MODIFICATION OF A CLINICAL PRACTICE GUIDELINE FOR THE TREATMENT OF POST-DURAL PUNCTURE HEADACHES TO INCLUDE SPHENOPALATINE GANGLION NERVE BLOCK

by

Gregg Alan Tidrick

A DNP Project Submitted to the Faculty of the

COLLEGE OF NURSING

In Partial Fulfillment of the Requirements

For the Degree of

DOCTOR OF NURSING PRACTICE

In the Graduate College

THE UNIVERSITY OF ARIZONA

2 0 1 9

THE UNIVERSITY OF ARIZONA
GRADUATE COLLEGE

As members of the DNP Project Committee, we certify that we have read the DNP Project prepared by *Gregg Tidrick* entitled *Modification of a Clinical Practice Guideline for the Treatment of Post-Dural Puncture Headaches to Include Sphenopalatine Ganglion Nerve Block* and recommend that it be accepted as fulfilling the DNP Project requirement for the Degree of Doctor of Nursing Practice.

Date: Feb 14, 2019
Kathleen Piotrowski, DNP, CRNA

Date: Feb 14, 2019
Sarah Torabi, DNP, CRNA

Date: Feb 14, 2019
Janet Rothers, PhD

Final approval and acceptance of this DNP Project are contingent upon the candidate's submission of the final copies of the DNP Project to the Graduate College.

I hereby certify that I have read this DNP Project prepared under my direction and recommend that it be accepted as fulfilling the DNP Project requirement.

Date: Feb 14, 2019
DNP Project Director: *Kathleen Piotrowski, DNP, CRNA*

ACKNOWLEDGMENTS

I would like to recognize and thank my wife, Irene, and our two boys, Aron and Christopher, who have provided unwavering support and encouragement throughout my lifelong journey of becoming a doctoral educated Certified Registered Nurse Anesthetist. I also acknowledge and thank the numerous mentors, preceptors and University of Arizona faculty who have provided guidance, encouragement and support throughout this process, most specifically my DNP committee members, Dr. Piotrowski, Dr. Torabi, and Dr. Rothers. It has taken 35 years and numerous life detours to finally accomplish the career goal I set for myself back in 1984. Never give up on your dreams!

TABLE OF CONTENTS

TABLE OF CONTENTS – *Continued*

TABLE OF CONTENTS – *Continued*

LIST OF FIGURES

LIST OF TABLES

ABSTRACT

Postdural puncture headache (PDPH) is a relatively common complication of neuraxial anesthesia, with an occurrence rate as high as 50% following inadvertent dural puncture (Kwak, 2017). Due to the disabling nature of these headaches, interventions are focused at bringing relief to those suffering from this complication. While epidural blood patches are highly effective at treating PDPH and are considered the gold standard, they are not risk-free. A less-invasive alternative to the epidural blood patch is emerging as an effective intervention for treating PDPH. There is now growing evidence and emerging consensus opinion among anesthesia experts that SPGNBs are useful as a treatment of PDPH before attempting the epidural blood patch. The purpose of this Doctor of Nursing Practice (DNP) project is to modify a current nationally published clinical practice guideline (CPG) for the treatment of PDPH to include the early consideration for SPGNB and to further adapt the CPG for local implementation. The question this project addressed is whether the modified CPG would be appraised, using the Appraisal of Guidelines for Research and Evaluation II (AGREE II) to be of higher quality than the original CPG. The theoretical framework guiding this project was Lewin's Change Theory. The modified CPG was presented to stakeholders at a local healthcare facility in metro Phoenix, Arizona for consideration of implementation. This DNP quality improvement project intended to translate emerging evidence into a local practice for the benefit of improving consistency of evidence-based care.

INTRODUCTION

Epidural and spinal anesthesia are modern, common neuraxial techniques used to provide safe and effective pain relief during surgical and diagnostic procedures. These neuraxial techniques are not risk-free. While the complication rate from neuraxial anesthesia is generally low, complications can cause serious repercussions. One of the most common complications of neuraxial anesthesia is that of a postdural puncture headache (Nguyen & Walters, 2014). These headaches result from a small tear in the dural membrane of the spinal column, allowing cerebral spinal fluid (CSF) to leak into the epidural space. The exact mechanism for these headaches is still debated in the literature; however, it is commonly believed to be related to an increased pressure gradient between atmospheric pressure and reduced CSF pressure resulting from the leak (Cohen et al., 2014). Some researchers suspect the mechanism to be related to cerebral vasodilation as a compensatory mechanism to the drop in CSF pressure (Bezov, Ashina, & Lipton, 2010).

Kwak (2017) reports that 1.5% of patients receiving an epidural will experience a dural tear and, of those, approximately 50% will go on to develop a postdural puncture headache (PDPH). These headaches are often mild and resolve within 24 hours without intervention, however, on occasion they can become quite severe and disabling, requiring medical intervention. PDPHs have been described in the literature as severe frontal or occipital headaches, postural in nature (worse sitting & standing) and often disabling in severity (Nguyen & Walters, 2014). PDPHs can be accompanied by visual and auditory disturbances, nausea, vomiting, and vertigo (Nguyen & Walters, 2014). The pain can be so disabling that patients become bed-ridden or they seek help from a hospital emergency room.

Nguyen and Walters (2014) reported that the onset of PDPH is typically within the first three days following a dural puncture (90%) and many (60%) develop PDPH within two days following a dural puncture. Cohen et al. (2014), reported that 40% of patients present with PDPH within "several hours" following a dural puncture. It is also known that approximately 47% of PDPH cases will self-resolve without medical management within four days and 85% of PDPH cases will resolve within six weeks (Bezov et al., 2010). Due to the severity and disabling nature of these PDPHs, the focus remains on interventions that will bring relief to those suffering from this complication.

Background Knowledge

Traditional treatments for PDPH are widely discussed in the literature and include interventions such as bed rest, intravenous (IV) fluids, IV caffeine, aminophylline, gabapentin, multiple other pharmacological agents, and epidural blood patch. Except for epidural blood patch, the generally accepted gold-standard of PDPH care, there is little consensus for other treatment modalities. Many of the current interventions and practices utilized by anesthesia providers lack the support by randomized, rigorous research-based studies (Nguyen & Walters, 2014). To compound the problem, in a broad survey of anesthesia providers in North America conducted in 2008 regarding the standard of care for PDPH, only 14% of practitioners reported following a standardized protocol or clinical practice guideline (CPG) for the treatment of PDPH (Baysinger, Pope, Lockhart, & Mercaldo, 2011).

The epidural blood patch, while considered the gold-standard with documented effectiveness ranging from 61% to 98% for patients with PDPH, is an invasive procedure requiring a skilled clinician (Cohen et al., 2014). Additionally, the epidural blood patch is

associated with numerous complications, including subdural and epidural hematoma, a secondary dural tear with the potential to exacerbate the original PDPH, increased back pain, and risk for infection within the central nervous system (Cohen et al., 2014).

A less-known and less invasive alternative to the epidural blood patch is emerging as an effective approach for treating PDPH are sphenopalatine ganglion nerve blocks (Kent & Mehaffey, 2016). Sphenopalatine ganglion nerve blocks (SPGNBs) are not new to medicine; they have been used effectively for over 100 years for the treatment of various other forms of a headache, neuralgias and even temporomandibular joint pain (Fulkerson, 2017).

The sphenopalatine ganglion is located immediately posterior to the middle turbinates in an area called the pterygopalatine fossa (Robbins et al., 2015). It is the most extensive collection of neurons within the peripheral nervous system and is composed primarily of parasympathetic fibers but also contains some sympathetic and sensory fibers as well (Robbins et al., 2015). The parasympathetic fibers from this ganglion innervate the cerebral and meningeal blood vessels. When the volume or pressure of cerebral spinal fluid is reduced, as can occur with a dural puncture, parasympathetic nerves reflexively stimulate the cerebral meningeal vessels to dilate in compensation (Robbins et al., 2015). Gharaei and Nabi (2015) describe three possible mechanisms for how SPGNBs may mitigate the symptoms of PDPH. These include:

1. Interruption of the post-ganglionic parasympathetic path, inhibiting nociception and blocking cephalic autonomic symptoms;
2. Modulation of the sensory process within the trigeminal nucleus; and
3. Interruption of postganglionic sympathetic outflow via neural blockade of sympathetic fibers.

While large randomized controlled clinical trials do not yet support the use of SPGNBs for the treatment of PDPHs, there is emerging and growing evidence from smaller cohort studies, case reports, study abstracts, and anecdotal experiences from numerous clinicians regarding SPGNB effectiveness (Fulkerson, 2017). Considering the ease of performing an SPGNB and the low-risk and non-invasive nature of this procedure, it is intuitive to consider this procedure before the more invasive and higher-risk epidural blood patch. When clinicians exclusively consider best practices that are exclusively backed by multiple, large, well-designed, double-blind, randomized control trials, they may overlook appropriate practices and interventions that are still supported, be it with smaller, less statistically powerful studies (Higgs, Burn, & Jones, 2001). The wealth of knowledge supporting best practices not only derives from formal research, but also that gained from individual clinical practice knowledge, scientific reasoning, and judgments based on professional experiences (Higgs et al., 2001). These authors' insight is applicable with the suggestion that PDPH treatment should include the early consideration for SPGNB.

Local Problem

A local healthcare facility in metro Phoenix, Arizona ("the local facility") was a primary anesthesia practice site for Anesthesia Physicians of Arizona (APA). The APA provided the local facility approximately 32 certified registered nurse anesthetists (CRNAs) and physician anesthesiologists (MDAs). Similar to the national data published by Baysinger et al. (2011), and from observations and conversations with anesthesia providers who practice at the local facility, variations to treatment approaches for PDPH were discovered. It appeared there were some

differences among anesthesia providers as to whether SPGNB was even considered or attempted before an epidural blood patch for the treatment of PDPH.

Purpose of the Project

The purpose of this DNP project was to modify an existing, and well respected, clinical practice guideline (CPG) published by the New York School of Regional Anesthesia (NYSORA) for the treatment of postdural puncture headaches (Appendix A) to include the early consideration of SPGNB (Harrington & Reina, 2019). This modified NYSORA CPG (Appendix B) was presented for review and consideration amongst key APA stakeholders practicing at the local facility. The APA's anesthesia providers at the local facility lacked a formal written, locally adopted clinical practice guideline for the treatment of PDPH at the local facility. This modified CPG potentially provided patients suffering from PDPH the less-invasive SPGNB alternative before attempting an epidural blood patch. The project aimed to introduce the SPGNB as an early intervention consideration for the treatment of PDPH, before more invasive and higher risk interventions are attempted. A clinical practice guideline for the treatment of PDPH was modified and disseminated to the key APA's anesthesia stakeholders practicing at the local facility, providing a step-wise, best-practices approach for treating this disabling condition.

Project Question

This DNP project was based on the following question: Would local stakeholders, using the AGREE II tool, score evidence supporting the recommendation of including SPGNB for the treatment of PDPH as equal or of higher quality than the existing or current modalities of treatment as provided by the NYSORA CPG for the treatment of PDPH?

THEORETICAL FRAMEWORK

Eccles, Foy, Sales, Wensing, and Mittman (2012) estimate that up to 40% of patient care in the United States does not reflect the latest evidence-based practices and up to 25% of patients receive care that has not been proven to be effective. It has been well documented that it takes as long as 17 years from when knowledge is gained from research to the time it is implemented into practice as a standard of care (Morris, Wooding, & Grant, 2011). Healthcare practitioners are under increasing pressure to deliver evidence-based patient care while at the same time being burdened with increased expectations for documentation, meeting compliance regulations, and addressing insurance demands for proper coding (Grimshaw, Eccles, Lavis, Hill, & Squires, 2012). There is also an ever-increasing demand for healthcare providers to improve efficiencies in their clinical practice; delivering better, evidence-based care that improves outcomes to more patients in a tighter timeframe.

Changing clinical practice requires a systematic, thoughtful approach; one that provides clinical leadership with the tools to strategically navigate through the maze of social psychology and overcome political power structures found within every organization. Introducing new clinical change into practice mandates a departure from the status quo; disruption to the daily routines that provide a haven of comfort to practitioners. The change theory, as developed and taught by Kurt Lewin (Mitchell, 2013) provides the theoretical framework for this DNP project and guiding principles for development and introduction of a new clinical practice guideline for the treatment of PDPH (Figure 1). Kurt Lewin understood human psychology, sociology, and the forces which must be overcome to motivate individuals and groups to give up their comfortable routines for something that is new and unfamiliar (Mitchell, 2013). The three fundamental

elements of the change theory include: *unfreezing*, *moving* and *refreezing* (Burnes, 2004). From an administrative perspective, this DNP project required the formation of a committee who served as counselors to help guide the project to completion using a systematic, team-based approach. Additionally, professional industry consultants from the local site were selected and involved in providing expert opinion and organizational insight as to how this DNP project would best suit the local stakeholder needs.

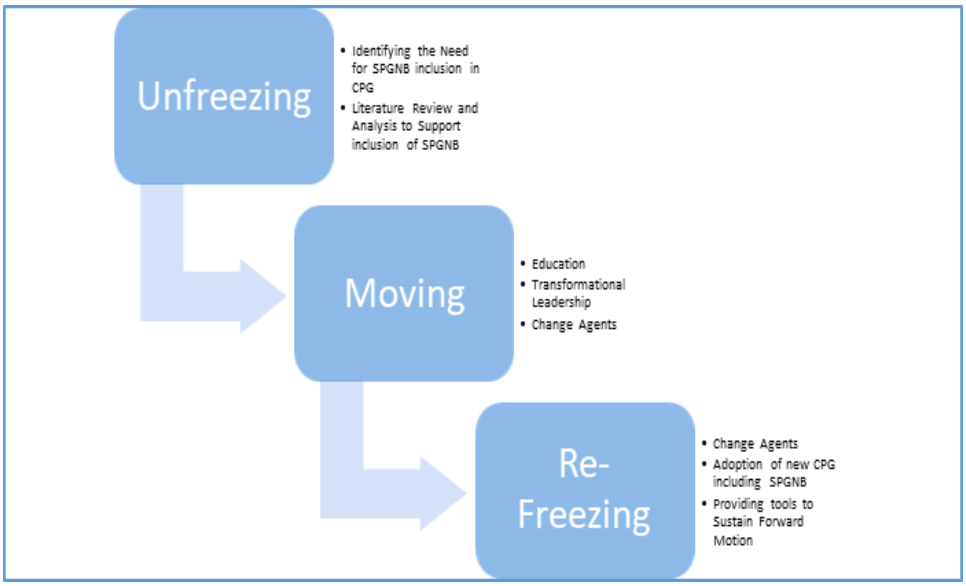


FIGURE 1. Adaptation of Lewin's change theory.

Change Theory – Unfreezing

It is human nature to resist change and cling to familiar practices (Burnes & Bargal, 2017). With a keen understanding of this human predisposition, Lewin proposed that change can only occur when: 1) the status quo becomes increasingly uncomfortable, and 2) it requires more energy to remain in the status quo than what would be required to change (Burnes & Bargal, 2017). Clinicians may be aware that a portion of their practice does not reflect evidence-based best practices. However, they become comfortable in their daily practice and are unwilling to

exert the energy needed to adopt new methods. Lewin suggested that the purposeful introduction of ‘controlled chaos' into a system, generating unease and discomfort as a catalyst for change was necessary for change to occur (Burnes & Bargal, 2017). In the absence of having an institutionalized CPG to follow when treating PDPH, clinicians are left to follow their best judgment, relying on formal and informal training, personal clinical experiences, vaguely defined treatment practices, and perhaps the need to search the literature for best practices. The creation of an institutionalized clinical practice guideline for the treatment of PDPH provides a standardized path and one that reflects the newest and latest research and evidence-based practices.

Problem Identification

Identification of a potential gap in care was at the heart of this DNP project. The problem identified within the DNP project addressed the then current treatment regime for PDPHs following neuraxial anesthesia and the frequent failure to consider using an SPGNB as a potential and viable treatment option before attempting more aggressive and invasive techniques. Unfreezing the present situation begins with the identification of a problem; targeting a clinical need and reason for the change. Current practices for the treatment of PDPH include a vast array of interventions, some proven to be effective, however many others are not yet strongly supported by the literature. Baysinger, Pope, Lockhart, and Mercaldo (2011), in their 2008 nationwide survey of 843 anesthesia practitioners regarding current treatment preferences for PDPH, found that: 1) standardized protocols for treatment of PDPH are uncommon and often not followed, and 2) current practices include everything from conservative measures (bed rest, oral hydration, IV fluids, caffeine, NSAIDs, & opioids) to the more aggressive intervention of an

epidural blood patch. The literature reflects other treatment modalities for PDPH that would require the *unfreezing* of current clinical practices, including the use of abdominal binders, IV aminophylline, dexamethasone and epidural morphine (Bezov et al., 2010).

Goals and Priorities

Establishing goals and priorities are critical to charting a way forward and providing a purpose for unfreezing the current state. Due to a wide variety of current practices for the treatment of PDPH and a lack of well-defined, evidence-based protocols, a need was established to provide local anesthesia practitioners with a clinical practice guideline. This CPG incorporated the best practices for the treatment of PDPH and introduced a promising, effective and less-invasive intervention, such as the SPGNB. Therefore, the goal of this DNP project was to modify and introduce a locally implementable CPG for the treatment of PDPH which would include the use of SPGNB. The CPG was modified following an extensive literature review and with input from industry expert advisors. The modification was necessary for local and institutional feasibility and recommendation for local implementation once it was determined to be valid, appropriate, and easy to follow, as determined by the AGREE II scoring instrument (Appendix C) (Brouwers et al., 2010). Stakeholder feedback was obtained following the presentation of the modified CPG to determine better their perceptions of the guidelines and willingness to adopt them into local clinical practice.

Change Theory – Moving

Lewin's *moving* step involves behavioral modification; departing from the status quo into new, seemingly uncharted and often uncomfortable territory. Key to the success of this critical step is that of strong, transformational leadership (Marshall & Broome, 2016). Vital to the

successful implementation of this CPG amongst APA anesthesia providers practicing at the local facility were the formal leaders and stakeholders that embraced the concept, as well as the strong involvement of multiple informal anesthesia providers who lacked the formal institutional positional authority, yet they had tremendous informal influence throughout the ranks of their peer colleagues. Local social networking channels and peer-to-peer influences were considered for this CPG implementation to be ultimately successful.

