthetics that do not contain cocaine. **Intervention:** Topical anesthetics (6 different cocaine-free anesthetics) **Sample Size:** 22 RCTs with 3190 pediatric and adult patients.	**Outcome Measure:** Efficacy & cost.	**Findings and Conclusions:** • Topical anesthetics are an efficacious, noninvasive means of providing analgesia for suturing of dermal lacerations. • Cocaine is not a mandatory component of topical anesthetics for dermal wound repair. • Topical anesthetics that do not contain cocaine are less costly. TAC $19.82, LAT $1.87, LE $1.86, Tetraphen $0.78, Prilophen $0.65, Tetralidophen $0.55, Bupivanor $0.51 per 5 ml dose. • Authors recommend	**Strengths:** -Large sample size. -Compared multiple topical anesthetics. **Limitations:** -Heterogeneity of included studies. -Critical appraisal of RCTs included in study not available.

			LAT for analgesia in dermal laceration.	
Authors: Crocker, Higginbotham, King, Taylor, & Milling **Year:** 2012 **Title:** Comprehensive pain management protocol reduces children's memory of pain at discharge from pediatric ED. **Design:** Pre and post-test. Quasi-experimental. **Level of Evidence: IIB**	**Purpose:** To measure the impact of pain management protocol on patients with painful conditions or undergoing painful procedures in the emergency department. **Intervention:** Pain management protocol. **Sample Size:** 531 pre-protocol & 263 protocol group; age 30 days to 18 years **Setting:** Dedicated Children's hospital emergency room	**Intervention Period:** 2, six week periods. **Outcome Measures:** Patient and parent pain levels before and after implementation. **Follow-up:** Adequate.	**Findings and Conclusions:** Pain management protocol reduced patients' pain during visits. Patient-recalled pain scores in the protocol group (263 patients) were lower than pre-protocol group (531 patients), $p < .001$. Recommend LMX cream or LAT gel be applied to affected area with pain score >1.	**Strengths:** -Regression done to control for extraneous variables. **Limitations:** -This protocol implemented a group of pain management techniques, so it is difficult to say what the impact was of each technique. -Pain was only scored at triage and discharge, requiring patients to recall pain levels during procedures. -Unbalanced comparison groups. -Pain scale used not well validated for patients younger than 4, so parental assessment of pain was used in younger children.
Authors: Taylor,	**Purpose:** To evaluate	**Intervention Period:**	**Findings and**	**Strengths:**

Taylor, Jao, Goh, & Ward **Year:** 2013 **Title:** Nurse-initiated analgesia pathway for pediatric patients in the emergency department: A clinical intervention trial. **Design:** Pre and post-test. Quasi-experimental. **Level of Evidence: IIB**	the impact of a nurse-initiated analgesia pathway for pediatric patients in the emergency department. **Intervention:** Pain management protocol. **Sample Size:** 51 pre-protocol & 51 protocol group; age 5 to 18 years **Setting:** Mixed (adult and pediatric) emergency department in a tertiary referral facility	2 months. **Outcome Measures:** Time to analgesia, adequate analgesia, and parental satisfaction with ED pain management. **Follow-up:** Adequate.	**Conclusions:** More patients received nurse-initiated analgesia $p < .001$ (3.0% pre-protocol vs. 43.9% post-protocol). The median time to analgesia was reduced $p < .001$ (58 minutes pre-protocol vs. 23 minutes post-protocol). Trend towards more parent's very satisfied with their child's overall pain management, although not statistically significant (47.1% pre-protocol vs. 66.7% post-protocol; $p = .07$).	-None of the investigators provided care to patients. -Use of valid pain assessment tools (Wong-Baker FACES and 0-10 numerical rating scale). **Limitations:** -Convenience sample. -The 2 groups were not well matched for indication for analgesia (more abdominal pain in post-protocol group).
Authors: Howard, Carter, Curry, Jain, Liossi, Morton, Rivett, Rose, Tyrrell, Walker, & Williams **Year:** 2012 **Location:** Great Britain & Ireland **Title:** Good practice	**Purpose:** To provide evidence-based guidelines for the management of children 0-18 years undergoing surgery or painful procedures in hospital settings.	**Stakeholder Involvement:** Includes a range of professional groups, was open to the public for comment, & target users defined. **Rigor of Development:**	**Findings and Conclusions for Laceration Repair:** -Topical anesthetic preparations, for example, LAT, if available can be used in preference to infiltrated anesthetics, as they are	**Strengths:** -Good stakeholder involvement, rigor, clarity, and editorial independence. - AGREE: Overall 7/7, Scope and Purpose 21/21, Stakeholder Involvement 21/21, Rigor of

in postoperative and procedural pain management 2nd edition **Design:** Practice Guideline **Level of Evidence: IVA**		Systematic methods used, criteria clearly stated, strengths and limitations described, risks were considered, supporting evidence provided. **Clarity of Presentation:** Key recommendations are specific, and clearly presented. **Editorial Independence:** Competing interests were addressed.	less painful to apply. Grade A. -It is not necessary to use a preparation containing cocaine. Grade A. -If infiltrated lidocaine is used, pretreatment of the wound with topical anesthetic reduces the pain of subsequent injection. Grade B.	Development 51/56, Clarity of Presentation 28/28, Applicability 26/28, Editorial Independence 14/14 **Limitations:** -The strengths and limitations of the evidence are not well stated. -Plans for updating not included.
Authors: Royal Australasian College of Physicians Sydney **Year:** 2005 **Location:** Sydney, Australia **Title:** Guideline Statement: Management of Procedure-related Pain in Children and Adolescents **Design:** Practice Guideline	**Purpose:** Provide a framework for managing procedural pain in children and adolescents so that people can write their own clinical practice guidelines relevant to their local situation and resources.	**Stakeholder Involvement:** Includes a range of professional groups and the target population is defined. **Rigor of Development:** Systematic methods used, criteria clearly stated, strengths and limitations described, risks were considered, supporting evidence	**Findings and Conclusions for Laceration Repair:** -When sutures are required, topical agents should be used in preference to infiltrated. -The mixture of lignocaine, adrenaline, and tetracaine (ALA or LET) should be used in preference to cocaine containing topical anesthetics because of	**Strengths:** -Good clarity and applicability. -AGREE: Overall 6/7, Scope and Purpose 21/21, Stakeholder Involvement 13/21, Rigor of Development 53/56, Clarity of Presentation 28/28, Applicability 24/28, Editorial Independence 8/14 **Limitations:** -Potential competing

Level of Evidence: IVB		provided. **Clarity of Presentation:** Key recommendations are specific, and clearly presented. **Applicability:** Facilitators and barriers addressed and resource implications considered.	equivalent efficacy and better safety profile. Level II.	interests not addressed. -Plans for updating not included. -No external review before publication.
Authors: Fein, Zempsky, & Cravero **Year:** 2012 **Location:** **Title:** Relief of Pain and Anxiety in Pediatric Patients in Emergency Medical Systems. **Design:** Practice Guideline **Level of Evidence: IVB**	**Purpose:** Provide guidance for the relief of pain and anxiety in pediatric patients for clinicians rendering pediatric care in emergency medical systems.	**Stakeholder Involvement:** Includes a range of representatives from several professional groups and the target population is defined. **Rigor of Development:** Methods were not clearly defined or stated. Minimal supporting evidence. Strengths and limitations were not described. **Clarity of Presentation:** Key recommendations are	**Findings and Conclusions for Laceration Repair:** -LET can be applied to simple lacerations and may be applied to complex or deeper lacerations that may require supplemental subcutaneous anesthetic administration. -Dose 3mL for children > 17 kg; 0.175 ml/kg in children < 17 kg. -Place LET on open wound and cover with occlusive dressing or place cotton ball soaked with LET solution into	**Strengths:** -Good clarity and applicability. -Developed by American Academy of Pediatrics. -Set expiration of guideline. **Limitations:** -Methods were not described well. -AGREE: Overall 5/7, Scope and Purpose 21/21, Stakeholder Involvement 21/21, Rigor of Development 38/56, Clarity of Presentation 21/28, Applicability 26/28, Editorial Independence 14/14

		specific and clearly presented. **Applicability:** Facilitators and barriers were addressed.	wound. -Allow LET to soak into wound for 10-20 minutes or until wound edges appear blanched.	

Appendix C

Topical Anesthetic	**Study**	**Dose**	**Duration of Application**	**No. Patients**	**Control Group**	**No. Patients**	**Outcome**	**Results**
LET	Harman, 2013	Did not state the dose of components. Gel	45-120 minutes	113	Placebo gel	108	Pain during application of tissue adhesive.	Children receiving LET reported less pain (51.6% receiving LET vs. 28.3% receiving placebo reported no pain with application of tissue adhesive).
							Wound hemostasis	Physicians more frequently rated wound hemostasis as complete in the treatment group (78.2%) than the placebo group (59.3%), $p < .008$.
							Difficulty of repair	No significant difference in physicians rating of difficulty of repair.
LE	Gaufberg, 2007	L 5% E 0.025% Solution	10-15 minutes	50	Infiltration with lidocaine	50	Pain intensity during application of anesthetic	Mean Pain Score LE 0.36 Lidocaine 4.34 $p < .001$
							Pain intensity during wound repair	Mean Pain Score LE 0.16 Lidocaine 0.20 $p = .59$
							Patient experience	LE 95% reported “excellent” experience Lidocaine 5% reported “excellent” experience
							Wound healing/infection	No reports of difficulty with wound healing or infection in either control