Team Formation

This DNP project embraced a team concept, both regarding this project's academic advisement committee and the inclusion of on-site APA anesthesia experts practicing at the local facility who assisted in the review and assessment of the proposed revised CPG and evaluated the applicability of it for local implementation. The APA's anesthesia consultants provided practice and institutional insight, which was instrumental to the unfreezing, moving and re-freezing steps leading to final clinical team acceptance of this CPG at their institution.

Review, Critique and Synthesis of Literature

Literature synthesis provided input that reflected the most relevant, valid and applicable evidence for the inclusion of SPGNBs within the clinical practice guideline for treating PDPH. Current practices for the treatment of PDPH, as described in the NYSORA CPG, were assessed and scored using the AGREE II instrument and a modified CPG with the inclusion of SPGNB was then developed and introduced, focusing the anesthesia clinicians at the local facility on a set of treatment guidelines that reflect best practices and current evidence.

Evaluation and Analysis

It was not the specific scope of this DNP project to fully implement a new or revised CPG at a local institution because this project author neither had the authority nor positional standing as a student in a clinical rotation to do so. However, the project did endeavor to present and disseminate relevant data and CPG recommendations to the APA's anesthesia stakeholders practicing at the local facility for their consideration of implementation, based upon the input and feedback from their expert consultations. In this regard, the data, tools, and modified CPG were provided to the anesthesia team stakeholders for their review. The NYSORA CPG that was modified as part of this DNP project was evaluated via the AGREE II assessment tool by two trained local anesthesia experts from the local facility. After the AGREE II scoring of the modified CPG, APA anesthesia stakeholder feedback was collected and evaluated, addressing their feedback of the modified CPG regarding local applicability for implementation at the local facility.

Change Theory – Refreezing

Permanent, lasting change is sustainable when new ideas, values, and clinical practices are fully embraced, become comfortable once again, and the emotional energy required to return to old practices is maintained higher than the energy level required to continue forward with the newly-acquired practices (Burnes, 2004). Vital to the success of this sustained effort was the early incorporation of the local facility's anesthesia stakeholder team, assuring the modified CPG for treatment of PHPH aligned well with their institutional needs and assured the treatment recommendations for PDPH reflected their professional clinical judgments for best practices. The use of both the AGREE II CPG assessment tool and the incorporation of input from local

anesthesia expert consultation (Appendix D & E) increased the likelihood for permanent, lasting change which embraces best-practices, as reflected in the modified CPG for PDPH that was presented.

Concepts and Terms

This DNP project addresses several significant concepts and terms, including postdural puncture headache (PDPH), sphenopalatine ganglion nerve block (SPGNB), clinical practice guidelines (CPG), and evidence-based practice (EBP).

Postdural puncture headache (PDPH) is defined as a headache that develops within a five-day timeframe following dural puncture that cannot be identified as having a more obvious etiology than the dural puncture itself (The International Classification of Headache Disorders, 2013). These headaches can range from mild to severe, most frequently exhibit a postural element and can be accompanied by visual and auditory disturbances, nausea, vomiting and a stiff neck (Nguyen & Walters, 2014). Some 40% develop with a few hours following a dural puncture and up to 90% present within three days (Nguyen & Walters, 2014).

Sphenopalatine ganglion nerve block (SPGNB) is defined in the literature as a block of the sphenopalatine ganglion using either topical local anesthetic, an injection of local anesthetic or ablation of the sphenopalatine ganglion (Puledda & Goadsby, 2016). For this DNP project, the SPG block is defined as a block of the sphenopalatine ganglion using a topical local anesthetic application using a trans-nasal approach with a cotton swab applicator or similar device.

Clinical practice guidelines (CPG) is defined as a recommended treatment standard, informed by a systematic review of the literature, that help guide a clinician, when combined with clinical experience and critical thinking, in developing a treatment plan which optimizes

patient outcomes (Murad, 2017). Clinical practice guidelines serve as sound, standardized clinical application of knowledge and evidence supported in the literature.

Evidence-based practice (EBP) is defined as the application of evidence-based research, modified through critical thinking, clinical experience and professional expertise adapted to local practice and needs in providing personalized patient care that represents the best and currently available information (Higgs, Burn, & Jones, 2001). It is argued by Higgs et al. (2001) that evidence-based practice not only includes qualitative and quantitative research data from large, well-designed randomized control trials but also, and importantly, should include knowledge gained from smaller observational cohort studies and case reports, combined with professional clinical experiences and application of expert critical reasoning.

REVIEW OF LITERATURE

Literature Search

Relevant validated and current research, both qualitative and quantitative, found in the peer-reviewed literature are at the heart of any honest inquiry regarding best practices (Jones, Stewart, Darer, & Sittig, 2013). Additionally, clinicians must also consider personal practice experiences and clinical reasoning when deciding how and when to modify their practices to reflect the best evidence (Higgs et al., 2001). This DNP project sought to answer a question regarding the modification of a clinical practice guideline for treating PDPH and whether local stakeholders at the local facility would consider the modified CPG to be evidence-based and applicable to their institution. In pursuit of answers to these questions, an existing NYSORA CPG (Appendix A) was updated and modified, including the early employment of an SPGNB, when appropriate, and a presentation to anesthesia stakeholders at the local facility was made

regarding the modifications and rationale for inclusion of SPGNB for the treatment of PDPH. To this effort, a literature search and synthesis of evidence was required to evaluate the support for the inclusion of SPG blocks for the treatment of PDPH.

Search Terms

Commonly accepted scientific literature search engines were used to query terms and phrases of interest. The CINAHL, Ovid, PubMed, Google Scholar, and clinicaltrials.gov databases were searched using keywords and phrases, including: “sphenopalatine ganglion” OR “SPG” OR “pterygopalatine ganglion” OR “Meckel's ganglion” AND “postdural puncture” OR “postdural puncture” OR “a headache.” Additionally, a search was conducted using: “clinical practice guidelines” OR “CPG” OR “treatment recommendations” OR “treatment guidelines” AND “postdural puncture headache” OR “postdural puncture headache” OR “PDPH.”

Search Criteria

Initially, no date, language or other filters were applied to aid in determining the breadth of available literature, in general. Titles and abstracts were reviewed to assess the relevance and for sorting duplications. Subsequent searches were conducted using restricted date ranges; however, due to the limited number of studies and data available, all filters were removed again for the inclusion of several reports and studies that would have otherwise been eliminated. It is recognized by this DNP project author that generally, only recent and relevant literature should be included, however, when there was a lack of recent literature and older literature still remains valid and supports current practices, it was included for review and analysis within this project.

Exclusion Criteria

Only original research studies, abstracts, and reports were selected, eliminating all other duplicate or editorial articles that were not directly reporting original study data or observations.

Review of Literature Findings

Of the 17 case-reports, case series, abstracts, and retrospective observational studies found on the topic, 11 were selected and included herein for further analysis and discussion (Table 1). While the number of studies, abstracts and reports were limited, all were supportive of SPGNBs, and no literature was found that did not, in some way, support the practice of SPGNB. Six studies or reports were ultimately eliminated due to either duplication of data or dates that were more than 10 years old with no additional value to newer information found within the literature.

Strengths

Sphenopalatine ganglion nerve blocks (SPGNBs) have a well-established and successful history spanning back as far as 1908 in treating various headache-related and neuropathic pain conditions (Waldman, 1993). There have been numerous case reports, published abstracts, peer-reviewed articles, and professional conference presentations on the topic of SPGNBs. Not only does the anesthesia literature support this procedure, but it is also well discussed within emergency medicine, headache and pain management journals, and at conferences worldwide. While many industry experts have acknowledged that larger randomized control trials (RCTs) are necessary to support the continued hypothesis of SPG effectiveness, the data within currently available literature and clinical experiences presently supports the inclusion of SPG in the

TABLE 1. *Literature review of sphenopalatine ganglion nerve blocks.*

Authors / Article	Study Design & Methods	Research Question or Hypothesis	Sample (n) & Setting	Variables, Data Types, and Results	Comments and Grade
Cady et al. (2014). A double-blind, placebo-controlled study of repetitive trans-nasal sphenopalatine ganglion blockade with Tx360® as an acute treatment for a chronic migraine. *Headache: The Journal of Head and Face Pain*, *55*(1), 101-116.	RCT, double-blinded study 0.3 ml of 0.5% bupivacaine using Tx 360 device. Repetitive SPGNBs using the Tx360 devise with a series of 12 SPGNBs provided 2 times per week for 6 weeks.	SPGNB using Tx360 device vs. normal saline placebo for treatment of chronic migraine headaches.	n=38 Control n= 12 SPGNB n = 26 Randomly assigned patients from two U.S. specialty headache clinics.	Treatment group experienced a significant reduction in headaches vs control group at 15 and 30 minutes (M=3.78 vs M-3.18, P=.10) and (M=3.51 vs M = 2.53, P<.001). From pre-treatment to final treatment (following 6-week period) the treatment group experienced a statistically significant reduction in headache pain vs. control (M diff = -4.52, P=.005) vs. (M dif = -1.5, P = .13).	Statistically significant headache relief using the Tx360 devise for SPGNB over a 6-week period was demonstrated. This study evaluated chronic migraine headaches specifically, not PDPHs. Tian Medical had no role in study design, subject selection or the exclusion or study criteria, data collection or analysis of data and had no role in article preparation, editing, review or approval. **Grade: 2B – Recommended (Figure 2, Figure 3)**
Cardoso et al. (2017). Sphenopalatine ganglion block for postdural puncture headache in ambulatory setting. *Brazilian Journal of Anesthesiology (English Edition)*, *67*(3), 311-313.	Case Report Cotton-tipped applicator saturated with 0.5% levobupivacaine for 5 minutes.	SPGNB versus prior trial with crystalloid, dexamethasone, parecoxib, Tylenol and caffeine.	n=1 41-year-old female s/p PDPH for 1 week The ambulatory setting in Brazil	The patient reported 0/10 pain after 5 minutes of SPGNB. Remained pain-free at 1 day and 7 days post-procedure, did have OTC pain medication to take at home PRN	No mention of volume (ml) of local anesthetic used. Patient positioning not discussed. No pain relief following all previous non-SPGNB interventions. Pain relief was achieved after 1 SPGNB, no subsequent block or epidural blood patch was required. No disclosed financial conflicts or other conflicts of interest. **Grade: 5D – Option (Figure 2, Figure 3)**
Channabasappa et al. (2017). Transnasal sphenopalatine ganglion block for the treatment of postdural puncture headache following spinal anesthesia. *Saudi Journal of Anaesthesia*, *11*(3), 362.	Case Study 5 ml of a pre-loaded syringe with 0.5% ropivacaine attached to a cotton-tipped 23-g spinal needle. SPGNB was accomplished with injection vs. topical saturation of local anesthetic on ganglia.	Will SPGNB prevent the need for epidural blood patch in PDPH parturient?	n=1 PDPH following combined spinal-epidural for C-section in hospital in India	Instantaneous and sustained pain relief. 24 hours post-procedure, the patient remained pain-free and follow-up at 3 weeks post-procedure revealed continued pain-free scores.	The patient initially treated with conventional fluids, NSAIDS, caffeine and bed-rest, all with no effect. Injection of LA vs. topical saturation increases the risk of bleeding, infection and painful injection in a sensitive area. N=1 with no controls merits further study needed to substantiate these findings. Financial interests not disclosed. **Grade: 5D – Option (Figure 2, Figure 3)**

TABLE 1. - *Continued*

Authors / Article	**Study Design & Methods**	**Research Question or Hypothesis**	**Sample (n) & Setting**	**Variables, Data Types, and Results**	**Comments and Grade**
Cohen et al. (2009). Sphenopalatine ganglion block for postdural puncture headache. *Anaesthesia*, *64*(5), 574-575.	Case Series Cotton-tipped applicator soaked with 4% lidocaine ointment	SPGNB effectiveness on 1st vs. subsequent blocks	n=13 Unknown setting	11 of the 13 patients received immediate and/or complete relief following 1st SPGNB (84.6% reported success)	Small case series reported in an editorial format Patients were given the option for blood patch or SPGNB. Controls for trial were not discussed The two patients that did not receive relief with first SPGNB were taught to self-administer blocks at home once per day, up to a week in duration. **Grade: 5D – Option (Figure 2, Figure 3)**
Cohen et al. (2014). Sphenopalatine ganglion block. *Regional Anesthesia and Pain Medicine*, *39*(6), 563.	Case Series Cotton-tipped applicator saturated with 5% water-soluble lidocaine ointment. Left in place for 10 minutes.	SPGNB effectiveness for treatment of PDPH amongst obstetric patients, eliminating the need for epidural blood patch.	n=32 Obstetrical patients suffering from PDPH following accidental dural puncture from a 17-gauge epidural needle.	69% reported success in relieving PDPH by use of SPGNB amongst 32 obstetric patients, eliminating the need for an epidural blood patch.	Case series. Controls and other possible interventions not discussed. These authors continue in subsequent literature to report their continued successes with SPGNB. Editorial concludes by saying: "In conclusion, we recommend that every patient with a PDPH receive the minimally invasive SPGNB, which is most cases can avoid the need for an EDBP and its potential complications." **Grade: 4C – Option (Figure 2, Figure 3)**
Cohen, S., Trnovski, S., & Zada, Y. (2001). A new interest in an old remedy for a headache and backache for our obstetric patients: A sphenopalatine ganglion block. *Anesthesia*, *56*(6), 606-607.	Case Report Cotton-tipped applicator saturated with EMLA cream for 10 minutes (2 of the 22 patients could not tolerate the EMLA cream; they were given Cetacaine nasal spray.	SPGNB for treatment of moderate to a severe backache or a headache amongst obstetrical patients.	n=22 Obstetrical patients complaining of moderate to severe backache and headache during a hospital stay.	100% of patients experienced complete relief of pain within 6-10 minutes of SPGNB procedure. No side-effects reported amongst any of the n=22 participants.	A limited case report of 22 patients is reported in an editorial, abstract format. Qualifying data, weaknesses, financial interests were not disclosed. No control, not randomized or blinded. Further, larger studies are needed to support the hypothesis of SPGNB effectiveness further. **Grade: 5D – Option (Figure 2, Figure 3)**
Kent, S., & Mehaffey, G. (2016). Transnasal sphenopalatine ganglion block for the treatment of postdural puncture headache in obstetric patients. *Journal of Clinical Anesthesia*, *34*, 194-196	Case Report 2% viscous lidocaine on long, cotton-tipped applicators, left in place for 10 min, then additional 2% lidocaine reapplied and applicator re-inserted for additional 20 min	SPGNB effectiveness in obstetric patients suffering from PDPH. Will the SPGNB avoid the need for epidural blood patch?	n=3 Labor and Delivery Suite. Post-partum obstetrical patients suffering from PDPH	All three patients had "significant" relief from PDPH following SPGNB and all three avoided the need for epidural blood patch. An initial headache vs. post-SPGNB headache scores as follows: Patient 1. 9/10 to 0/10 Patient 2. 8/10 to 0/10 Patient 3. 9/10 to 0/10	Small case report. Patients were discharged following SPGNB with instructions to drink plenty of fluids and include caffeinated drinks. None of the three patients required subsequent treatment. No conflicts of interest disclosed. A larger study is needed. **Grade: 5D – Option (Figure 2, Figure 3)**

TABLE 1. - *Continued*

Authors / Article	**Study Design & Methods**	**Research Question or Hypothesis**	**Sample (n) & Setting**	**Variables, Data Types, and Results**	**Comments and Grade**
Patel, P., Zhao, R., Cohen, S., Mellender, S., Shah, S., & Grubb, W. (2016). Sphenopalatine ganglion block (SPGB) versus epidural blood patch for accidental postdural puncture headache (PDPH) in obstetric patients: A retrospective observation. *The American Academy of Pain Medicine, Abstract 145*, 1.	Retrospective observational study over a 17-year period (Abstract Only)	Epidural blood patch vs SPGNB for PDPH	n=72 n=33 SPGNB n=39 = epidural blood patch Patients with no previous history of primary headache disorders who were experiencing PDPH	Retrospective data analysis of 72 records spanning 17 years. No differences in ASA scores, patient age, height, weight or BMI At 24 hours post-treatment, no difference in pain scores amongst SPGNB and epidural blood patch group. SPGNB group experienced improved headache scores at 30 min post procedure vs epidural blood patch (54.55% relief vs. 20.51%) and at 60 minutes post procedure, SGNB group had 63.64% relief vs. 30.77% for epidural blood patch group. SPNB group had no complications, versus the epidural blood patch group had nine patients return to ED for complications.	Abstract report of a retrospective observational study. The details of this study were never published, thus limiting the information and analysis of data that was presented in abstract form. The SPGNB group had better relief with fewer side-effects vs. the epidural blood patch group. Continued, fully-published and disclosed studies of this nature would be helpful to further support the use of SPGNBs for the treatment of PDPHs. **Grade: 3C – Option (Figure 2, Figure 3)**
Schaffer, J., Hunter, B., Ball, K., & Weaver, C. (2015). Noninvasive sphenopalatine ganglion block for acute headache in the emergency department: A randomized placebo-controlled trial. *Annals of Emergency Medicine*, *65*(5), 503-510.	Randomized, Placebo-Controlled Trial Tx360 devise for application of SPGNB using 0.3 ml of 0.5% bupivacaine delivered by the Tx 360 device.	SPGNB vs. placebo treatment for acute headache in the ED. The hypothesis was that the Tx360 SPGNB devise would achieve a 50% reduction in anterior headache pain vs. saline placebo delivered using same technique at the 15-minute post-procedure mark.	n=93 Control n = 48 SPGNB n = 45 Two large academic emergency departments of Level 1 facilities between Oct 2012 to Oct 2013	The treatment group n=45 did not experience a statistically significant improvement (risk difference of 7.5% with 95% CI) at the 15-minute mark and secondary outcomes revealed similar nausea scores at 15 minutes post-procedure (risk difference of 3.5% with 95% CI of 15.3% vs. 21.8%). Post-24-hour follow-up revealed treatment group was a headache free (with a statistical significance) with 72.2% vs. 47.5% for the control group.	RCT was funded in part by Tian Medical LLC who is the manufacturer of the Tx360 device; however, Tian Medical had no role in the study design, subject selection or the exclusion or study criteria, data collection or analysis of data and had no role in article preparation, editing, review or approval. Further studies are needed using alternative techniques. This study did not support the hypothesis of SPGNB effectiveness at the 15-minute post-procedure mark, however, it did provide some supportive secondary data that was significant and merits further study, including post-procedure nausea and reduced headache pain at the 24-hour post-procedure mark. **Grade: 2C – Option (Figure 2, Figure 3)**

treatment of PDPH, especially in light of the relative ease, low risk, low cost and effectiveness of this intervention (Fulkerson, 2017).