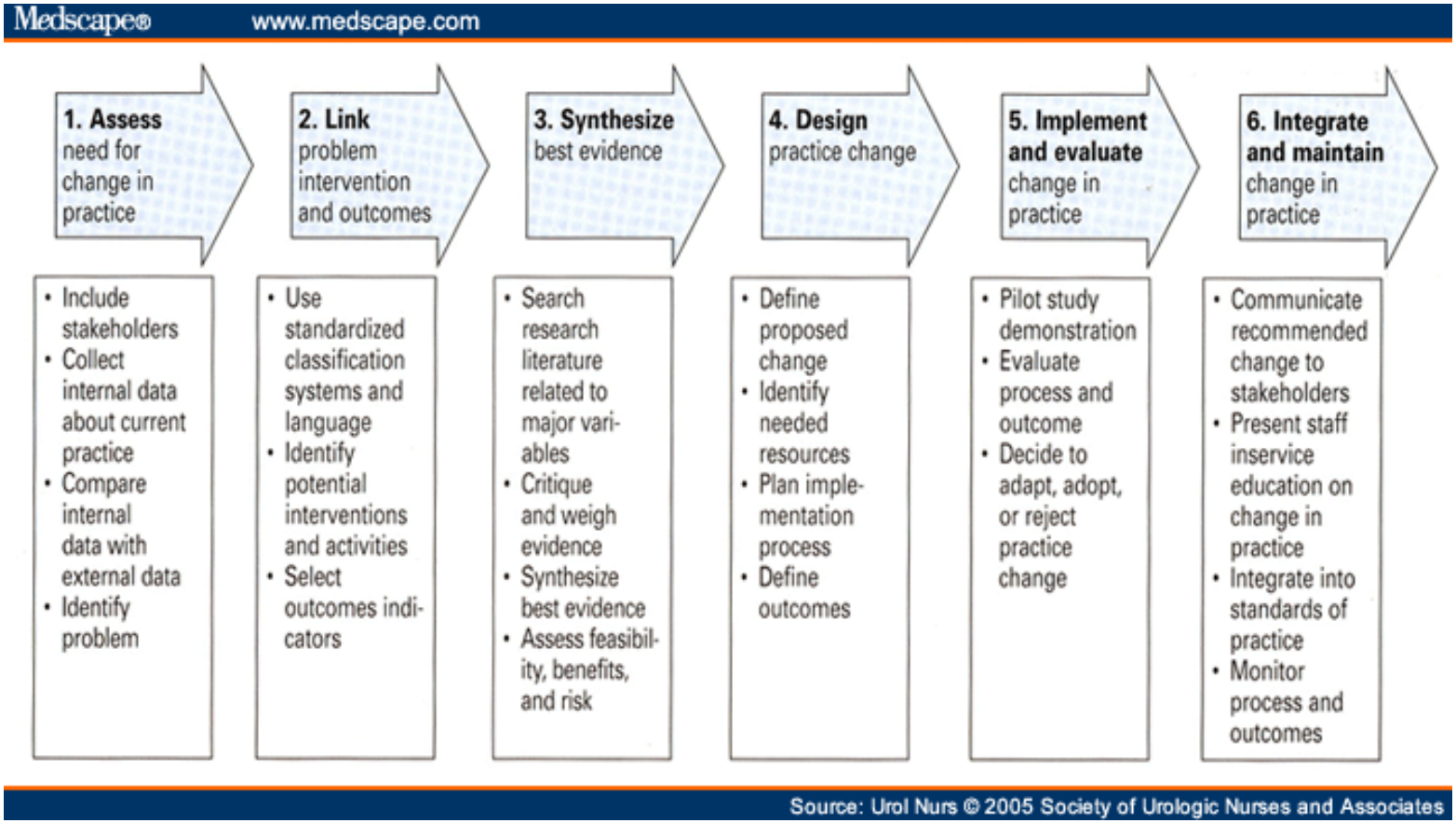
								or study group
LET	Krief, 2002	L 4.0% E 1:2000 T 0.5% Gel	60 minutes	22	EMLA	19	Requirement for supplemental lidocaine infiltration	13/19 EMLA required supplemental lidocaine 5/22 LET required supplemental lidocaine
LET	Singer, 2000	L 2% E 1:1000 T 2% Solution	31-41 minutes	22	Placebo Solution	21	Pain of lidocaine infiltration Proportion of lacerations adequately anesthetized Pain of application Infection	Those who received LET experienced less pain with injection of lidocaine, $p = .02$ Those who received LET were more likely to be completely anesthetized, $p = .03$. No difference between LET and placebo for pain of application. No infections were reported in either group.
LAT	Adler et al, 1998	L 4.0% A 1:1000 T 0.5% Solution	20-30 minutes	30	Placebo Solution	30	Pain intensity Requirement for further anesthesia	Patient reported pain on needle probing was reduced with LET group $p < 0.05$ LAT 43% required additional anesthesia Placebo 100% required additional anesthesia
LAT	Resch et al, 1998	L 4.0% A 1:2000 T 0.5% Solution	20 minutes	103	LET Gel	91	Adequacy of anesthesia Requirement for further anesthesia Adverse Effects	Solution 84% adequate Gel 82% adequate Solution 76% complete anesthesia Gel 85% complete anesthesia No acute anesthetic adverse effects.
LET	Ernst et al,	L 4.0%	10-20	33	Infiltrated	33		Injection was more painful $p < .001$

	1997	E 1:2000 T 0.5% Gel	minutes		Lidocaine and Bicarbonate		Pain intensity (patient-rated by VAS score)	No difference in effectiveness p = .48
LAT	Ernst et al, 1995	L 4.0% A 1:2000 T 0.5% Gel	10-30 minutes	48	TAC gel	47	Pain relief	Patients did not report a difference in effectiveness p = .266
LE	Blackburn, 1995	L 5% E 1:2000 Solution	20 minutes	17	TAC	18	Pain intensity Requirement for supplemental lidocaine infiltration	Mean Faces pain scale LE 3.29 TAC 2.66 p = 0.33 LE 6% required lidocaine infiltration TAC 6% required lidocaine infiltration
LAT	Schilling et al, 1995	L 4.0% A 1:2000 T 0.5% Solution	15 minutes	78	TAC Solution	73	Adequacy of anesthesia Anesthetic Effectiveness Adverse Effects	TAC 79.5% adequate LAT 74.4% adequate p = 0.46 LAT 82.4% TAC 75.9% p = 0.18 No acute anesthetic adverse effects

A: Adrenaline; E: Epinephrine; L: Lidocaine, T: Tetracaine

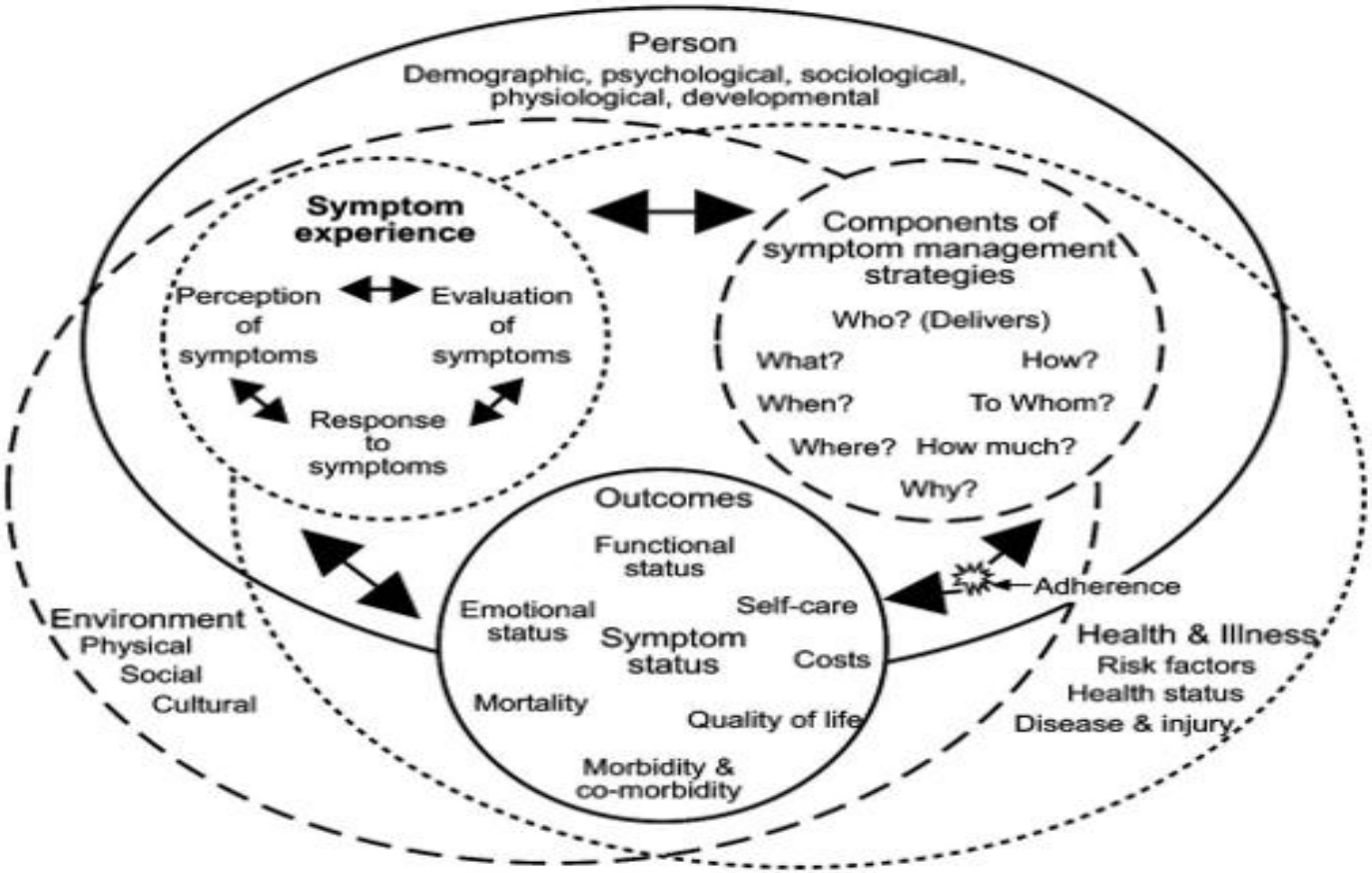
Appendix D

Rosswurm & Larrabee's Model for Evidence-Based Practice Change



Appendix E

Theory of Symptom Management



NURSE-INITIATED TOPICAL ANESTHESIA PROTOCOL

Appendix F

Data Collection Chart

Adult/Child 1= Adult ≥18 0= Child 1-17	Month	Topical Anesthesia	Infiltrated Anesthesia	Dose	Admission Time	Discharge Time	Pain (0-10) at Admit	Pain (0-10) at Discharge

Appendix G

Competency Based Checklist

Avera De Smet Memorial Hospital
Competency Testing

Topical LAT (Lidocaine, Adrenalin, Tetracaine) Administration

Name: _____ Date: _____

The above named employee will be observed in the performance of the indicated procedure. For each step of the procedure that conforms to the correct procedure, place a check mark in the "yes" column. If any step is performed incorrectly, place a check mark in the "no" column and give instructions for corrective action in the comment section.