Weaknesses

Large, randomized control trials on the effectiveness of SPG blocks for the treatment of PDPH are limited and more research is needed; however, the evidence obtained even in these smaller case studies may be significant, especially when pooled together. The majority of current studies reported in the literature supporting SPG blocks have a level of evidence ranging from 2B to 4D (Figure 2, Figure 3).

Level	Type of evidence
1A	Systematic review (with homogeneity) of RCTs
1B	Individual RCT (with narrow confidence interval)
1C	All or none study
2A	Systematic review (with homogeneity) of cohort studies
2B	Individual cohort study (including low quality RCT)
2C	"Outcomes" research; Echological studies
3A	Systematic review (withhomogeneity) of case-control studies
3B	Individual case-control studies
4	Case series (and poor quality cohort and case-control studies)
5	Expert opinion; case report or clinical example; or evidence based on physiology
Burns, P., Rochrich, R., Chung, K. (2011). The levels of evidence and their role in evidence-based medicine. Plastic and Reconstructive Surgery, 128(1), 305-310. Reprinted with permission.	

FIGURE 2. Adaptation of levels of evidence for therapeutic studies.

Grade	Descriptor	Qualifying Evidence	Implications for Practice
A	Strong recommendation	Level 1 evidence or consistent findings from multiple studies of levels II, III, or IV	Clinicians should follow strong recommendations unless clear or compelling rationale for an alternative approach is present
B	Recommendation	Levels II, III, or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preferences
C	Option	Levels II, III, or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role
D	Option	Level V evidence; little or no systematic empirical evidence	Clinicians should consider all options in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role
Burns, P., Rochrich, R., Chung, K. (2011). The levels of evidence and their role in evidence-based medicine. Plastic and Reconstructive Surgery, 128(1), 305-310. Reprinted with permission.			

FIGURE 3. Adaptation of grade practice recommendations.

Higgs, Burn, and Jones (2001) emphasize the value of data gleaned and pooled from smaller data sets. This approach supports the argument for including SPGNBs for the treatment of PDPH.

Gaps

The most significant gap discovered during the literature review process was the lack of current, large, well-designed trials supporting the hypothesis of SPGNB inclusion for the treatment of PDPHs. Also identified was the frequent lack of standardized care and failure to follow a clinical practice guideline for treatment of PDPH. There was virtually no literature contradicting or failing to support the use of SPGNB in some way, however, the suggestion or recommendation for its inclusion in the guidelines for treatment of PDPH continues to be elusive. This gap between knowledge and clinical practice was at the heart of this DNP project, which sought to update clinical practice guidelines to reflect best practices supported by the literature and inform local anesthesia providers regarding this information.

Synthesis of Evidence

Of the 11 original studies and reports selected for analysis and synthesis (Table 1), five were case reports, three were case series, two were RCTs and one was a retrospective observational study. Synthesis of the literature generally supported the effectiveness of SPGNBs for the treatment of both PDPH and the more generalized headache pain syndromes of various etiologies (Table 1).

Cohen, Sakr, Katyal, and Chopra (2009) and Cohen et al. (2014) describe two case series and one case report with impressive results (84.6% & 69% success rates, respectively) from SPGNBs. The SPGNB technical procedures vary considerably amongst the various reports and

studies reviewed, further contributing to perhaps a disparity in outcomes. The most recent information that is being presented at conferences reflecting the highest success rate involves the use of 4% liquid lidocaine on cotton-tipped applicators left in place for 30-60 minutes.

Table 1 outlines and grades 11 recent studies, reports and RCTs reporting original data which provide support for the success of SPGNBs for the treatment of PDPH; however, further, more extensive and better-controlled trials are needed to validate this data. Patel et al. (2016) reported on a 17-year retrospective observational study involving 72 patients that were randomized into two groups — SPGNB intervention versus epidural blood patch intervention for PDPH. At the 30-minute post-procedure mark, the SPGNB group had a statistically significant reduced pain score (54.55% relief versus 20.51%) and at 60 minutes' post-procedure, the SPGNB group had 63.64% relief versus 30.77% for the epidural blood patch group (Patel et al., 2016).

Cady et al. (2014) in their double-blinded RCT (n=38), reported a statistically significant reduction in migraine headache pain versus the control group (mean difference = -4.52, P = .005) versus (mean difference = -1.5, P = 0.13). This study, while demonstrating the effectiveness of SPG blocks for the treatment of migraine headaches following a six-week evaluation period, did not specifically address postdural puncture headaches. This study was also specifically evaluating a commercially available device designed for application of SPGNG manufactured by Tian Medical called the Tx360 (Cady et al., 2014).

Another RCT authored by Schaffer, Hunter, Ball, and Weaver (2015) was also evaluating the effectiveness of the TX360 devise versus placebo for treatment of patients with acute headaches presenting in the emergency department. This study (n=45) did not provide a

statistically significant difference between treatment and control groups in headache reduction at the 15-minute post-treatment mark, however it did provide a statistical reduction in headache pain when evaluated at the 24-hour post-intervention mark (72.2% reduction in pain for treatment group versus 47.5% reduction for the control group) (Schaffer et al., 2015).

While larger studies are still lacking, the cumulative support from smaller data points provide support for the inclusion of SPGNBs for the treatment of PDPH, based on current literature. Higgs et al. (2001, p. 488) argued that evidence-based practice should not be based on a "cookbook" approach, but rather, embrace a broader approach including not only the latest literature but also inclusion of professional judgment, practice experiences and critical thinking.

METHODS

Project Design

The purpose of this project was to modify and disseminate a clinical practice guideline (CPG) for the treatment of PDPH adapted for the Anesthesia Physicians of Arizona's (APA) anesthesia providers practicing at Mountain Vista Medical Center (MVMC). This project included a comprehensive and systematic approach to the literature review, consultation with on-sight anesthesia experts regarding existing practices, CPG modification and validity assessment, and presentation to a local facility for implementation consideration. Information gained from the literature and assessment of current clinical practice was used to inform the modified guidelines. The original NYSORA CPG for the treatment of PDPH and published on the NYSORA website were reviewed and selected for CPG modification (Harrington & Reina, 2019).

The newly modified CPG was specifically created for utilization by APA anesthesia providers at the local facility. Comparisons of the original and modified CPG were conducted by two anesthesia providers using the AGREE II instrument (Brouwers et al., 2010) (Appendix F). Those participating in the AGREE II assessment first completed an online training module provided by the AGREE II Trust and attested to their training by signing the AGREE II Appraiser Training Confirmation document (Appendix G), affirming they have completed the standardized online training for the use of the AGREE II scoring instrument.

Development and modification of the clinical practice guideline within this DNP project were intended to strengthen the AGREE II score from the original NYSORA CPG, strengthening each of the domains where weaknesses were identified. The implementation and dissemination portion of this project included the presentation of the newly modified CPG and data input results and AGREE II scores to the anesthesia department stakeholders from APA practicing at the local facility and a poster presentation to the CRNA community at a local conference in March 2019. Feedback and analysis of data were obtained using a standardized Pre- and Post-CPG Modification AGREE II Scores Form (Appendix D).

Setting

The setting for this DNP project was the anesthesia department at the local facility where anesthesia providers from Anesthesia Physicians of Arizona (APA) practice anesthesia. The local facility is a 178-bed, community-based hospital serving the residents of a suburb within the metro Phoenix, Arizona community and surrounding cities. The Anesthesia Physicians of Arizona (APA) provides anesthesia services at the local facility serving their surgery department, which operates 10 operating rooms, a cardiac catheterization laboratory consisting of two

interventional suites, the endoscopy department comprised of two procedure rooms, and the obstetrical department which consists of one general anesthesia operating room and administration of epidural and spinal anesthesia to that hospital population. The APA practice was selected for project presentation due to: 1) close geographical proximity to the author of this project; and, 2) familiarization with this anesthesia clinical rotation site by the author. A site approval letter was signed on June 9, 2018, by Dr. Ned Sciortino who serves as the medical director for APA at the local facility clinical site (Appendix G).

Participants

There are approximately 32 full-time and part-time APA anesthesia providers at the local facility, including primarily CRNAs and a few physician anesthesiologists. Two local anesthesia providers were invited to participate in the AGREE II CPG review process and four on-site anesthesia providers were invited to provide consultation, input and feedback.

Intervention and Dissemination

The intervention and dissemination element of this DNP project involved the presentation of the newly modified CPG for the treatment of PDPH for local application by APA anesthesia providers at the local facility, along with the AGREE II validity data and summary of qualitative data from local industry experts gained throughout the process of the SPGNB literature review and CPG modification process. Summary qualitative data was included in the presentation and dissemination portion of this project. Dissemination also involved a poster presentation on the topic to the local CRNA community at an annual anesthesia conference in Scottsdale, AZ.

Tools

The Agree Reporting Checklist (Appendix J) was one of the primary tools used for the evaluation and reporting of the CPG referenced within this DNP project. Additional tools used included a Consult Input Form (Appendix D), and a Stakeholder Feedback Form (Appendix I).

Data Collection Process

This DNP project followed a systematic review of the literature supporting the use of SPGNB. Assessing the original and modified CPG followed the AGREE II Reporting Checklist, which guides the process of data collection (Appendix H). Two project participants were selected to be trained in AGREE II evaluation methods and then asked to appraise this modified PDPH CPG. Following final presentation to APA stakeholders practicing at the local facility, feedback was obtained and analyzed using the Stakeholder Feedback Form (Appendix I).

Data Analysis

Quantitative data was collected and analyzed as part of this project. Qualitative data was gathered from local industry expert consultants at the local facility. Data from the AGREE II CPG assessments were analyzed and summarized, addressing the pre- and post-CPG modification for quality, validity, clarity, applicability, and independence. This tool utilizes a seven-point Likert-scale to evaluate 23 individual CPG items within six domains (Brouwers et al., 2010).

Ethical Considerations

Respect for Persons

This project was submitted to the University of Arizona's College of Nursing for Institutional Review Board (IRB) consideration using the standardized Human Research Form

(Consent Templates | Research Gateway, 2018). This DNP project was not defined as research or research involving human subjects. A Determination of Human Research exemption was granted (Appendix K), therefore a full IRB application and approval process was not necessary (45 CFR 46 – Protection of Human Subjects, 2018).

Each participant, consultant, and stakeholder involved in this DNP project was on a voluntary basis. This project contained no discussions, considerations or questions relating to age, ethnicity, religion or sexual orientation. Confidentiality and data security was maintained through use of a secure, password-protected hard drive.

Beneficence

There were no risks, including financial, emotional or safety risks associated with this project. The project did not involve human subject studies or trials. Benefits from this DNP project include increased knowledge and awareness of literature and professional consultant support for CPG revision for the treatment of PDPH. The APA anesthesia stakeholders practicing at the local facility also benefited from having an updated clinical practice guideline that can be implemented, at their discretion, to treat patients suffering from PDPH with the latest evidence-based protocols.

Justice

Following the CPG presentation, feedback from APA anesthesia stakeholders practicing at the local facility provided valuable data to assure the presentation of the material was deemed to meet this project's objectives. This project did not involve human subject studies, recruitment or human data collection. All those involved in this project, including the DNP committee members, expert consultants, and stakeholders, participated on a voluntary basis without regard

to any discriminatory or financial interest factors. The APA anesthesia stakeholders practicing at the local facility were selected as the beneficiary of this project solely due to geographical convenience and clinical rotation scheduling. There were no financial, educational, economic or professional conflicts, disclosures or known ancillary affiliations related to this DNP project that would create a conflict of interest.

RESULTS

Following tabulation of the pre- and post-CPG modification AGREE II scores (Appendix D) and input from local expert consultants (Appendix E), the NYSORA CPG for the treatment of PDPH was modified (Appendix B) and a more simplified algorithm was developed for presentation and implementation consideration by stakeholders at the local facility (Figure 4).

Brouwers et al. (2010) suggest a minimum of two trained evaluators are needed to complete the AGREE II scoring tool of a CPG to assess its rigor, quality, and transparency adequately. Two anesthesia providers practicing at the local facility were invited to participate in the AGREE II appraisal process. Each provider was given a copy of the *Appraisal of Guidelines for Research & Evaluation II*, which outlines detailed instructions on how to accurately score a CPG using the AGREE II tool (Brouwers et al., 2010). Additionally, each appraiser completed an online training tutorial provided by the AGREE II Trust (Brouwers et al., 2010) and attested to the completion of such training (Appendix F)

Overall, 23 key elements were assessed across six domains, as well as two broad, overall assessments comparing the original and modified CPG. The six domains included: *Scope and Purpose*, *Stakeholder Involvement*, *Rigour of Development*, *Clarity of Presentation*, *Applicability*, and *Editorial Independence;* the two broad assessments included *Overall Quality*

and *Overall Guideline Assessment* (Brouwers et al., 2010). The goal of this assessment was to provide an answer to the study question as to whether local stakeholders would score the revised

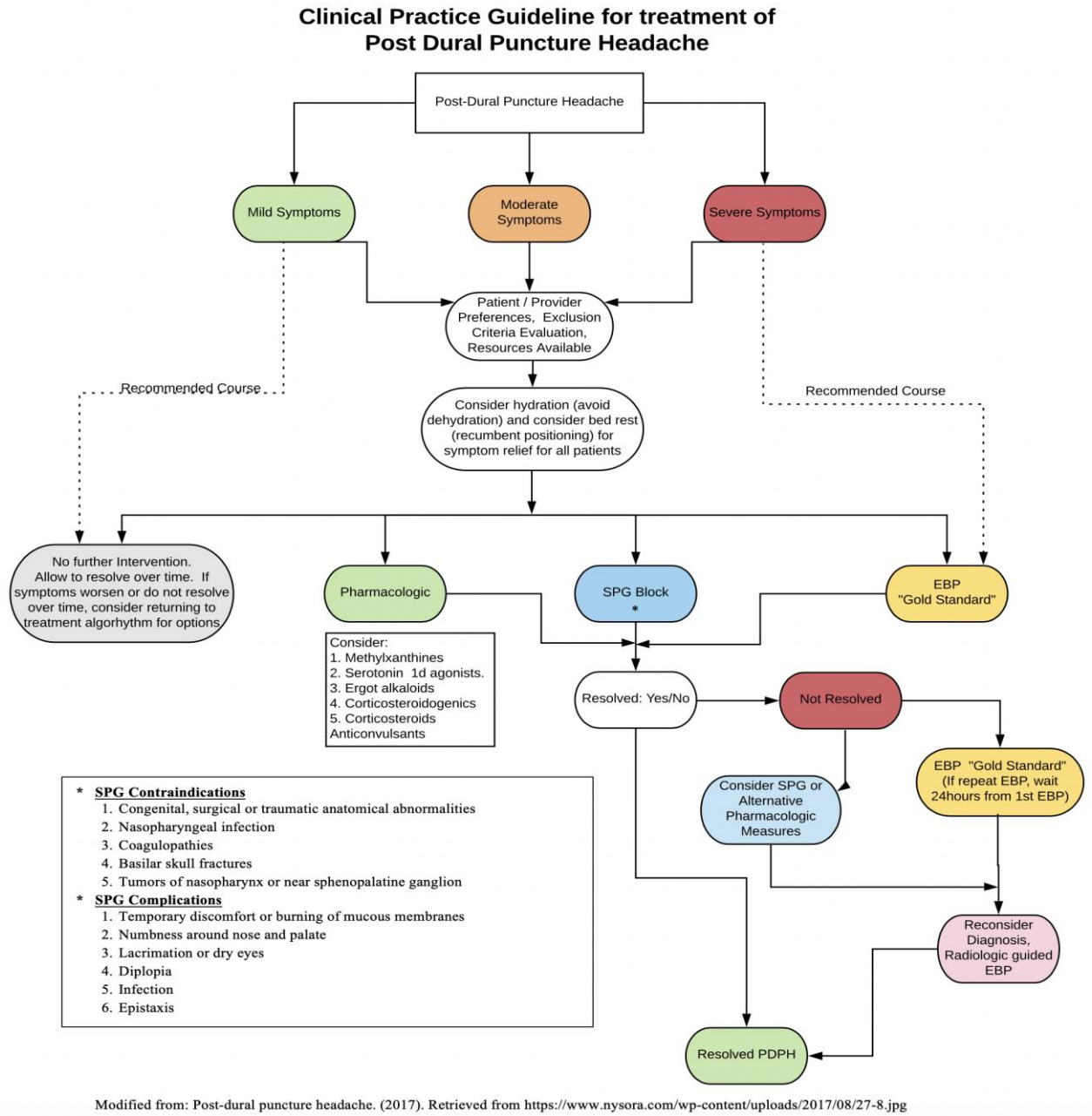


FIGURE 4. Modified New York School of Regional Anesthesia (NYSORA) postdural puncture headaches treatment flow chart.

CPG, which includes the recommendation for using an SPGNB for the treatment of PDPH, as equal or higher quality than the original unmodified NYSORA CPG for the treatment of PDPH.

Overall, the modified CPG received higher scores in each of the six domains, with an overall increase from 55% to 80%, providing an affirmative answer to the study question. Domain 1, Scope and Purpose, increased from 64% to 97%. Domain 2, Stakeholder Involvement, increased from 44% to 86%. Domain 3, Rigour of Development was scored 49% initially and 86% for the modified CPG. Domain 4, Clarity of Presentation, went from 86% to 94%. Domain 5, Applicability, increased from 54% to 67% and Domain 6, Editorial Independence, increased from 38% to 42%.

Figure 5 reflects the summary data across each of the six domains and highlights the improvements within each category; blue represents the pre-modification scores and orange represents the post-CPG modification scores.

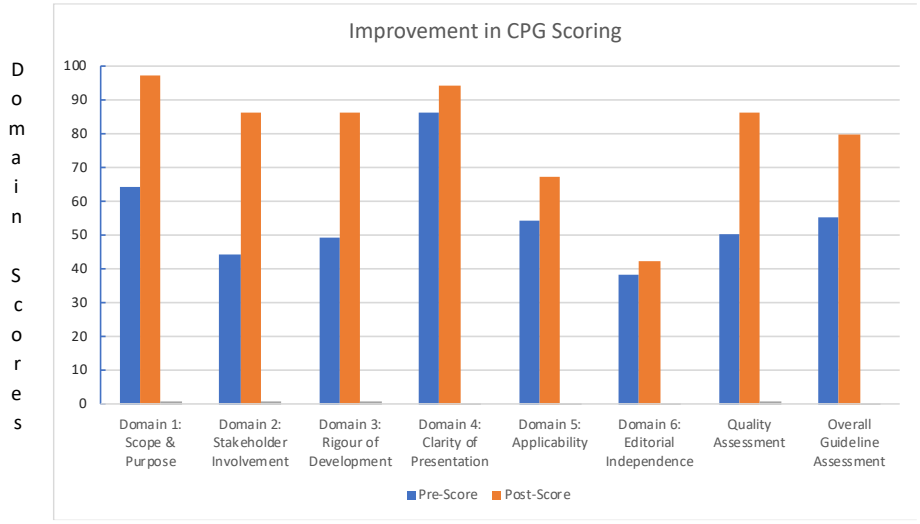


FIGURE 5. Improvement in CPG scoring.