Procedure Step	Yes	No	Comments
1. Identify Indications Used in simple, superficial lacerations to decrease pain during repair and decrease bleeding.			
2. Identify Contraindications Avoid use in children < 1 year Avoid mucus membranes/oral administration Avoid contact with large abrasions/lacerations (>7cm) Avoid use on burns Avoid eye contact: may result in corneal abrasion Check for allergy to "caines" ***Avoid the following locations due to superficial vasoconstriction: ears, penis, digits, tip of nose***			
3. Equipment LAT solution (stored in Omnicell refrigerator) Cotton balls or gauze Occlusive dressing (Tegaderm) Gloves			
4. Procedure • Gloves worn by nurse applying LAT. • 3 ml LAT solution will be dropped onto gauze or cotton ball. • LAT saturated gauze or cotton ball will be applied directly to the wound for 20 minutes, either by direct pressure or clear dressing (tegaderm). • Patient will note numbness at wound edges and skin surrounding wound will blanch due to vasoconstriction. • Cleanse the wound. • If local infiltration with anesthetic is required after LAT, caution should be taken in using epinephrine in combination with anesthetic.			
5. Documentation • Order LAT using an order source of "protocol". • Document on eMAR			

_____
Signature of Validating Nurse

Appendix H

Email to Staff

Reminder:

We will be implementing the ***Topical Anesthesia Protocol*** next week.

It is a nurse-initiated protocol, and can be initiated prior to provider arrival. It is intended to be used on all patients greater than 1 year of age presenting to the emergency department with simple, superficial lacerations to decrease pain. Do not use for lacerations involving mucus membranes, burns, eyes, ears, penis, digits, or tip of nose. Expect the area surrounding the wound to blanch due to vasoconstriction from the epinephrine component.

Attached is a copy of the protocol and competency based checklist.

If you have any questions, please contact me.

Jennifer Anderson, RN
Avera De Smet Memorial Hospital
jennifer.anderson@avera.org

Appendix I

Letter of Support

Avera
De Smet Memorial Hospital

306 Prairie Ave SW
PO Box 160
De Smet, SD 57231
(605) 854-3329
(800) 307-6830
Fax: (605) 854-3161

www.AveraDeSmet.org

January 13, 2014

South Dakota State University
DNP Program
College of Nursing
Brookings, SD 57007

To whom it may concern:

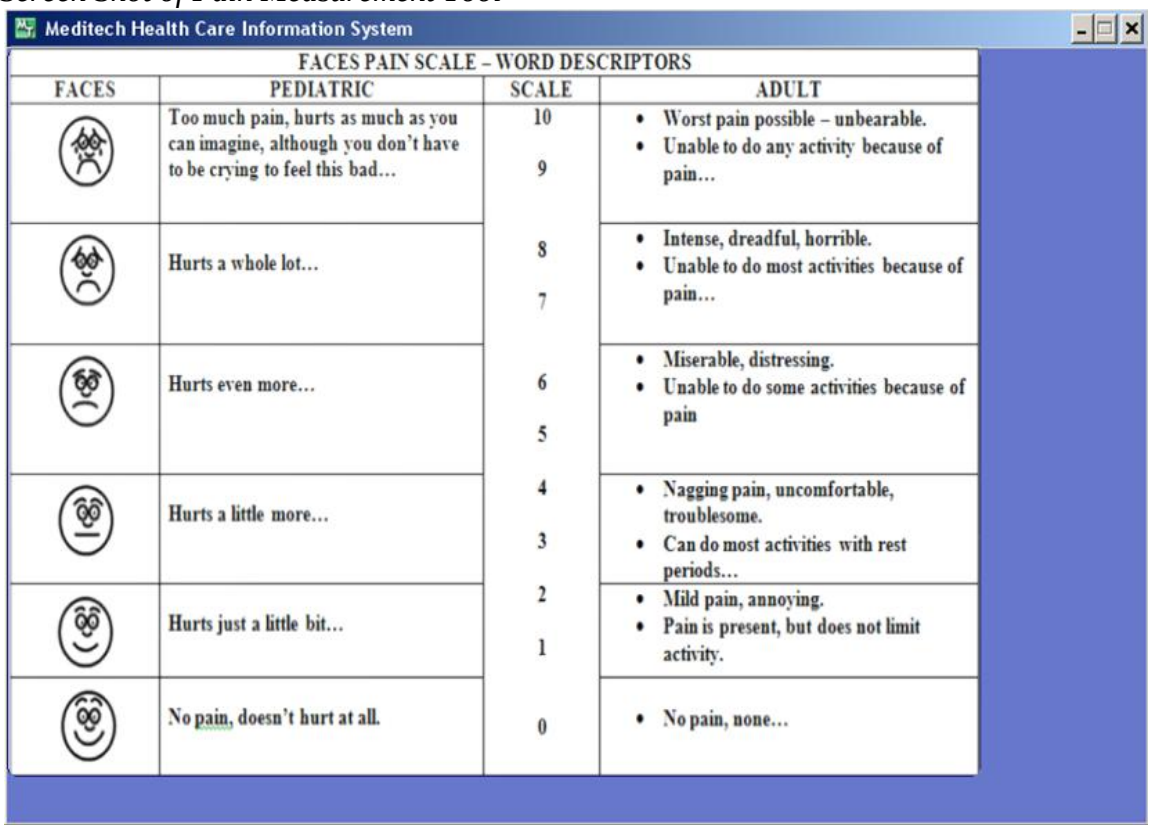
Avera De Smet Memorial Hospital is writing to express its support for the proposed quality improvement project: Implementation of a Nurse-Initiated Topical Anesthesia Protocol being submitted by Jennifer Anderson, as her practice improvement project for South Dakota State University's DNP program. We will provide existing health data and focus group feedback from staff.

Sincerely,

Janice Schardin, RN, MS
CEO/Administrator

Appendix J

Screen Shot of Pain Measurement Tool



Meditech Health Care Information System

FACES PAIN SCALE – WORD DESCRIPTORS

FACES	PEDIATRIC	SCALE	ADULT
	Too much pain, hurts as much as you can imagine, although you don't have to be crying to feel this bad…	10 9	• Worst pain possible – unbearable. • Unable to do any activity because of pain…
	Hurts a whole lot…	8 7	• Intense, dreadful, horrible. • Unable to do most activities because of pain…
	Hurts even more…	6 5	• Miserable, distressing. • Unable to do some activities because of pain
	Hurts a little more…	4 3	• Nagging pain, uncomfortable, troublesome. • Can do most activities with rest periods…
	Hurts just a little bit…	2 1	• Mild pain, annoying. • Pain is present, but does not limit activity.
	No pain, doesn't hurt at all.	0	• No pain, none…

Appendix K

Avera IRB Approval Letter

Avera

Institutional Review Board
3900 W. Avera Drive
Sioux Falls, SD 57108
605-322-4755
Fax: 605-322-4799

Avera.org

March 5, 2014

Jennifer Anderson, RN,BS
509 4th Street SW
DeSmet SD 57231

RE: Our Study #2014.012

Dear Jennifer. Anderson:

Protocol Title: Implementation of a Nurse-Initiated Topical Anesthesia Protocol
Meeting date: 2/27/2014

This is to advise you that the Avera Institutional Review Board (IRB) has reviewed and **Approved** the use of **Implementation of a Nurse-Initiated Topical Anesthesia Protocol**. At the IRB meeting held on 2/27/2014. This **Approval** is good for a period of **12 months** and must be renewed annually. The approval period expires: **2/26/2015.** Further you were recognized as principal investigator for the study.

The following items were received and Approved by the Board:

- **Application for approval of Research;**
- **Study protocol version 2013**

Continued approval is conditional upon your compliance with the following requirements:

- An approved, stamped copy of the Informed Consent Document (ICD) as noted above is included. No other consent document should be used. Each subject must sign the approved ICD prior to initiation of any protocol procedures. The original signed informed consent document must be placed in each subject's medical/research chart. In addition, each subject must be given a copy of the signed consent document.
- All protocol amendments and changes to approved research must be submitted to the IRB and not be implemented until approved by the IRB except where necessary to eliminate apparent immediate hazards to the study subjects.
- Significant changes to the study site and significant deviations from the research protocol must be reported.
- All deaths, life-threatening problems or serious or unexpected adverse events, *whether related to the study article or not*, must be reported to the IRB within ten (10) working days of the event (or your knowledge thereof). An Adverse Event/Unanticipated Problem Report should be used for reporting all SAEs or Unanticipated problems.

Please contact the Avera IRB directly at 605.322.4755 if you have any questions about the terms of this approval.

If your project is being done as part of an advanced degree or residency. A final report must be completed and submitted to the Avera IRB with your findings prior to your leaving whichever Avera facility you are currently working at.