Four expert anesthesia consultants practicing at the local facility provided input relating to the various treatment modalities for PDPH and their inclination to include or exclude specific

treatment modalities at the local level of their practice. The consultants were asked to consider ten treatment modalities identified within the original NYSORA CPG and consider which of these they would be most inclined or least inclined to consider for the treatment of PDPH at the local facility. Treatment considerations included: 1) bed rest; 2) hydration with IV or PO fluids; 3) use of aminophylline, theophylline or caffeine; 4) use of serotonin type 1d receptor agonists such as sumatriptan; 5) use of ergot alkaloids such as methylergonovine; 6) use of corticosteroidogenics such as cosyntropin/tetracosactin; 7) use of corticosteroids such as hydrocortisone; 8) use of anticonvulsants such as gabapentin; 9) application of a sphenopalatine ganglion nerve block; and, 10) epidural blood patch (Appendix D). The summary results of the expert recommendations were included in the local facility Anesthesia Provider Preferences (Figure 6). Of particular interest and applicability to this DNP project was that 100% of the expert consultants indicated they would consider the inclusion of SPGNB for the treatment of PDPH.

This data and local expert recommendation further strengthen the argument to include consideration for SPGNB for the treatment of PDPH in the CPG modification.

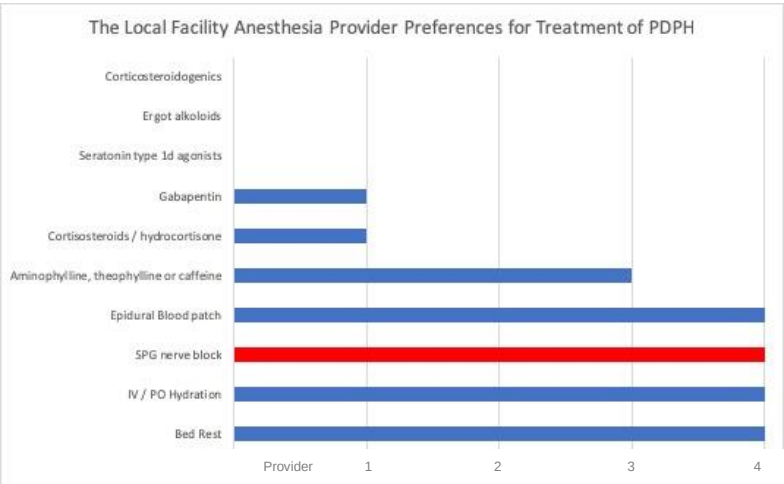


FIGURE 6. The local facility anesthesia provider preferences.

DISCUSSION

Modification of the NYSORA CPG for the treatment of PDPH to include SPGNB provides anesthesia stakeholders and practitioners at the local facility a locally applicable, high-quality clinical practice guideline for implementation consideration. This study's question is addressed and answered in the affirmative; the AGREE II assessment of the modified CPG was scored 45% higher (80% versus 55%) than the original NYSORA CPG. This finding was important for several reasons. Current practices for the treatment of PDPH have been inconsistent, and CPGs on the topic have failed to include SPGNB, even though there is emerging evidence within the literature and a plethora of positive anecdotal experiences amongst anesthesia practitioners regarding its success. Anesthesia practitioners at the local facility have not had a standardized CPG at their institution for the treatment of PDPH. The results of this DNP project provide the local facility a systematic, stepwise approach which includes the low-risk, less-invasive SPGNB before attempting more aggressive interventions for the treatment of PDPH. Healthcare facilities rely on clinical practice guidelines that are adapted to their preferences, needs, and goals. This DNP project provides the local facility such a locally adapted CPG. The input and practice preferences provided by the four local anesthesia experts from the local facility further addresses the preferences, practices, and experiences of their local providers.

The modified CPG presented to stakeholders at the local facility addressed numerous areas of focus identified as weaknesses in the original NYSORA CPG. Additional clarity was provided under the following headings: objectives, CPG modification question, target population, intended users, overall modifications and recommendations, literature-based

evidence and strength of evidence/grading, a simplified algorithm, a review of the pre- and post-AGREE II scoring, updating procedures, stakeholder involvement, facilitators and barriers to implementation, and funding/conflict of interest. There are multiple ways of administering a successful SPGNB, and the literature varies significantly on the topic. It was not the objective of this DNP project to delve into this specific question and explore the nuances of various techniques, however, there was a consensus of expert opinion that was provided as a brief suggestion to the stakeholders at the local facility which does appear to reflect current best practices amongst practitioners experienced with SPGNB.

Stakeholders at the local facility should remain cognizant that this topic is one of emerging fluidity and there will likely be new information, studies, and expert opinion that may either reinforce or contradict some of the modifications suggested within this DNP project's modified CPG. There have been considerable recent discussions on the topic of SPGNB for the treatment of PDPH at anesthesia conferences and seminars and some indication that more on the topic will soon be reflected and addressed in upcoming anesthesia textbooks.

Dissemination Plan

The goal of this DNP project was to provide a local facility a modified clinical practice guideline for the treatment of PDPH that provides for the early consideration for the lesser-invasive SPGNB. Translating evidence into practice is often a challenging task, taking up to seventeen years to overcome the status-quo and various implementation barriers (Morris et al., 2011). Fundamental to overcoming these barriers is the incorporation of local influence agents who have the respect of their peers and can provide some level of peer support and energy to overcome the status quo. Four anesthesia experts practicing at the local facility were sought out

early and involved in the process of providing insight and expert consultation. The original NYSORA CPG and the modified CPG for the treatment of PDPH were assessed using the AGREE II instrument by the local facility anesthesia providers as well, providing an element of local applicability. Moreover, the presentation of the modified CPG and the supporting data and AGREE II scoring was presented to the Medical Director of Anesthesia at the local facility and the chief CRNA. The modified CPG was presented to the stakeholders at the local facility (Appendix B) providing a simple-to-implement guideline at their local level for the treatment of PDPH. Included was the expert input from four of their anesthesia providers and the summary AGREE II scoring data from two of their anesthesia providers. Further dissemination of this modified PDPH CPG and the literature supporting the early consideration for SPGNB was presented in the form of a poster presentation at an annual state CRNA conference in March 2019.

Following the presentation and discussion of the modified CPG for implementation at the local facility, feedback was obtained from the two main anesthesia stakeholders at the local facility using a standardized Stakeholder Feedback Form (Appendix G). Summarizing this data, both the director of anesthesiology and their head CRNA indicated that they would recommend the modified CPG for approval as a clinical practice guideline at their institution and, if and when approved, they would apply the CPG recommendations to their patients. Having both the stakeholder and local anesthesia experts and change agents involved throughout this process will hopefully bode well for translation into practice at the local facility.

Strengths, Weaknesses and Limitations

The strength of this DNP lies within the premise that evidence-based practice is not only those practices that are strongly supported within the literature with highly-rated and graded research but also those practices that reflect sound clinical judgment based upon practitioner experiences and consensus expert opinions (Nguyen & Walters, 2014). Often, this is how new best practices evolve. In fact, many of the practices and interventions used today by anesthesia providers are not yet fully supported by large, randomized, double-blind studies, simply due to the ethical nature and difficulty of these studies, yet are still accepted as best practices and supported amongst the experts within the field (Nguyen & Walters, 2014). Another strength of this project is the notion that a locally adapted clinical practice guideline, reviewed and accepted by the key stakeholders and change agents, has been reviewed, graded and accepted as a viable, suitable, and appropriate CPG for their facility. Baysinger, Pope, Lockard, and Mercaldo (2011) report that nationally, only 14% of practitioners are routinely following clinical practice guidelines in their patient care. It is also reported by Eccles and colleagues (2012) that approximately 40% of patient care in the U.S. today does not reflect known best practices and as many as 25% of patient care interventions are known to be ineffective. Providing the anesthesia practitioners at the local facility a CPG for the treatment of PDPH that they can systematically follow standardizes the care based on currently available best-known practices. Additionally, the revised CPG provides a benefit to patients at the local facility suffering from PDPH in that they now have an option for a less-invasive intervention which may potentially eliminate the need for an epidural blood patch.

Weaknesses of this DNP project include the fact that this modified CPG is not yet strongly supported by robust, randomized, multi-institutional highly-graded studies. The modified CPG produced as a result of this project also was the product of a single DNP student without any direct human subject data collection. This project was not directed at generating new knowledge; it was focused on compiling broadly discriminated current knowledge and practices into a single point for CPG modification and local implementation. The author of this DNP project, as a clinical student at the local facility, lacked the positional authority and formal influences needed for the policy changes required for CPG implementation; however, the tools and information were presented to stakeholders at the local facility with such authority so they can continue and follow-through to full implementation at their discretion.

An additional weakness of this DNP project was the limited use of AGREE II appraisers. The AGREE II guidelines recommend a minimum of two and a maximum of four appraisers. Due to limited resources at the local facility, two appraisers were used for this assessment which potentially provides some limitations in the quality of CPG assessments completed. In an attempt to mitigate this limitation, the two appraisers were required to complete the online AGREE II tutorial and review the printed AGREE II instructions before their assessments.

Incorporation of DNP Essentials

The American Association of Colleges of Nursing (2006) mandates eight essential education requirements within every DNP program. This DNP project incorporated several of these DNP essential elements as follows: Essential I, *scientific underpinnings for practice* were incorporated through the identification of and use of scientific practices involved in research, literature review and grading of evidence. Anatomy and physiologic processes were identified as

the cause of PDPH and the reasons why SPGNB are often effective in eliminating the symptoms; Essential III, *clinical scholarship and analytical methods for evidence-based practice* was at the heart of the entire project, seeking out best practices both within the literature and amongst expert practitioners, the use of analytical tools such as the AGREE II CPG assessment instrument, and various other data collection and analytical methods incorporated within this project; Essential VI, *interprofessional collaboration for improving patient and population health outcomes* was incorporated into this DNP project as well. A project team was formed consisting of faculty from the University of Arizona's College of Nursing and expert anesthesia consultants and stakeholders at the local facility were involved as well throughout the duration of the project; finally, DNP Essential VIII, *advanced nursing practice* focuses on this DNP author's newly gained knowledge and expertise in the specialty field of nurse anesthesia and the application of this knowledge in identifying a specific clinical problem and presenting a viable, evidence-based solution to address it.

Conclusion

Patients suffering from postdural puncture headaches and those treating them have been at odds for some time as to the best, most efficacious treatment options. While the sphenopalatine ganglion nerve block has been used for decades to treat a wide variety of other headache maladies, the bridge to using this option for treating PDPH has been elusive. Of late, increasing experiences and reports in the literature are supporting the use of SPGNB for the treatment of PDPH before attempting an epidural blood patch, as has been the increasing accumulation of expert opinions on the topic. Translating best-known practices into CPGs and implementing them for standardized care, however, is often difficult, time-consuming, and met

with a multitude of obstacles. This project identified a local institution where they lacked a CPG for the treatment of PDPH, identified a problem with inconsistent treatment regimens and practices that perhaps did not always reflect best practices, and it provided a solution to their problem. The study question as to whether local stakeholders would find a revised CPG that had been crafted and locally adapted to suit their local goals, needs, and preferences to be of higher quality than a nationally published CPG for the treatment of PDPH was answered in the affirmative. The result of this DNP project was the presentation of a much-improved clinical practice guideline for the treatment of PDPH which included the early consideration of SPGNB.

As an advanced practice nurse specializing in nursing anesthesia and completing a DNP degree at the University of Arizona, this author was pleased to be able to participate in a project that produced a locally-adapted, high-quality CPG ready for implementation at the local facility which will provide more consistent care based upon current literature and emerging expert consensus opinion. Translating evidence and knowledge into practice is often a long, difficult process and through the incorporation of a team-based approach, the use of Lewin's change theory and inclusion of local practitioners as potential change agents, the stage has been set for a successful implementation.

APPENDIX A:

NYSORA CPG FOR THE TREATMENT OF POSTDURAL PUNCTURE HEADACHES

Website link to the NYSORA's CPG for the treatment of postdural puncture headaches: https://www.nysora.com/foundations-of-regional-anesthesia/complications/postdural-puncture-headache

APPENDIX B:

MODIFIED NYSORA CLINICAL PRACTICE GUIDELINE

Modification of NYSORA Clinical Practice Guideline for Treatment of Postdural Puncture Headache Adapted for Anesthesia Physicians of Arizona practicing at Mountain Vista Medical Center, Mesa, AZ

Report Date: October 12, 2018

Scope and Purpose

Objectives

This modified Clinical Practice Guideline (CPG) is intended to provide updated, evidence-based practice recommendations to the anesthesia providers practicing at Mountain Vista Medical Center (MVMC) for the treatment of postdural puncture headaches (PDPH). Combining current literature-based evidence on the topic, along with input from expert consultation from local anesthesia experts, this modified CPG has been specifically adapted for implementation at MVMC in Mesa, AZ. Specifically, the introduction of early consideration for use of a sphenopalatine ganglion nerve block will provide anesthesia providers and their patients a minimally-invasive option for treating PDPH.

CPG modification Questions

Is there an effective, minimally-invasive intervention option (versus the gold-standard Epidural Blood Patch) for the treatment of Postdural Puncture Headache for patients at Mountain Vista Medical Center? Is there evidence supporting the early consideration for a Sphenopalatine Ganglion nerve block prior to attempting more invasive techniques? Considering expert consultation input from anesthesia providers at Mountain Vista Medical Center, what are their preferences for treatment of Postdural Puncture Headache? Based upon currently available industry expert consensus, what is the optimal technique for performing an SPG nerve block that can be implemented at Mountain Vista Medical Center?

Target Population

Intended patient population for this CPG modification includes adult patients, 18-years of age or older, who are suffering from a postdural puncture headache at Mountain Vista Medical Center. While the majority of these patients are likely to include the obstetrical population, this guideline is not limited solely to the OB population. Adult patients who have received either a diagnostic spinal tap or spinal anesthetic or for those patients that may been administered an epidural injection or catheter placement for non-OB related reasons with inadvertent dural puncture resulting in postdural puncture headache.

Intended Users

This modification to the NYSORA CPG for treatment of postdural puncture headache is intended for local implementation by anesthesia providers practicing at Mountain Vista Medical Center in Mesa, AZ.

Overview of Modifications and Recommendations

This supplemental modification to the NYSORA CPG for the treatment of postdural puncture headache has focused primarily on suggesting the addition for early consideration for an SPG block prior to attempting the more invasive epidural blood patch. Additionally, the original NYSORA treatment algorithm (decision tree) has been modified to: 1) make it easier to follow and 2) introduce the SPG step as an early consideration. Finally, a section has been added covering expert consensus opinion on the SPG procedure itself which can be implemented at MVMC.

1. **Based upon patient presentation, severity of symptoms, prior modalities already attempted and anesthesia provider experience and preference, consider the option for early SPG block prior to attempting more invasive Epidural Blood Patch.**

2. **Recommended SPG block technique. Multiple techniques for administering an SPG block have been attempted with varied results. Based upon expert consensus and the most recently available information, the following points are recommended to maximize results** (Rigdon, S., 2017).

    a. 1-3 ml (slowly over 30-60 min) of 4% lidocaine (per side) is preferred versus 2% lidocaine or other topical anesthetics
    b. Use cotton-tipped, hollow-tubed culture swabs soaked in 4% lidocaine and insert slowly until terminal depth is achieved. Mark depth level of each swab and re-check depth frequently as patient talking and swallowing will displace swab and require slight advancement.
    c. Once the initial lidocaine-soaked swab is inserted and maximal depth is achieved, remove the swab and replace it with a new clean soaked swab (this removes the mucous coating that often accumulates on the initial swab during insertion. Fill the hollow tube with 4% lidocaine and allow to soak with patient in supine position.
    d. Every 10 min, gently rotate each swab 180 degrees and assure hollow swab tube is full and swab remains in contact with sphenopalatine and assess for relief.
    e. It often takes at least 20 minutes and can take as long as 60 minutes for relief.