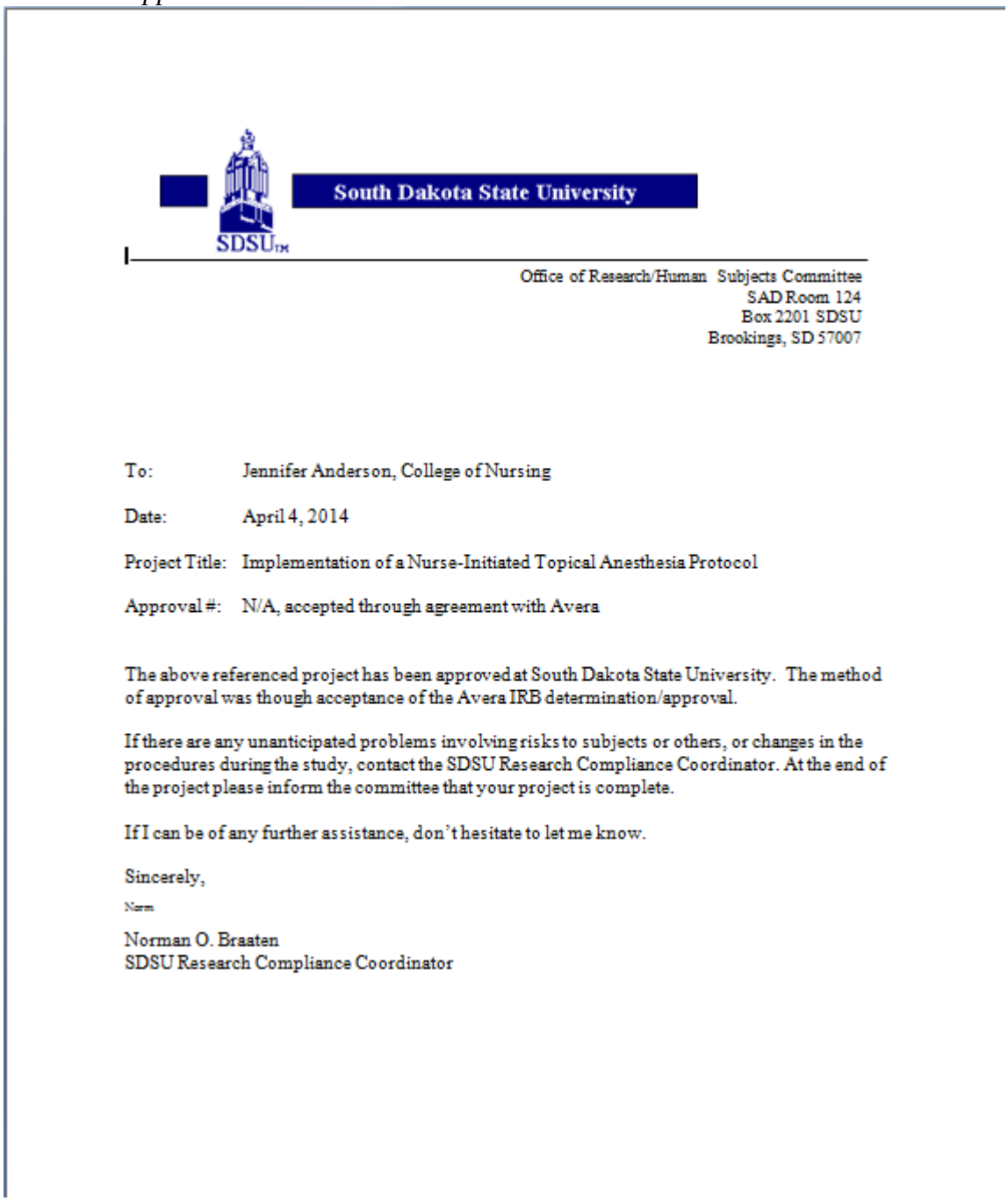
Sincerely yours,

Jovette Van Hoorn, CIM, CIP
Manager, Avera Institutional Review Board

Sponsored by the Benedictine and Presentation Sisters

Appendix L

SDSU IRB Approval Letter



South Dakota State University

SDSU

Office of Research/Human Subjects Committee
SAD Room 124
Box 2201 SDSU
Brookings, SD 57007

To: Jennifer Anderson, College of Nursing

Date: April 4, 2014

Project Title: Implementation of a Nurse-Initiated Topical Anesthesia Protocol

Approval #: N/A, accepted through agreement with Avera

The above referenced project has been approved at South Dakota State University. The method of approval was though acceptance of the Avera IRB determination/approval.

If there are any unanticipated problems involving risks to subjects or others, or changes in the procedures during the study, contact the SDSU Research Compliance Coordinator. At the end of the project please inform the committee that your project is complete.

If I can be of any further assistance, don't hesitate to let me know.

Sincerely,

Norm

Norman O. Brasten
SDSU Research Compliance Coordinator

References

Adler, A., Dubinsky, I., & Ersen, J. (1998). Does the use of topical lidocaine epinephrine and tetracaine solution provide sufficient anesthesia for laceration repair? *Academic Emergency Medicine, 5*(2), 108-112.

Blackburn, P., Butler, K., Hughes, M., Clark, M., & Riker, R. Comparison of TAC with TLE: efficacy and cost. *American Journal of Emergency Medicine, 13*(3), 315 317.

CDC. (2010). *National hospital ambulatory medical care survey.* Retrieved from http://www.cdc.gov/nchs/data/ahcd/nhamcs_emergency/2010_ed_web_tables.pdf

CMS (2011). *Hospital inpatient value-based purchasing program: final rule.* Retrieved from http://www.gpo.gov/fdsys/pkg/FR-2011-05-06/pdf/2011-10568.pdf.

Crocker, P., Higginbotham, E., King, B., Taylor, D., & Milling, T. (2012). Comprehensive pain management protocol reduces children's memory of pain at discharge from the pediatric ED. *American Journal of Emergency Medicine, 30*(6), 861-871.

Dodd, M., Janson, S., Fancione, N., Faucett, J., Froelicher, E., Humphreys, & Taylor, D. (2001). Advancing the science of symptom management. *Journal of Advanced Nursing 33*(5), 668-676.

Eidelman, A., Weiss, J., Baldwin, C., Enu, I., McNicol, E., & Carr, D. (2012). Topical anesthetics for repair of dermal laceration (review). *The Cochrane Collaboration, 7,* 1-63.

Eidelman, A., Weiss, J., Enu, I., Lau, J., & Carr, D. (2005). Comparative efficacy and costs of various topical anesthetics for repair of dermal lacerations: a systematic

review of randomized, controlled trials. *Journal of Clinical Anesthesia, 14*(2), 106-116.

Ernst, A., Marvez, E., Nick, T., Chin, E., Wood, E., & Gonzaba, W. (1995). Lidocaine adrenaline tetracaine gel versus tetracaine adrenaline cocaine gel for topical anesthesia in linear scalp and facial lacerations in children aged 5 to 17 years. *Pediatrics, 95*(2), 255-258.

Ernst, A., Marvez-Valls, E., Nick, T., Mills, T., Minvielle, L, & Houry, D. (1997). Topical LAT gel versus injectable buffered lidocaine for local anesthesia in laceration repair. *Western Journal of Medicine, 167*(2), 79-81.

Flarity, K. & Hoyt, K. (2010). Wound care and laceration repair for nurse practitioners in emergency care: Part I. *Advanced Emergency Nursing Journal, 32*(4), 360-372.

Fein, J., Zempsky, W., & Cravero, J. (2012). Relief of pain and anxiety in pediatric patients in emergency medical systems. *Pediatrics, 130*(5), e1391-1405.

Forsch, R. (2008). Essentials of skin laceration repair. *American Family Physician, 78*(8), 945-951.

Gaufberg, S., Walta, M., & Workman, T. (2007). Expanding the use of topical anesthesia in wound management: sequential layered application of topical lidocaine with epinephrine. *The American Journal of Emergency Medicine, 25*(4), 79-81.

Harman, S., Zemek, R. Duncan, M. J., Ying, Y., & Petrcich, W. (2013). Efficacy of pain control with topical lidocaine-epinephrine-tetracaine during laceration repair with tissue adhesive in children: a randomized controlled trial.

Howard, R., Carter, B., Curry, J., Jain, A., Liossi, C., Morton, N., & Williams, G. (2012). Good practice in postoperative and procedural pain management 2nd

edition. *Pediatric Anesthesia, 22*(Suppl. 1), 1-79.

Hsu, D. (2013). Topical anesthetics in children. *UpToDate*. Retrieved from http://www.uptodate.com/home/index.html.

International Association for the Study of Pain. (2012). *IASP Taxonomy*. Retrieved from http://www.iasppain.org/AM/Template.cfm?Section=Pain_Definitions&Templat =/CM/HTMLDisplay.cfm&ContentID=1728.

Kleiber, C., Jennissen, C., McCarthy, A.M., & Ansley, T. (2011). Evidence-based pediatric pain management in emergency departments of a rural state. *The Journal of Pain, 12*(8), 900-910.

Krief, W., Sadock, V., Tunik, M., & Manikian, A. (2002). EMLA vs LET for topical anesthesia in wound repair. *Academic Emergency Medicine, 9*(5), 398.

Little, C., Kelly, O., Jenkins, M., Murphy, D., McCarron, P. (2009). The use of topical anesthesia during repair of minor lacerations in departments of emergency medicine: A literature review. *International Emergency Nursing, 17*, 99-107.

Lutz, S. & Root, D. (2007). Nurses, consumer satisfaction, and pay for performance. *Healthcare Financial Management, 61*(10), 56-63.

Mcmurtry, C. (2013). Pediatric Needle Procedures: Parent-Child Interactions, Child Fear, and Evidence-Based Treatment. *Canadian Psychology, 54*(1), 75-79.

Melnyk, B. & Fineout-Overholt, E. (2011). Evidence-based practice in nursing and healthcare: A guide to best practice (2nd Ed.). Philadelphia, PA: Wolters Kluwer Health | Lippincott Williams & Wilkins.

Priestley, S., Kelly, A., Chow, L., Powell, C., & Williams, A. (2003). Application of topical local anesthetic at triage reduces treatment time for children with

lacerations: a randomized controlled trial. *Annals of Emergency Medicine, 42*(1), 34-40.

Resch, K., Schilling, C., Borchert, B., Klatzko, M., & Uden, D. (1998). Topical anesthesia for pediatric lacerations: a randomized trial of lidocaine-epinephrine tetracaine solution versus gel. *Annals of Emergency Medicine, 32*(6), 693-697.

Rosswurm, M. A. & Larrabee, J. H. (1999). A model for change to evidence-based practice. *Image: the Journal of Nursing Scholarship, 31*, 317-322.

Royal Australasian College of Physicians. (2006). Guideline statement: Management of procedure-related pain in children and adolescents. *Journal of Paediatric and Child Health, 42*(Suppl. 1), 1-29.

Schilling, C., Bank, D., Borchert, B., Klatzko, M., & Uden, D. (1995). TAC versus LET for anesthesia of lacerations in children. *Annals of Emergency Medicine, 25*(2), 203-208.

Singer, A. J. & Stark, M. J. (2000). Pretreatment of lacerations with lidocaine, epinephrine, and tetracaine at triage: a randomized double-blind trial. *Academic Emergency Medicine, 7*(7), 751-755.

Taylor, S., Taylor, D., Jao, K., Goh, S., & Ward, M. (2013). Nurse-initiated analgesia pathway for paediatric patients in the emergency department: A clinical intervention trial. *Emergency Medicine Australasia 25*, 316-323.

Trott, A. (2012). Wounds and lacerations: Emergency Care and Closure (4nd Ed). Philadelphia, PA: Elsevier Saunders.