Literature-based Evidence and Strength of Evidence / Grading

Authors / Article	Study Design & Methods	Research Question or Hypothesis	Sample (n) & Setting	Variables, data types, and results	Strength of Evidence
Cady, R., Saper, J., Dexter, K., & Manley, H. (2014). A double-blind, placebo-controlled study of repetitive transnasal sphenopalatine ganglion blockade with Tx360® as an acute treatment for a chronic migraine *Headache: The Journal of Head and Face Pain*, *55*(1), 101-116.	RCT, double-blinded study 0.3 ml of 0.5% bupivacaine using Tx 360 device Repetitive SPGNBs using the Tx360 devise with a series of 12 SPGNBs provided 2 times per week for 6 weeks.	SPGNB using Tx360 device vs. normal saline placebo for treatment of chronic migraine headaches	n=38 Control n= 12 SPGNB n = 26 Randomly assigned patients from two US specialty headache clinics	Treatment group experienced a significant reduction in headaches vs control group at 15 and 30 minutes (M=3.78 vs M-3.18, P=.10) and (M=3.51 vs M = 2.53, P<.001). From pre-treatment to final treatment (following 6-week period) the treatment group experienced a statistically significant reduction in headache pain vs. control (M diff = -4.52, P=.005) vs. (M dif = -1.5, P = .13).	**2B – Recommended** Clinicians should generally follow a recommendation but should remain alert to new information and remain sensitive to patient preferences
Cardoso, J., Sá, M., Graça, R., Reis, H., Almeida, L., Pinheiro, C., & Machado, D. (2017). Sphenopalatine ganglion block for postdural puncture headache in ambulatory setting. *Brazilian Journal of Anesthesiology (English Edition)*, *67*(3), 311-313.	Case Report Cotton-tipped applicator saturated with 0.5% levobupivacaine for 5 minutes.	SPGNB versus prior trial with crystalloid, dexamethasone, parecoxib, Tylenol and caffeine.	n=1 41-year-old female s/p PDPH for 1 week The ambulatory setting in Brazil	The patient reported 0/10 pain after 5 minutes of SPGNB. Remained pain-free at 1 day and 7 days post-procedure, did have OTC pain medication to take at home PRN	**5D – Option** Clinicians should consider all options in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role
Channabasappa, S., Manjunath, S., Bommalingappa, B., Ramachandra, S., & Banuprakash, S. (2017). Transnasal sphenopalatine ganglion block for the treatment of postdural puncture headache following spinal anesthesia. *Saudi Journal of Anaesthesia*, 11(3), 362.	Case Study 5 ml of a pre-loaded syringe with 0.5% ropivacaine attached to a cotton-tipped 23-g spinal needle. SPGNB was accomplished with injection vs. topical saturation of local anesthetic on ganglia.	Will SPGNB prevent the need for epidural blood patch in PDPH parturient?	n=1 PDPH following combined spinal-epidural for C-section in hospital in India	Instantaneous and sustained pain relief. 24 hours post-procedure, the patient remained pain-free and follow-up at 3 weeks post-procedure revealed continued pain-free scores.	**5D – Option** Clinicians should consider all options in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role
Cohen, S., Sakr, A., Katyal, S., & Chopra, D. (2009). Sphenopalatine ganglion block for postdural puncture headache. *Anaesthesia*, *64*(5), 574-575	Case Series Cotton-tipped applicator soaked with 4% lidocaine ointment	SPGNB effectiveness on 1st vs. subsequent blocks	n=13 Unknown setting	11 of the 13 patients received immediate and/or complete relief following 1st SPGNB (84.6% reported success)	**4C – Option** Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role
Cohen, S., Ramos, D., Grubb, W., Mellender, S., Mohiuddin, A., & Chiricolo, A. (2014). Sphenopalatine Ganglion Block. *Regional Anesthesia and Pain Medicine*, *39*(6), 563.	Case Series Cotton-tipped applicator saturated with 5% water-soluble lidocaine ointment left in place for 10 minutes	SPGNB effectiveness for treatment of PDPH amongst obstetric patients, eliminating the need for epidural blood patch	n=32 Obstetrical patients suffering from PDPH following accidental dural puncture from a 17-gauge epidural needle	69% reported success in relieving PDPH by use of SPGNB amongst 32 obstetric patients, eliminating the need for an epidural blood patch	**4C – Option** Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role

Cohen, S., Trnovski, S., & Zada, Y. (2001). A new interest in an old remedy for a headache and backache for our obstetric patients: a sphenopalatine ganglion block. *Anesthesia, 56*(6), 606-607.	Case Report Cotton-tipped applicator saturated with EMLA cream for 10 minutes (2 of the 22 patients could not tolerate the EMLA cream and so they were given Cetacaine nasal spray instead)	SPGNB for treatment of moderate to a severe backache or a headache amongst obstetrical patients	n=22 Obstetrical patients Complaining of moderate to a severe backache and headache during a hospital stay	100% of patients experienced complete relief of pain within 6-10 minutes of SPGNB procedure. No side-effects reported amongst any of the n=22 participants.	**5D – Option** Clinicians should consider all options in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role
Furtado, I., Lima, I., & Pedro, S. (2017). Ropivacaine use in Transnasal Sphenopalatine ganglion block for post dural a puncture headache in obstetric patients – case series. *Brazilian Journal of Anesthesiology (English Edition)*.	Case Series 4 ml of 0.75% ropivacaine Applicator left in place for 15-20 minutes	SPGNB effectiveness in obstetrical patients suffering from PDPH. Will the application of SPGNB prevent the need for epidural blood patch?	N=4 Labor and Delivery, OB patients in Portugal	Case 1. No relief from conservative treatment x 24 hrs. SPGNB provided 100% relief without remission following 7 days Case 2. PDPH pain went from 6-8/10 immediately to 0/10 following SPGNB. The pain returned to 4/10 and required 2nd SPGNB with 100% relief and no remission Case3. The patient reported PDPH pain of 4-6/10 with 100% relief following SPGNB, however, patient required epidural blood patch which failed to resolve PDPH. Ultimately patient was discharged home with 3/10 pain Case 4. PDPH pain score of 7/10 was immediately relieved to 0/10 following SPGNB. The patient remained pain-free for48 hrs, the however pain returned and epidural blood patch was performed.	**4C – Option** Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role
Kent, S., & Mehaffey, G. (2015). Transnasal sphenopalatine ganglion block for the treatment of postdural puncture headache in the ED. *The American Journal of Emergency Medicine, 33*(11), 1714.e1-1714.e2.	Case Report 2% viscous lidocaine on long, cotton-tipped applicators, left in place for 10 minutes, re-applied for additional 20 minutes.	SPGNB effectiveness for PDPH following diagnostic lumbar punctures	n=3 Emergency department. PDPH following diagnostic lumbar punctures using spinal needles	Patient 1. An initial headache 8/10 went to 1/10 with no further treatment needed Patient 2. An initial headache 9/10 was reduced to 4/10 following SPGNB, however patient later sought out epidural blood patch at another facility Patient 3. An initial headache 9/10 with SPGNB relief of 1/10	**5D – Option** Clinicians should consider all options in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role
Kent, S., & Mehaffey, G. (2016). Transnasal sphenopalatine ganglion block for the treatment of postdural puncture headache in obstetric *of Clinical Anesthesia, 34*, 194-196.	Case Report 2% viscous lidocaine on long, cotton-tipped applicators, left in place for 10 min, then additional 2% lidocaine reapplied and applicator re-inserted for additional 20 min.	SPGNB effectiveness in obstetric patients suffering from PDPH. Will the SPGNB avoid the need for epidural blood patch?	n=3 Labor and Delivery Suite. Post-partum obstetrical patients suffering from PDPH	All 3 patients had "significant" relief from PDPH following SPGNB and all three avoided the need for epidural blood patch. An initial headache vs. post-SPGNB headache scores as follows: Patient 1. 9/10 to 0/10 Patient 2. 8/10 to 0/10 Patient 3. 9/10 to 0/10	**5D – Option** Clinicians should consider all options in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role
Patel, P., Zhao, R., Cohen, S., Mellender, S., Shah, S., & Grubb, W. (2016). Sphenopalatine ganglion block (SPGB) versus	Retrospective observational study over a 17-year period (Abstract Only)	Epidural blood patch vs SPGNB for PDPH	n=72 n=33 SPGNB n=39 = epidural blood patch Parturients with no previous history of primary headache	Retrospective data analysis of 72 records spanning 17 years. No differences in ASA scores, patient age, height, weight or BMI At 24 hours post-treatment, no difference in pain scores amongst SPGNB	**3C – Option** Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial

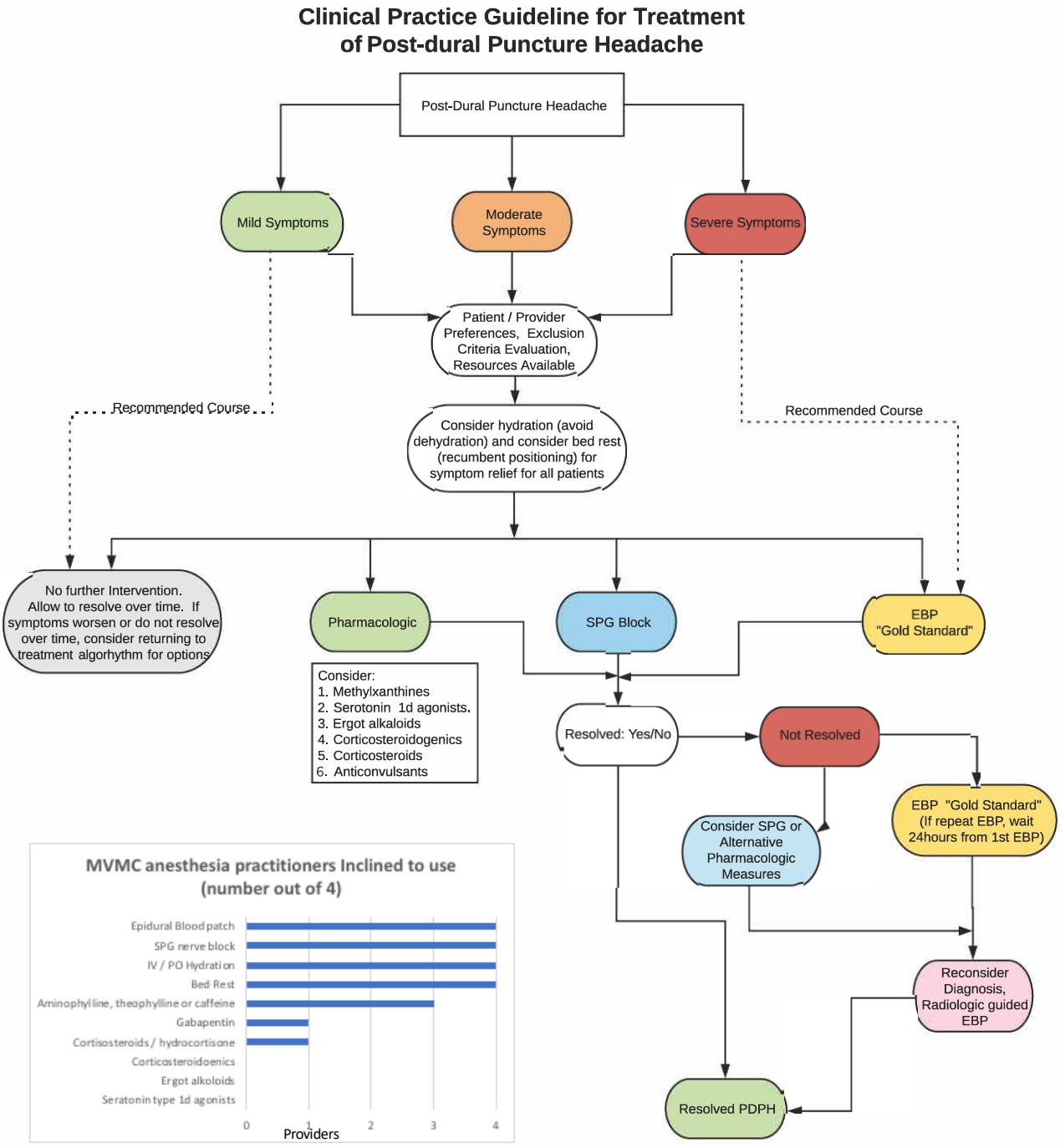
epidural blood patch for accidental postdural puncture headache (PDPH) in obstetric patients: A retrospective *The American Academy of Pain Medicine, Abstract 145*, 1.			disorders who were experiencing PDPH	and epidural blood patch group SPGNB group experienced improved headache scores at 30 min post procedure vs epidural blood patch (54.55% relief vs. 20.51%) and at 60 minutes post procedure, SGNB group had 63.64% relief vs. 30.77% for epidural blood patch group. SPNB group had no complications, vs epidural blood patch group had 9 patients return to ED for complications, including radiating back pain, vasovagal reaction or hearing loss.	influencing role
Schaffer, J., Hunter, B., Ball, K., & Weaver, C. (2015). Noninvasive sphenopalatine ganglion block for acute headache in the emergency department: A randomized placebo-controlled trial. *Annals of Emergency Medicine*, *65*(5), 503-510.	Randomized, Placebo-Controlled Trial Tx360 devise for application of SPGNB using 0.3 ml of 0.5% bupivacaine delivered by the Tx 360 device.	SPGNB vs. placebo treatment for Acute Headache in ED. The hypothesis was that the Tx360 SPGNB devise would achieve a 50% reduction in anterior headache pain vs. saline placebo delivered using same technique at the 15-minute post-procedure mark.	n=93 Control n = 48 SPGNB n = 45 2 large academic emergency departments of Level 1 facilities between Oct 2012 to Oct 2013	The treatment group n=45, did not experience a statistically significant improvement (risk difference of 7.5% with 95% CI) at the 15-minute mark and secondary outcomes revealed similar nausea scores at 15 minutes post-procedure (risk difference of 3.5% with 95% CI of 15.3% vs. 21.8%). Post 24-hour follow-up revealed treatment group was a headache free (with a statistical significance) with 72.2% vs. 47.5% for the control group.	2C – Option Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role

Level / Grade of Evidence Tables

Level	Type of evidence
1A	Systematic review (with homogeneity) of RCTs
1B	Individual RCT (with narrow confidence interval)
1C	All or none study
2A	Systematic review (with homogeneity) of cohort studies
2B	Individual cohort study (including low quality RCT)
2C	"Outcomes" research; Echological studies
3A	Systematic review (withhomogeneity) of case-control studies
3B	Individual case-control studies
4	Case series (and poor quality cohort and case-control studies)
5	Expert opinion; case report or clinical example; or evidence based on physiology
Burns, P., Rochrich, R., Chung, K. (2011). The levels of evidence and their role in evidence-based medicine. Plastic and Reconstructive Surgery, 128(1), 305-310. Reprinted with permission.	

Grade	Descriptor	Qualifying Evidence	Implications for Practice
A	Strong recommendation	Level 1 evidence or consistent findings from multiple studies of levels II, III, or IV	Clinicians should follow strong recommendations unless clear or compelling rationale for an alternative approach is present
B	Recommendation	Levels II, III, or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preferences
C	Option	Levels II, III, or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role
D	Option	Level V evidence; little or no systematic empirical evidence	Clinicians should consider all options in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role
Burns, P., Rochrich, R., Chung, K. (2011). The levels of evidence and their role in evidence-based medicine. Plastic and Reconstructive Surgery, 128(1), 305-310. Reprinted with permission.			

Modified NYSORA Algorithm



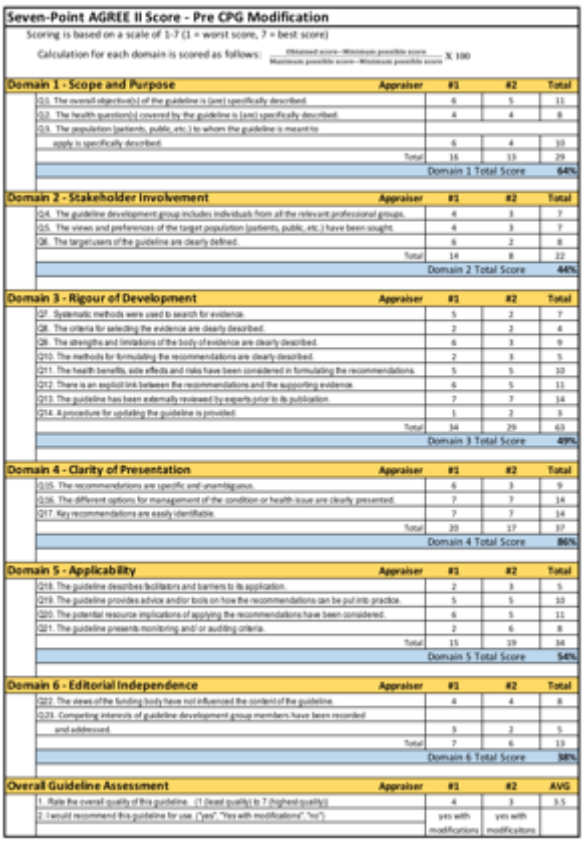
Modified from: Post-dural puncture headache. (2017). Retrieved from https: / /www.nysora.com /wp-content /uploads /2017 /08 /27-8.jpg

Methods

Search Methods and Criteria Selection

Commonly accepted scientific literature search engines were used to find relevant literature supporting the inclusion of SPG blocks for PDPH. CINAHL, Ovid, PubMed, Google Scholar and clinicaltrials.gov were searched using keywords and phrases, including "sphenopalatine ganglion" OR "SPG" OR "pterygopalatine ganglion" OR "Meckel's ganglion" AND "postdural puncture" OR "postdural puncture" OR "a headache". Additionally, a search was conducted using "clinical practice guidelines" OR "CPG" OR "treatment recommendations" OR "treatment guidelines" AND "postdural puncture headache" OR “postdural puncture headache” OR “PDPH”. Only original research studies, abstracts, and reports were selected, eliminating all other duplicate or editorial articles that were not directly reporting original study data or observations.

AGREE II CPG Scoring Assessment



Seven-Point AGREE II Score - Pre CPG Modification

Scoring is based on a scale of 1-7 (1 = worst score, 7 = best score)

Calculation for each domain is scored as follows: (Obtained score - Minimum possible score) / (Maximum possible score - Minimum possible score) X 100

Domain 1 - Scope and Purpose	Appraiser	#1	#2	Total
Q1. The overall objective(s) of the guideline is (are) specifically described.		6	5	11
Q2. The health question(s) covered by the guideline is (are) specifically described.		4	4	8
Q3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.		6	4	10
	Total	16	13	29
		Domain 1 Total Score		64%

Domain 2 - Stakeholder Involvement	Appraiser	#1	#2	Total
Q4. The guideline development group includes individuals from all the relevant professional groups.		4	3	7
Q5. The views and preferences of the target population (patients, public, etc.) have been sought.		4	3	7
Q6. The target users of the guideline are clearly defined.		6	2	8
	Total	14	8	22
		Domain 2 Total Score		44%

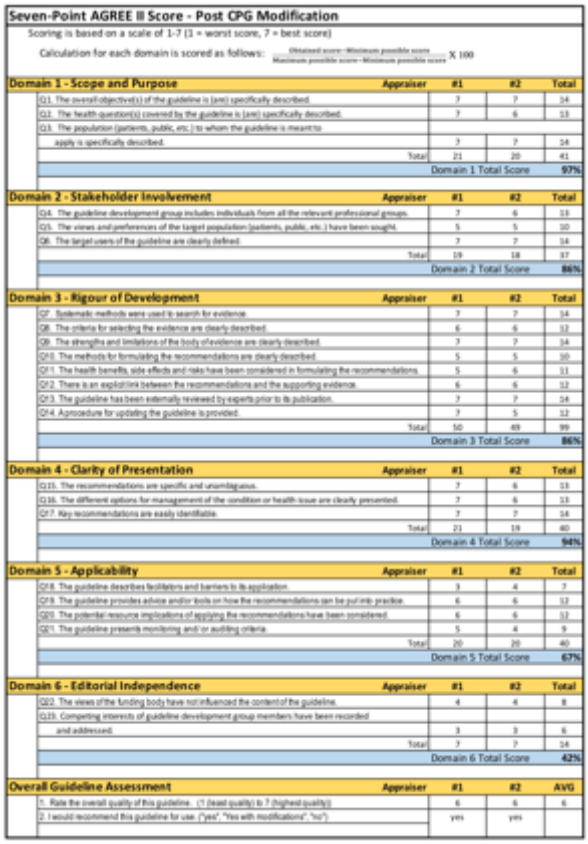
Domain 3 - Rigour of Development	Appraiser	#1	#2	Total
Q7. Systematic methods were used to search for evidence.		5	2	7
Q8. The criteria for selecting the evidence are clearly described.		2	2	4
Q9. The strengths and limitations of the body of evidence are clearly described.		6	3	9
Q10. The methods for formulating the recommendations are clearly described.		2	3	5
Q11. The health benefits, side effects and risks have been considered in formulating the recommendations.		5	5	10
Q12. There is an explicit link between the recommendations and the supporting evidence.		6	5	11
Q13. The guideline has been externally reviewed by experts prior to its publication.		7	7	14
Q14. A procedure for updating the guideline is provided.		1	2	3
	Total	34	29	63
		Domain 3 Total Score		49%

Domain 4 - Clarity of Presentation	Appraiser	#1	#2	Total
Q15. The recommendations are specific and unambiguous.		6	3	9
Q16. The different options for management of the condition or health issue are clearly presented.		7	7	14
Q17. Key recommendations are easily identifiable.		7	7	14
	Total	20	17	37
		Domain 4 Total Score		86%

Domain 5 - Applicability	Appraiser	#1	#2	Total
Q18. The guideline describes facilitators and barriers to its application.		2	3	5
Q19. The guideline provides advice and/or tools on how the recommendations can be put into practice.		5	5	10
Q20. The potential resource implications of applying the recommendations have been considered.		6	5	11
Q21. The guideline presents monitoring and/or auditing criteria.		2	6	8
	Total	15	19	34
		Domain 5 Total Score		54%

Domain 6 - Editorial Independence	Appraiser	#1	#2	Total
Q22. The views of the funding body have not influenced the content of the guideline.		4	4	8
Q23. Competing interests of guideline development group members have been recorded and addressed.		3	2	5
	Total	7	6	13
		Domain 6 Total Score		38%

Overall Guideline Assessment	Appraiser	#1	#2	AVG
1. Rate the overall quality of this guideline. (1 (least quality) to 7 (highest quality))		4	3	3.5
2. I would recommend this guideline for use. ("yes", "Yes with modifications", "no")		yes with modifications	yes with modifications	



Seven-Point AGREE II Score - Post CPG Modification

Scoring is based on a scale of 1-7 (1 = worst score, 7 = best score)

Calculation for each domain is scored as follows: (Obtained score - Minimum possible score) / (Maximum possible score - Minimum possible score) X 100

Domain 1 - Scope and Purpose	Appraiser	#1	#2	Total
Q1. The overall objective(s) of the guideline is (are) specifically described.		7	7	14
Q2. The health question(s) covered by the guideline is (are) specifically described.		7	6	13
Q3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.		7	7	14
	Total	21	20	41
		Domain 1 Total Score		97%

Domain 2 - Stakeholder Involvement	Appraiser	#1	#2	Total
Q4. The guideline development group includes individuals from all the relevant professional groups.		7	6	13
Q5. The views and preferences of the target population (patients, public, etc.) have been sought.		5	5	10
Q6. The target users of the guideline are clearly defined.		7	7	14
	Total	19	18	37
		Domain 2 Total Score		86%

Domain 3 - Rigour of Development	Appraiser	#1	#2	Total
Q7. Systematic methods were used to search for evidence.		7	7	14
Q8. The criteria for selecting the evidence are clearly described.		6	6	12
Q9. The strengths and limitations of the body of evidence are clearly described.		7	7	14
Q10. The methods for formulating the recommendations are clearly described.		5	5	10
Q11. The health benefits, side effects and risks have been considered in formulating the recommendations.		5	6	11
Q12. There is an explicit link between the recommendations and the supporting evidence.		6	6	12
Q13. The guideline has been externally reviewed by experts prior to its publication.		7	7	14
Q14. A procedure for updating the guideline is provided.		7	5	12
	Total	50	49	99
		Domain 3 Total Score		86%

Domain 4 - Clarity of Presentation	Appraiser	#1	#2	Total
Q15. The recommendations are specific and unambiguous.		7	6	13
Q16. The different options for management of the condition or health issue are clearly presented.		7	6	13
Q17. Key recommendations are easily identifiable.		7	7	14
	Total	21	19	40
		Domain 4 Total Score		94%

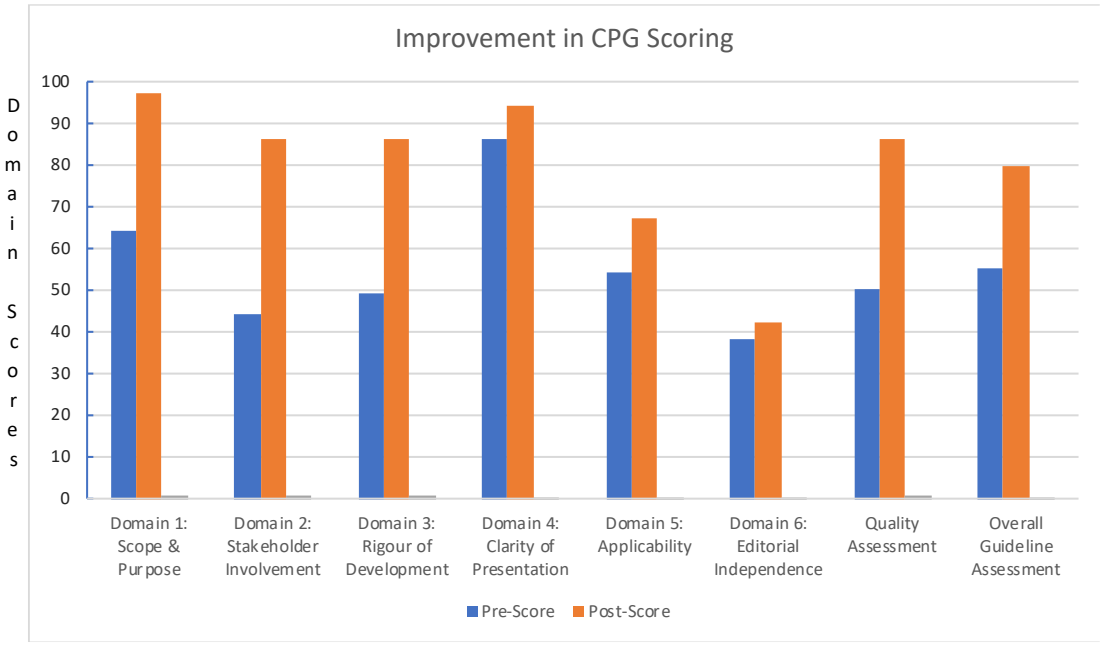
Domain 5 - Applicability	Appraiser	#1	#2	Total
Q18. The guideline describes facilitators and barriers to its application.		3	4	7
Q19. The guideline provides advice and/or tools on how the recommendations can be put into practice.		6	6	12
Q20. The potential resource implications of applying the recommendations have been considered.		6	6	12
Q21. The guideline presents monitoring and/or auditing criteria.		5	4	9
	Total	20	20	40
		Domain 5 Total Score		67%

Domain 6 - Editorial Independence	Appraiser	#1	#2	Total
Q22. The views of the funding body have not influenced the content of the guideline.		4	4	8
Q23. Competing interests of guideline development group members have been recorded and addressed.		3	3	6
	Total	7	7	14
		Domain 6 Total Score		42%

Overall Guideline Assessment	Appraiser	#1	#2	AVG
1. Rate the overall quality of this guideline. (1 (least quality) to 7 (highest quality))		6	6	6
2. I would recommend this guideline for use. ("yes", "Yes with modifications", "no")		yes	yes	

This CPG was scored by two anesthesia providers practicing at MVMC using the AGREE II CPG assessment tool. Six domains were evaluated, including Scope and Purpose,

Stakeholder Involvement, Rigour of Development, Clarity of Presentation, Applicability, Editorial Independence and Overall Guideline Assessment. In the two graphics above, both the original, unmodified NYSORA CPG (left graphic) and the post-modification CPG were graded using the AGREE II tool and scores can be compared between the pre and post CPG modification. Across all six domains and all 23 individuals, the post-modification scores have increased significantly, providing stakeholders at MVMC an improved and locally adapted CPG for the treatment of PDPH. The overall CPG score improved from 55% to 80% and four out of the six domains achieved the 70% quality threshold mark which was determined to be threshold as a quality domain. The graph below depicts a graphical representation of each of the six domains reflecting the improvement across each of these measurements.



Updating Procedure

To reflect current and emerging literature and research, the recommendations contained within this modified CPG will undergo periodic (every 3 to 5 year) review by key stakeholders at MVMC with input, as requested, from additional outside peers and experts.

Stakeholder Involvement

Stakeholders from Anesthesia Physicians of Arizona practicing at MVMC have participated in this CPG modification. Involvement included expert consultation and input on the CPG modification and grading of the CPG using the ARGEE II tool. This effort has been the product of a Doctor of Nursing Practice project, authored by Gregg Tidrick, SRNA from the University of Arizona College of Nursing / Anesthesia Specialty Program. Local participating

stakeholders from MVMC included Ned Sciortino MD, Craig Ryan, chief CRNA, Aaron Whitley, DNP, CRNA, Chad Boesl, CRNA and Ryan Wight, CRNA.

Facilitators/Barriers to Implementation

This CPG modification has been developed for implementation at Mountain Vista Medical Center. Stakeholders from the site have provided input and expert opinion aiding in the modification process improving the applicability for anesthesia providers practicing at MVMC. As part of this input and consideration, barriers and limitations to implementation have been considered, as have potential financial and familiarization of technique concerns.

Funding/Conflict of Interest

The modification of the NYSORA CPG for application at MVMC is part of an educational Doctor of Nursing Practice project and as such, there are no conflicts of interest or financial conflicts to disclose. The project was completed free of funding requirements and all participants did so on a volunteer basis.

Disclaimer

The information and recommendations presented in this CPG modification represent current literature and expert concensus opinion. As an anesthesia professional considering any of these recommendations or relying on data presented in this CPG modification are reminded to use professional independent judgement, consult reliable resources and, where appropriate, seek additional expert consultation.

REFERENCES

Burns, P., Rohrich, R., & Chung, K. (2011). The levels of evidence and their role in evidence-based medicine. *Plastic and Reconstructive Surgery*, *128*(1), 305-310.

Cady, R., Saper, J., Dexter, K., & Manley, H. (2014). A double-blind, placebo-controlled study of repetitive transnasal sphenopalatine ganglion blockade with Tx360® as an acute treatment for chronic migraine. *Headache: The Journal of Head and Face Pain*, *55*(1), 101-116.

Cardoso, J., Sá, M., Graça, R., Reis, H., Almeida, L., Pinheiro, C., & Machado, D. (2017). Sphenopalatine ganglion block for postdural puncture headache in ambulatory setting. *Brazilian Journal of Anesthesiology (English Edition)*, *67*(3), 311-313.

Channabasappa, S., Manjunath, S., Bommalingappa, B., Ramachandra, S., & Banuprakash, S. (2017). Transnasal sphenopalatine ganglion block for the treatment of postdural puncture headache following spinal anesthesia. *Saudi Journal of Anaesthesia*, *11*(3), 362.

Cohen, S., Trnovski, S., & Zada, Y. (2001). A new interest in an old remedy for headache and backache for our obstetric patients: A sphenopalatine ganglion block. *Anaesthesia, 56*(6), 606-607.

Cohen, S., Ramos, D., Grubb, W., Mellender, S., Mohiuddin, A., & Chiricolo, A. (2014). Sphenopalatine ganglion block. *Regional Anesthesia and Pain Medicine, 39*(6), 563.

Cohen, S., Sakr, A., Katyal, S., & Chopra, D. (2009). Sphenopalatine ganglion block for postdural puncture headache. *Anaesthesia*, *64*(5), 574-575.http://dx.doi.org/10.1111/j.1365-2044.2009.05925.x

Furtado, I., Lima, I., & Pedro, S. (2017). Ropivacaine use in transnasal Sphenopalatine ganglion block for post dural puncture headache in obstetric patients – case series. *Brazilian Journal of Anesthesiology (English Edition)*.

Kent, S., & Mehaffey, G. (2015). Transnasal sphenopalatine ganglion block for the treatment of postdural puncture headache in the ED. *The American Journal of Emergency Medicine*, *33*(11), 1714.e1-1714.e2.

Kent, S., & Mehaffey, G. (2016). Trans-nasal sphenopalatine ganglion block for the treatment of postdural puncture headache in obstetric patients. *Journal of Clinical Anesthesia, 34*, 194-196.

Patel, P., Zhao, R., Cohen, S., Mellender, S., Shah, S., & Grubb, W. (2016). Sphenopalatine ganglion block (SPGB) versus epidural blood patch for accidental postdural puncture headache (PDPH) in obstetric patients: A retrospective observation. *The American Academy of Pain Medicine*, *Abstract 145*, 1.

Rigdon, S (2017). Sphenopalatine Ganglion Block: Clinical Use and Placement [PowerPoint presentation]. Retrieved from http://ce2you.com/events/phoenix-usgra-and-vascular-access-workshop/

Schaffer, J., Hunter, B., Ball, K., & Weaver, C. (2015). Noninvasive sphenopalatine ganglion block for acute headache in the emergency department: A randomized placebo-controlled trial. *Annals of Emergency Medicine, 65*(5), 03-510.

APPENDIX C:

AGREE II SCORE SHEET

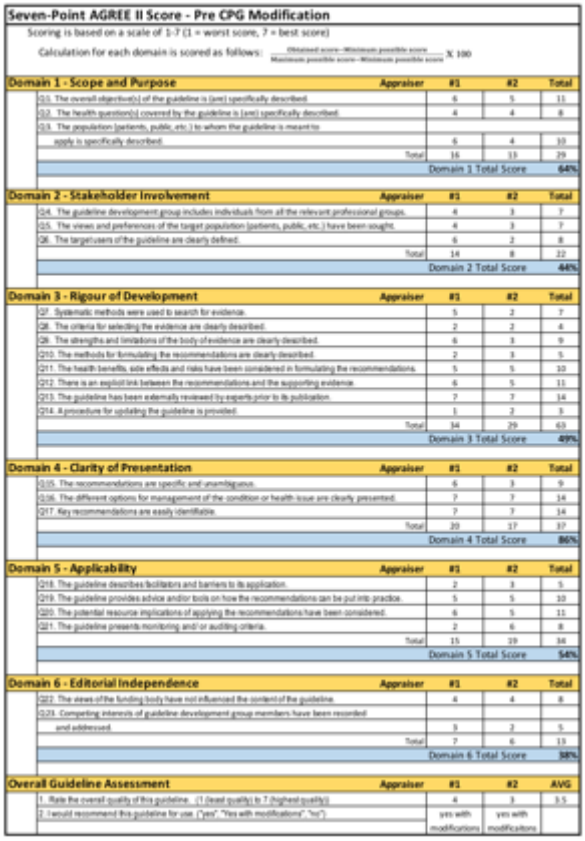
AGREE II Score Sheet

Domain	Item	AGREE II Rating 1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Scope and purpose	1. The overall objective(s) of the guideline is (are) specifically described.							
	2. The health question(s) covered by the guideline is (are) specifically described.							
	3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.							
Stakeholder involvement	4. The guideline development group includes individuals from all the relevant professional groups.							
	5. The views and preferences of the target population (patients, public, etc.) have been sought.							
	6. The target users of the guideline are clearly defined.							
Rigor of development	7. Systematic methods were used to search for evidence.							
	8. The criteria for selecting the evidence are clearly described.							
	9. The strengths and limitations of the body of evidence are clearly described.							
	10. The methods for formulating the recommendations are clearly described.							
	11. The health benefits, side effects and risks have been considered in formulating the recommendations.							
	12. There is an explicit link between the recommendations and the supporting evidence.							
	13. The guideline has been externally reviewed by experts prior to its publication.							
	14. A procedure for updating the guideline is provided.							
Clarity of presentation	15. The recommendations are specific and unambiguous.							
	16. The different options for management of the condition or health issue are clearly presented.							
	17. Key recommendations are easily identifiable.							
Applicability	18. The guideline describes facilitators and barriers to its application.							
	19. The guideline provides advice and/or tools on how the recommendations can be put into practice.							
	20. The potential resource implications of applying the recommendations have been considered.							
	21. The guideline presents monitoring and/or auditing criteria.							
Editorial independence	22. The views of the funding body have not influenced the content of the guideline.							
	23. Competing interests of guideline development group members have been recorded and addressed.							
Overall Guideline Assessment	1. Rate the overall quality of this guideline.	1 Lowest possible quality	2	3	4	5	6	7 Highest possible quality
Overall Guideline Assessment	2. I would recommend this guideline for use.	Yes		Yes, with modifications				No

APPENDIX D:

PRE- AND POST-CPG MODIFICATION AGREE II SCORES

PRE- AND POST-CPG MODIFICATION AGREE II SCORES



Seven-Point AGREE II Score - Pre CPG Modification

Scoring is based on a scale of 1-7 (1 = worst score, 7 = best score)

Calculation for each domain is scored as follows: $\frac{\text{Obtained score} - \text{Minimum possible score}}{\text{Maximum possible score} - \text{Minimum possible score}} \times 100$

Domain 1 - Scope and Purpose	Appraiser	#1	#2	Total
Q1. The overall objective(s) of the guideline is (are) specifically described.		6	5	11
Q2. The health question(s) covered by the guideline is (are) specifically described.		4	4	8
Q3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.		6	4	10
	Total	16	13	29
	Domain 1 Total Score			64%

Domain 2 - Stakeholder Involvement	Appraiser	#1	#2	Total
Q4. The guideline development group includes individuals from all the relevant professional groups.		4	3	7
Q5. The views and preferences of the target population (patients, public, etc.) have been sought.		4	3	7
Q6. The target users of the guideline are clearly defined.		6	2	8
	Total	14	8	22
	Domain 2 Total Score			44%

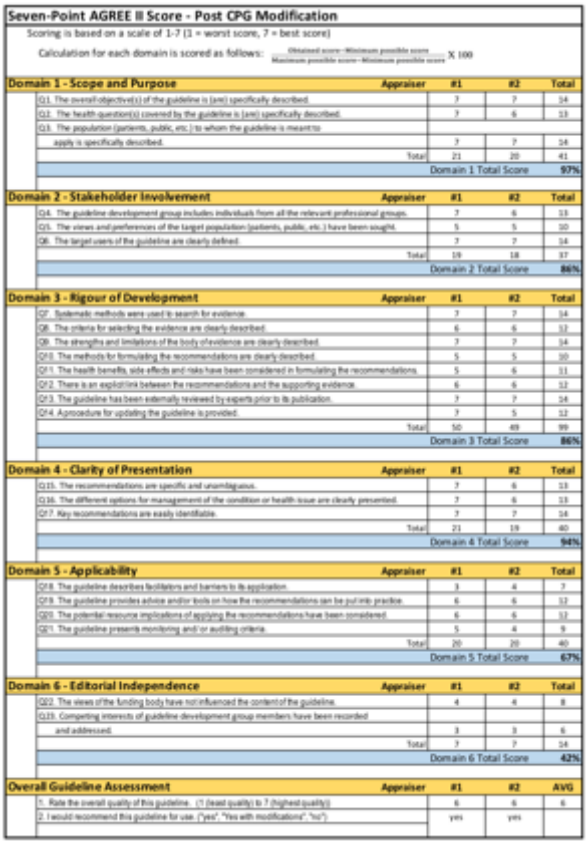
Domain 3 - Rigour of Development	Appraiser	#1	#2	Total
Q7. Systematic methods were used to search for evidence.		5	2	7
Q8. The criteria for selecting the evidence are clearly described.		2	2	4
Q9. The strengths and limitations of the body of evidence are clearly described.		6	3	9
Q10. The methods for formulating the recommendations are clearly described.		2	3	5
Q11. The health benefits, side effects and risks have been considered in formulating the recommendations.		5	5	10
Q12. There is an explicit link between the recommendations and the supporting evidence.		6	5	11
Q13. The guideline has been externally reviewed by experts prior to its publication.		7	7	14
Q14. A procedure for updating the guideline is provided.		1	2	3
	Total	34	29	63
	Domain 3 Total Score			49%

Domain 4 - Clarity of Presentation	Appraiser	#1	#2	Total
Q15. The recommendations are specific and unambiguous.		6	3	9
Q16. The different options for management of the condition or health issue are clearly presented.		7	7	14
Q17. Key recommendations are easily identifiable.		7	7	14
	Total	20	17	37
	Domain 4 Total Score			86%

Domain 5 - Applicability	Appraiser	#1	#2	Total
Q18. The guideline describes facilitators and barriers to its application.		2	3	5
Q19. The guideline provides advice and/or tools on how the recommendations can be put into practice.		5	5	10
Q20. The potential resource implications of applying the recommendations have been considered.		6	5	11
Q21. The guideline presents monitoring and/or auditing criteria.		2	6	8
	Total	15	19	34
	Domain 5 Total Score			54%

Domain 6 - Editorial Independence	Appraiser	#1	#2	Total
Q22. The views of the funding body have not influenced the content of the guideline.		4	4	8
Q23. Competing interests of guideline development group members have been recorded and addressed.		3	2	5
	Total	7	6	13
	Domain 6 Total Score			38%

Overall Guideline Assessment	Appraiser	#1	#2	AVG
1. Rate the overall quality of this guideline. (1 (least quality) to 7 (highest quality))		4	3	3.5
2. I would recommend this guideline for use. ("yes", "Yes with modifications", "no"):		yes with modifications	yes with modifications	



Seven-Point AGREE II Score - Post CPG Modification

Scoring is based on a scale of 1-7 (1 = worst score, 7 = best score)

Calculation for each domain is scored as follows: $\frac{\text{Obtained score} - \text{Minimum possible score}}{\text{Maximum possible score} - \text{Minimum possible score}} \times 100$

Domain 1 - Scope and Purpose	Appraiser	#1	#2	Total
Q1. The overall objective(s) of the guideline is (are) specifically described.		7	7	14
Q2. The health question(s) covered by the guideline is (are) specifically described.		7	6	13
Q3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.		7	7	14
	Total	21	20	41
	Domain 1 Total Score			97%

Domain 2 - Stakeholder Involvement	Appraiser	#1	#2	Total
Q4. The guideline development group includes individuals from all the relevant professional groups.		7	6	13
Q5. The views and preferences of the target population (patients, public, etc.) have been sought.		5	5	10
Q6. The target users of the guideline are clearly defined.		7	7	14
	Total	19	18	37
	Domain 2 Total Score			86%

Domain 3 - Rigour of Development	Appraiser	#1	#2	Total
Q7. Systematic methods were used to search for evidence.		7	7	14
Q8. The criteria for selecting the evidence are clearly described.		6	6	12
Q9. The strengths and limitations of the body of evidence are clearly described.		7	7	14
Q10. The methods for formulating the recommendations are clearly described.		5	5	10
Q11. The health benefits, side effects and risks have been considered in formulating the recommendations.		5	6	11
Q12. There is an explicit link between the recommendations and the supporting evidence.		6	6	12
Q13. The guideline has been externally reviewed by experts prior to its publication.		7	7	14
Q14. A procedure for updating the guideline is provided.		7	5	12
	Total	50	49	99
	Domain 3 Total Score			86%

Domain 4 - Clarity of Presentation	Appraiser	#1	#2	Total
Q15. The recommendations are specific and unambiguous.		7	6	13
Q16. The different options for management of the condition or health issue are clearly presented.		7	6	13
Q17. Key recommendations are easily identifiable.		7	7	14
	Total	21	19	40
	Domain 4 Total Score			94%

Domain 5 - Applicability	Appraiser	#1	#2	Total
Q18. The guideline describes facilitators and barriers to its application.		3	4	7
Q19. The guideline provides advice and/or tools on how the recommendations can be put into practice.		6	6	12
Q20. The potential resource implications of applying the recommendations have been considered.		6	6	12
Q21. The guideline presents monitoring and/or auditing criteria.		5	4	9
	Total	20	20	40
	Domain 5 Total Score			67%

Domain 6 - Editorial Independence	Appraiser	#1	#2	Total
Q22. The views of the funding body have not influenced the content of the guideline.		4	4	8
Q23. Competing interests of guideline development group members have been recorded and addressed.		3	3	6
	Total	7	7	14
	Domain 6 Total Score			42%

Overall Guideline Assessment	Appraiser	#1	#2	AVG
1. Rate the overall quality of this guideline. (1 (least quality) to 7 (highest quality))		6	6	6
2. I would recommend this guideline for use. ("yes", "Yes with modifications", "no"):		yes	yes	

This CPG was scored by two anesthesia providers practicing at the local facility using the AGREE II CPG assessment tool. Six domains were evaluated, including Scope and Purpose, Stakeholder Involvement, Rigour of Development, Clarity of Presentation, Applicability, Editorial Independence and Overall Guideline Assessment. In the two graphics above, both the original, unmodified NYSORA CPG (left graphic) and the post-modification CPG were graded using the AGREE II tool and scores can be compared between the pre- and post-CPG modification. Across all six domains and all twenty-three individuals, the post-modification scores have increased significantly, providing stakeholders at the local facility an improved and locally adapted CPG for the treatment of PDPH. The overall CPG score improved from 55% to 80% and four out of the six domains achieved the 70% quality threshold mark which was determined to be threshold as a quality domain.

APPENDIX E:

CONSULTANT INPUT

Treatment Options for Post-Dural Puncture Headache

Anesthesia Expert Consultation Data Collection

Name: Title: Date

Clinical Practice Guidelines (CPGs) for the treatment of PDPH, including that from NYSORA, provide numerous treatment modalities for treatment consideration. Of the following interventions, which four would you, based upon your clinical practice, professional experiences and expert opinion, would you be most likely to recommend trying (mark as a "+") and which four would you likely not recommend trying (mark as a "-") for patients experiencing post dural puncture headaches at Mountain Vista Medical Center in Mesa, AZ?

+ Bed rest in recumbent position

+ Hydration with IV or PO fluids

+ Use of aminophylline, theophylline or caffeine

__ Use of serotonin type 1d receptor agonist such as sumatriptan

__ Use of ergot alkaloid such as methylergonovine

__ Use of Corticosteroidogenics such as cosyntropin/tetracosactin

__ Use of Corticosteroids such as hydrocortisone

__ Use of anticonvulsants such as gabapentin

+ Application of a sphenopalantine ganglion nerve block

+ Epidural Blood Patch

Treatment Options for Post-Dural Puncture Headache

Anesthesia Expert Consultation Data Collection

Name: Title: Date

Clinical Practice Guidelines (CPGs) for the treatment of PDPH, including that from NYSORA, provide numerous treatment modalities for treatment consideration. Of the following interventions, which four would you, based upon your clinical practice, professional experiences and expert opinion, would you be most likely to recommend trying (mark as a "+") and which four would you likely not recommend trying (mark as a "-") for patients experiencing post-dural puncture headaches at Mountain Vista Medical Center in Mesa, AZ?

\+ Bed rest in recumbent position

\+ Hydration with IV or PO fluids

__ Use of aminophylline, theophylline or caffeine

__ Use of serotonin type 1d receptor agonist such as sumatriptan

__ Use of ergot alkaloid such as methylergonovine

__ Use of Corticosteroidogenics such as cosyntropin/tetracosactin

__ Use of Corticosteroids such as hydrocortisone

__ Use of anticonvulsants such as gabapentin

\+ Application of a sphenopalantine ganglion nerve block

\+ Epidural Blood Patch

Treatment Options for Post-Dural Puncture Headache

Anesthesia Expert Consultation Data Collection

Name: Title: Date

Clinical Practice Guidelines (CPGs) for the treatment of PDPH, including that from NYSORA, provide numerous treatment modalities for treatment consideration. Of the following interventions, which four would you, based upon your clinical practice, professional experiences and expert opinion, would you be most likely to recommend trying (mark as a "+") and which four would you likely not recommend trying (mark as a "-") for patients experiencing post-dural puncture headaches at Mountain Vista Medical Center in Mesa, AZ?

+ Bed rest in recumbent position

+ Hydration with IV or PO fluids

+ Use of aminophylline, theophylline or caffeine

− Use of serotonin type 1d receptor agonist such as sumatriptan

− Use of ergot alkaloid such as methylergonovine

− Use of Corticosteroidogenics such as cosyntropin/tetracosactin

+ Use of Corticosteroids such as hydrocortisone

+ Use of anticonvulsants such as gabapentin

+ Application of a sphenopalatine ganglion nerve block

+ Epidural Blood Patch

Treatment Options for Post-Dural Puncture Headache

Anesthesia Expert Consultation Data Collection

Name: Title: Date

Clinical Practice Guidelines (CPGs) for the treatment of PDPH, including that from *NYSORA*, provide numerous treatment modalities for treatment consideration. Of the following interventions, which four would you, based upon your clinical practice, professional experiences and expert opinion, would you be most likely to recommend trying (mark as a "+") and which four would you likely not recommend trying (mark as a "-") for patients experiencing post-dural puncture headaches at Mountain Vista Medical Center in Mesa, AZ?

\+ Bed rest in recumbent position

\+ Hydration with IV or PO fluids

\+ Use of aminophylline, theophylline or caffeine

\- Use of serotonin type 1d receptor agonist such as sumatriptan

\- Use of ergot alkaloid such as methylergonovine

\- Use of Corticosteroidogenics such as cosyntropin/tetracosactin

\- Use of Corticosteroids such as hydrocortisone

\- Use of anticonvulsants such as gabapentin

\+ Application of a sphenopalantine ganglion nerve block

\+ Epidural Blood Patch

APPENDIX F:

AGREE II PRE- AND POST-SCORE SHEETS

AGREE II Score Sheet (Pre CPG modification)

Completed by: Title: Date:

Domain	Item	AGREE II Rating 1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Scope and purpose	1. The overall objective(s) of the guideline is (are) specifically described.					✓		
	2. The health question(s) covered by the guideline is (are) specifically described.					✓		
	3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.						✓	
Stakeholder involvement	4. The guideline development group includes individuals from all the relevant professional groups.					✓		
	5. The views and preferences of the target population (patients, public, etc.) have been sought.				✓			
	6. The target users of the guideline are clearly defined.						✓	
Rigor of development	7. Systematic methods were used to search for evidence.						✓	
	8. The criteria for selecting the evidence are clearly described.					✓		
	9. The strengths and limitations of the body of evidence are clearly described.						✓	
	10. The methods for formulating the recommendations are clearly described.					✓		
	11. The health benefits, side effects and risks have been considered in formulating the recommendations.					✓		
	12. There is an explicit link between the recommendations and the supporting evidence.						✓	
	13. The guideline has been externally reviewed by experts prior to its publication.					✓		
	14. A procedure for updating the guideline is provided.	✓						
Clarity of presentation	15. The recommendations are specific and unambiguous.						✓	
	16. The different options for management of the condition or health issue are clearly presented.						✓	
	17. Key recommendations are easily identifiable.						✓	
Applicability	18. The guideline describes facilitators and barriers to its application.					✓		
	19. The guideline provides advice and/or tools on how the recommendations can be put into practice.				✓			
	20. The potential resource implications of applying the recommendations have been considered.				✓			
	21. The guideline presents monitoring and/or auditing criteria.		✓					
Editorial independence	22. The views of the funding body have not influenced the content of the guideline.				✓			
	23. Competing interests of guideline development group members have been recorded and addressed.				✓			
Overall Guideline Assessment	1. Rate the overall quality of this guideline.	1 Lowest possible quality	2	3	✓4	5	6	7 Highest possible quality
Overall Guideline Assessment	2. I would recommend this guideline for use.	Yes		Yes, with modifications ✓				No

AGREE II Score Sheet (Post CPG modification)

Completed by: Title: Date:

Domain	Item	AGREE II Rating 1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Scope and purpose	1. The overall objective(s) of the guideline is (are) specifically described.						✓	
	2. The health question(s) covered by the guideline is (are) specifically described.							✓
	3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.							✓
Stakeholder involvement	4. The guideline development group includes individuals from all the relevant professional groups.						✓	
	5. The views and preferences of the target population (patients, public, etc.) have been sought.				✓			
	6. The target users of the guideline are clearly defined.							✓
Rigor of development	7. Systematic methods were used to search for evidence.							✓
	8. The criteria for selecting the evidence are clearly described.					✓		
	9. The strengths and limitations of the body of evidence are clearly described.						✓	
	10. The methods for formulating the recommendations are clearly described.						✓	
	11. The health benefits, side effects and risks have been considered in formulating the recommendations.					✓		
	12. There is an explicit link between the recommendations and the supporting evidence.						✓	
	13. The guideline has been externally reviewed by experts prior to its publication.					✓		
	14. A procedure for updating the guideline is provided.	✓						
Clarity of presentation	15. The recommendations are specific and unambiguous.						✓	
	16. The different options for management of the condition or health issue are clearly presented.							✓
	17. Key recommendations are easily identifiable.							✓
Applicability	18. The guideline describes facilitators and barriers to its application.							✓
	19. The guideline provides advice and/or tools on how the recommendations can be put into practice.					✓		
	20. The potential resource implications of applying the recommendations have been considered.						✓	
	21. The guideline presents monitoring and/or auditing criteria.		✓					
Editorial independence	22. The views of the funding body have not influenced the content of the guideline.				✓			
	23. Competing interests of guideline development group members have been recorded and addressed.				✓			
Overall Guideline Assessment	1. Rate the overall quality of this guideline.	1 Lowest possible quality	2	3	4	5	6	7 Highest possible quality
Overall Guideline Assessment	2. I would recommend this guideline for use.	Yes ✓		Yes, with modifications				No

AGREE II Score Sheet (Pre CPG modification)

Completed by: Title: Date:

Domain	Item	AGREE II Rating 1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Scope and purpose	1. The overall objective(s) of the guideline is (are) specifically described.					X		
	2. The health question(s) covered by the guideline is (are) specifically described.					X		
	3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.							X
Stakeholder involvement	4. The guideline development group includes individuals from all the relevant professional groups.				X			
	5. The views and preferences of the target population (patients, public, etc.) have been sought.			X				
	6. The target users of the guideline are clearly defined.							X
Rigor of development	7. Systematic methods were used to search for evidence.							X
	8. The criteria for selecting the evidence are clearly described.					X		
	9. The strengths and limitations of the body of evidence are clearly described.					X		
	10. The methods for formulating the recommendations are clearly described.				X			
	11. The health benefits, side effects and risks have been considered in formulating the recommendations.						X	
	12. There is an explicit link between the recommendations and the supporting evidence.						X	
	13. The guideline has been externally reviewed by experts prior to its publication.						X	
	14. A procedure for updating the guideline is provided.			X				
Clarity of presentation	15. The recommendations are specific and unambiguous.						X	
	16. The different options for management of the condition or health issue are clearly presented.						X	
	17. Key recommendations are easily identifiable.						X	
Applicability	18. The guideline describes facilitators and barriers to its application.						X	
	19. The guideline provides advice and/or tools on how the recommendations can be put into practice.					X		
	20. The potential resource implications of applying the recommendations have been considered.					X		
	21. The guideline presents monitoring and/or auditing criteria.	X						
Editorial independence	22. The views of the funding body have not influenced the content of the guideline.				X			
	23. Competing interests of guideline development group members have been recorded and addressed.				X			
Overall Guideline Assessment	1. Rate the overall quality of this guideline.	1 Lowest possible quality	2	3	4	(5)	6	7 Highest possible quality
Overall Guideline Assessment	2. I would recommend this guideline for use.	Yes		Yes, with modifications				No
				X				

AGREE II Score Sheet (Post CPG modification)

Complete Title: Date:

Domain	Item	AGREE II Rating 1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree
Scope and purpose	1. The overall objective(s) of the guideline is (are) specifically described.							X
	2. The health question(s) covered by the guideline is (are) specifically described.							X
	3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.							X
Stakeholder involvement	4. The guideline development group includes individuals from all the relevant professional groups.						X	
	5. The views and preferences of the target population (patients, public, etc.) have been sought.			X				
	6. The target users of the guideline are clearly defined.							X
Rigor of development	7. Systematic methods were used to search for evidence.							X
	8. The criteria for selecting the evidence are clearly described.					X		
	9. The strengths and limitations of the body of evidence are clearly described.					X		
	10. The methods for formulating the recommendations are clearly described.					X		
	11. The health benefits, side effects and risks have been considered in formulating the recommendations.							X
	12. There is an explicit link between the recommendations and the supporting evidence.						X	
	13. The guideline has been externally reviewed by experts prior to its publication.							X
	14. A procedure for updating the guideline is provided.							X
Clarity of presentation	15. The recommendations are specific and unambiguous.							X
	16. The different options for management of the condition or health issue are clearly presented.							X
	17. Key recommendations are easily identifiable.							X
Applicability	18. The guideline describes facilitators and barriers to its application.							X
	19. The guideline provides advice and/or tools on how the recommendations can be put into practice.						X	
	20. The potential resource implications of applying the recommendations have been considered.						X	
	21. The guideline presents monitoring and/or auditing criteria.	X						
Editorial independence	22. The views of the funding body have not influenced the content of the guideline.				X			
	23. Competing interests of guideline development group members have been recorded and addressed.				X			
Overall Guideline Assessment	1. Rate the overall quality of this guideline.	1 Lowest possible quality	2	3	4	5	6	7 Highest possible quality
Overall Guideline Assessment	2. I would recommend this guideline for use.	Yes		Yes, with modifications				No
		X						

APPENDIX G:

AGREE II APPRAISER TRAINING CONFIRMATION

AGREE II Appraiser Training Confirmation

I have completed the online AGREE II Overview Tutorial and received a copy of the AGREE II Instrument, which includes the user's manual with instruction for completion of the clinical practice guideline evaluation. Additionally, I have been provided the AGREE II Practice Exercise and understand it is recommended to improve standardization of scoring.

Signature removed

10/3/18
Date

AGREE II Appraiser Training Confirmation

I have completed the online AGREE II Overview Tutorial and received a copy of the AGREE II Instrument, which includes the user's manual with instruction for completion of the clinical practice guideline evaluation. Additionally, I have been provided the AGREE II Practice Exercise and understand it is recommended to improve standardization of scoring.

Signature removed

9/17/18
Date

APPENDIX H:

SITE APPROVAL LETTER

Anesthesia Physicians of Arizona
1301 South Crimson Road
Mesa, AZ 85209

June 9, 2018

University of Arizona Institutional Review Board
c/o Office of Human Subjects
1618 E Helen St
Tucson, AZ 85721

Please note that Mr. Gregg Tidrick, UA Doctor of Nursing Practice student, has permission of Anesthesia Physicians of Arizona to conduct an evidence-based project at our facility for his project, "Modification of a clinical practice guideline for the treatment of post-dural puncture headaches to include sphenopalantine ganglion nerve block."

Mr. Tidrick will modify a clinical practice guideline (CPG) with the input, in part, of a CRNA from one of our primary practice sites, Mountain Vista Medical Center. The CRNA will provide expert opinion and valuable organizational insight. This will include communications conducted off site as agreed upon from both parties. Mr. Tidrick's activities will be completed by December 31, 2018.

Mr. Tidrick has agreed to provide and present the final modified CPG and evaluation results upon his completion to the anesthesia stakeholders of Anesthesia Physicians of Arizona.

If there are any questions, please contact my office.

Signed,

Dr. Ned Sciortino
Medical Director of Anesthesia

V 2018-01

APPENDIX I:

STAKEHOLDER FEEDBACK FORM

Stakeholder Feedback on Revised CPG for treatment of PDPH at [redacted]

Type of anesthesia provider:			Years practiced in current role:					
☐ SRNA	☐ CRNA	☑ Physician	☐ <5	☐ 5-10	☑ 11-15	☐ 16-20	☐ 21-25	☐ 25+

1. Are you responsible for the care of patients for whom this draft guideline report is relevant? This may include the referral, diagnosis, treatment, or follow-up of patients.	Yes ☑	No ☐	Unsure ☐

If you answered "*No*" or "*Unsure*", there is no need to answer or return this questionnaire. If you answered "*Yes*", please answer the questions below and return to Gregg Tidrick SRNA

	Strongly agree	Neither agree or disagree	Strongly disagree
2. The rationale for developing a guideline is clear.	☑	☐	☐
3. There is a need for a guideline on this topic.	☑	☐	☐
4. The literature search is relevant and complete (e.g., no key evidence was missed nor any included that should not have been) in this draft guideline.	☑	☐	☐
5. I agree with the methodology used to summarize the evidence included in this draft guideline.	☑	☐	☐
6. The results of the evidence described in this draft guideline are interpreted according to my understanding of the evidence.	☑	☐	☐
7. The draft recommendations in this report are clear.	☑	☐	☐
8. I agree with the draft recommendations as stated.	☑	☐	☐
9. The draft recommendations are suitable for the patients for whom they are intended.	☑	☐	☐
10. The draft recommendations are too rigid to apply to individual patients.	☐	☑	☐
11. When applied, the draft recommendations will produce more benefits for patients than harms.	☑	☐	☐
12. The draft guideline presents options that will be acceptable to patients.	☑	☐	☐
13. To apply the draft recommendations will require reorganization of services/care in my practice setting.	☐	☑	☐
14. To apply the draft guideline recommendations will be technically challenging.	☐	☐	☑
15. The draft guideline recommendations are too expensive to apply.	☐	☐	☑
16. The draft guideline recommendations are likely to be supported by a majority of my colleagues.	☑	☐	☐
17. If I follow the draft guideline recommendations, the expected effects on patient outcomes will be obvious.	☐	☑	☐
18. The draft guideline recommendations reflect a more effective approach for improving patient outcomes than is current usual practice. (If they are the same as current practice, please tick NA). *NA* ☐	☐	☑	☐
19. When applied, the draft guideline recommendations will result in better use of resources than current usual practice. (If they are the same as current practice, please tick NA). *NA* ☐	☐	☑	☐
20. I would feel comfortable if my patients received the care recommended in the draft guideline.	☑	☐	☐
21. This draft guideline should be approved as a practice guideline.	☑	☐	☐
22. If this draft guideline were to be approved as a practice guideline, I would use it in my own practice.	☑	☐	☐
23. If this draft guideline were to be approved as a practice guideline, I would apply the recommendations to my patients.	☑	☐	☐

Adapted From: Brouwers M, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, Fervers B, Graham ID, Grimshaw J, Hanna S, Littlejohns P, Makarski J, Zitzelsberger L for the AGREE Next Steps Consortium. AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *Can Med Assoc J. 2010*. Available online May 31, 2018. doi:10.1503/cmaj.090449

Stakeholder Feedback on Revised CPG for treatment of PDPH at [redacted]

Type of anesthesia provider:			Years practiced in current role:					
☐ SRNA	☒ CRNA	☐ Physician	☐ <5	☐ 5-10	☐ 11-15	☒ 16-20	☐ 21-25	☐ 25+

1. Are you responsible for the care of patients for whom this draft guideline report is relevant? This may include the referral, diagnosis, treatment, or follow-up of patients.	Yes ☒	No ☐	Unsure ☐
If you answered "*No*" or "*Unsure*", there is no need to answer or return this questionnaire. If you answered "*Yes*", please answer the questions below and return to Gregg Tidrick SRNA			
	Strongly agree	Neither agree or disagree	Strongly disagree
2. The rationale for developing a guideline is clear.	☒	☐	☐
3. There is a need for a guideline on this topic.	☒	☐	☐
4. The literature search is relevant and complete (e.g., no key evidence was missed nor any included that should not have been) in this draft guideline.	☒	☐	☐
5. I agree with the methodology used to summarize the evidence included in this draft guideline.	☒	☐	☐
6. The results of the evidence described in this draft guideline are interpreted according to my understanding of the evidence.	☒	☐	☐
7. The draft recommendations in this report are clear.	☒	☐	☐
8. I agree with the draft recommendations as stated.	☒	☐	☐
9. The draft recommendations are suitable for the patients for whom they are intended.	☒	☐	☐
10. The draft recommendations are too rigid to apply to individual patients.	☐	☐	☒
11. When applied, the draft recommendations will produce more benefits for patients than harms.	☒	☐	☐
12. The draft guideline presents options that will be acceptable to patients.	☒	☐	☐
13. To apply the draft recommendations will require reorganization of services/care in my practice setting.	☐	☒	☐
14. To apply the draft guideline recommendations will be technically challenging.	☐	☒	☐
15. The draft guideline recommendations are too expensive to apply.	☐	☒	☐
16. The draft guideline recommendations are likely to be supported by a majority of my colleagues.	☒	☐	☐
17. If I follow the draft guideline recommendations, the expected effects on patient outcomes will be obvious.	☐	☒	☐
18. The draft guideline recommendations reflect a more effective approach for improving patient outcomes than is current usual practice. (If they are the same as current practice, please tick NA). *NA* ☒	☐	☐	☐
19. When applied, the draft guideline recommendations will result in better use of resources than current usual practice. (If they are the same as current practice, please tick NA). *NA* ☒	☐	☐	☐
20. I would feel comfortable if my patients received the care recommended in the draft guideline.	☒	☐	☐
21. This draft guideline should be approved as a practice guideline.	☒	☐	☐
22. If this draft guideline were to be approved as a practice guideline, I would use it in my own practice.	☒	☐	☐
23. If this draft guideline were to be approved as a practice guideline, I would apply the recommendations to my patients.	☒	☐	☐

Adapted From: Brouwers M, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, Fervers B, Graham ID, Grimshaw J, Hanna S, Littlejohns P, Makarski J, Zitzelsberger L, for the AGREE Next Steps Consortium. AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *Can Med Assoc J. 2016.* Available online May 31, 2018. doi:10.1503/cmaj.090449

APPENDIX J:

AGREE II REPORTING CHECKLIST

AGREE Reporting Checklist
2016

This checklist is intended to guide the reporting of clinical practice guidelines.

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
DOMAIN 1: SCOPE AND PURPOSE		
1. OBJECTIVES *Report the overall objective(s) of the guideline. The expected health benefits from the guideline are to be specific to the clinical problem or health topic.*	☐ Health intent(s) (i.e., prevention, screening, diagnosis, treatment, etc.) ☐ Expected benefit(s) or outcome(s) ☐ Target(s) (e.g., patient population, society)	
2. QUESTIONS *Report the health question(s) covered by the guideline, particularly for the key recommendations.*	☐ Target population ☐ Intervention(s) or exposure(s) ☐ Comparisons (if appropriate) ☐ Outcome(s) ☐ Health care setting or context	
3. POPULATION *Describe the population (i.e., patients, public, etc.) to whom the guideline is meant to apply.*	☐ Target population, sex and age ☐ Clinical condition (if relevant) ☐ Severity/stage of disease (if relevant) ☐ Comorbidities (if relevant) ☐ Excluded populations (if relevant)	
DOMAIN 2: STAKEHOLDER INVOLVEMENT		
4. GROUP MEMBERSHIP *Report all individuals who were involved in the development process. This may include members of the steering group, the research team involved in selecting and reviewing/rating the evidence and individuals involved in formulating the final recommendations.*	☐ Name of participant ☐ Discipline/content expertise (e.g., neurosurgeon, methodologist) ☐ Institution (e.g., St. Peter's hospital) ☐ Geographical location (e.g., Seattle, WA) ☐ A description of the member's role in the guideline development group	
5. TARGET POPULATION PREFERENCES AND VIEWS *Report how the views and preferences of the target population were sought/considered and what the resulting outcomes were.*	☐ Statement of type of strategy used to capture patients'/publics' views and preferences (e.g., participation in the guideline development group, literature review of values and preferences) ☐ Methods by which preferences and views were sought (e.g., evidence from literature, surveys, focus groups) ☐ Outcomes/information gathered on patient/public information ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	
6. TARGET USERS *Report the target (or intended) users of the guideline.*	☐ The intended guideline audience (e.g. specialists, family physicians, patients, clinical or institutional leaders/administrators) ☐ How the guideline may be used by its target audience (e.g., to inform clinical decisions, to inform policy, to inform standards of care)	

DOMAIN 3: RIGOUR OF DEVELOPMENT		
7. SEARCH METHODS *Report details of the strategy used to search for evidence.*	☐ Named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, PsychINFO, CINAHL) ☐ Time periods searched (e.g., January 1, 2004 to March 31, 2008) ☐ Search terms used (e.g., text words, indexing terms, subheadings) ☐ Full search strategy included (e.g., possibly located in appendix)	
8. EVIDENCE SELECTION CRITERIA *Report the criteria used to select (i.e., include and exclude) the evidence. Provide rationale, where appropriate.*	☐ Target population (patient, public, etc.) characteristics ☐ Study design ☐ Comparisons (if relevant) ☐ Outcomes ☐ Language (if relevant) ☐ Context (if relevant)	
9. STRENGTHS & LIMITATIONS OF THE EVIDENCE *Describe the strengths and limitations of the evidence. Consider from the perspective of the individual studies and the body of evidence aggregated across all the studies. Tools exist that can facilitate the reporting of this concept.*	☐ Study design(s) included in body of evidence ☐ Study methodology limitations (sampling, blinding, allocation concealment, analytical methods) ☐ Appropriateness/relevance of primary and secondary outcomes considered ☐ Consistency of results across studies ☐ Direction of results across studies ☐ Magnitude of benefit versus magnitude of harm ☐ Applicability to practice context	
10. FORMULATION OF RECOMMENDATIONS *Describe the methods used to formulate the recommendations and how final decisions were reached. Specify any areas of disagreement and the methods used to resolve them.*	☐ Recommendation development process (e.g., steps used in modified Delphi technique, voting procedures that were considered) ☐ Outcomes of the recommendation development process (e.g., extent to which consensus was reached using modified Delphi technique, outcome of voting procedures) ☐ How the process influenced the recommendations (e.g., results of Delphi technique influence final recommendation, alignment with recommendations and the final vote)	
11. CONSIDERATION OF BENEFITS AND HARMS *Report the health benefits, side effects, and risks that were considered when formulating the recommendations.*	☐ Supporting data and report of benefits ☐ Supporting data and report of harms/side effects/risks ☐ Reporting of the balance/trade-off between benefits and harms/side effects/risks ☐ Recommendations reflect considerations of both benefits and harms/side effects/risks	
12. LINK BETWEEN RECOMMENDATIONS AND EVIDENCE *Describe the explicit link between the recommendations and the evidence on which they are based.*	☐ How the guideline development group linked and used the evidence to inform recommendations ☐ Link between each recommendation and key evidence (text description and/or reference list) ☐ Link between recommendations and evidence summaries and/or evidence tables in the results section of the guideline	

13. EXTERNAL REVIEW *Report the methodology used to conduct the external review.*	☐ Purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence) ☐ Methods taken to undertake the external review (e.g., rating scale, open-ended questions) ☐ Description of the external reviewers (e.g., number, type of reviewers, affiliations) ☐ Outcomes/information gathered from the external review (e.g., summary of key findings) ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations (e.g., guideline panel considered results of review in forming final recommendations)	
14. UPDATING PROCEDURE *Describe the procedure for updating the guideline.*	☐ A statement that the guideline will be updated ☐ Explicit time interval or explicit criteria to guide decisions about when an update will occur ☐ Methodology for the updating procedure	
DOMAIN 4: CLARITY OF PRESENTATION		
15. SPECIFIC AND UNAMBIGUOUS RECOMMENDATIONS *Describe which options are appropriate in which situations and in which population groups, as informed by the body of evidence.*	☐ A statement of the recommended action ☐ Intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects) ☐ Relevant population (e.g., patients, public) ☐ Caveats or qualifying statements, if relevant (e.g., patients or conditions for whom the recommendations would not apply) ☐ If there is uncertainty about the best care option(s), the uncertainty should be stated in the guideline	
16. MANAGEMENT OPTIONS *Describe the different options for managing the condition or health issue.*	☐ Description of management options ☐ Population or clinical situation most appropriate to each option	
17. IDENTIFIABLE KEY RECOMMENDATIONS *Present the key recommendations so that they are easy to identify.*	☐ Recommendations in a summarized box, typed in bold, underlined, or presented as flow charts or algorithms ☐ Specific recommendations grouped together in one section	
DOMAIN 5: APPLICABILITY		
18. FACILITATORS AND BARRIERS TO APPLICATION *Describe the facilitators and barriers to the guideline's application.*	☐ Types of facilitators and barriers that were considered ☐ Methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation) ☐ Information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the	

	population receive mammography) ☐ How the information influenced the guideline development process and/or formation of the recommendations	
19. IMPLEMENTATION ADVICE/TOOLS *Provide advice and/or tools on how the recommendations can be applied in practice.*	☐ Additional materials to support the implementation of the guideline in practice. For example: ▫ Guideline summary documents ▫ Links to check lists, algorithms ▫ Links to how-to manuals ▫ Solutions linked to barrier analysis (see Item 18) ▫ Tools to capitalize on guideline facilitators (see Item 18) ▫ Outcome of pilot test and lessons learned	
20. RESOURCE IMPLICATIONS *Describe any potential resource implications of applying the recommendations.*	☐ Types of cost information that were considered (e.g., economic evaluations, drug acquisition costs) ☐ Methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.) ☐ Information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course) ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	
21. MONITORING/ AUDITING CRITERIA *Provide monitoring and/or auditing criteria to measure the application of guideline recommendations.*	☐ Criteria to assess guideline implementation or adherence to recommendations ☐ Criteria for assessing impact of implementing the recommendations ☐ Advice on the frequency and interval of measurement ☐ Operational definitions of how the criteria should be measured	
DOMAIN 6: EDITORIAL INDEPENDENCE		
22. FUNDING BODY *Report the funding body's influence on the content of the guideline.*	☐ The name of the funding body or source of funding (or explicit statement of no funding) ☐ A statement that the funding body did not influence the content of the guideline	
23. COMPETING INTERESTS *Provide an explicit statement that all group members have declared whether they have any competing interests.*	☐ Types of competing interests considered ☐ Methods by which potential competing interests were sought ☐ A description of the competing interests ☐ How the competing interests influenced the guideline process and development of recommendations	

APPENDIX K:

THE UNIVERSITY OF ARIZONA INSTITUTIONAL REVIEW BOARD (IRB) DETERMINATION OF HUMAN RESEARCH

THE UNIVERSITY OF ARIZONA
Research, Discovery & Innovation

Human Subjects Protection Program

1618 E. Helen St.
P.O.Box 245137
Tucson, AZ 85724-5137
Tel: (520) 626-6721
http://rgw.arizona.edu/compliance/home

Date:	September 13, 2018
Principal Investigator:	Gregg Alan Tidrick
Protocol Number:	1809921971
Protocol Title:	MODIFICATION OF A CLINICAL PRACTICE GUIDELINE FOR THE TREATMENT OF POST-DURAL PUNCTURE HEADACHES TO INCLUDE SPHENOPALATINE GANGLION NERVE BLOCK
Determination:	Human Subjects Review not Required

Documents Reviewed Concurrently:

Data Collection Tools: *AGREE II SCORE SHEET.DOCX*
Data Collection Tools: *Practicioner Feedback Questionnaire.docx*
HSPP Forms/Correspondence: *Advisor Confirmation Email.pdf*
HSPP Forms/Correspondence: *Determination of Human Research_Tidrick_v3.pdf*
Other: *AGREE II Appraiser Training Confirmation.docx*
Other: *Clinical Practice Guideline.docx*
Other Approvals and Authorizations: *Site Authorization Letter.docx*
Recruitment Material: *E-mail- AGREE Assessment Template.doc*
Recruitment Material: *E-mail- Expert Consultation Template.doc*

Regulatory Determinations/Comments:

- Not Human Subjects Research as defined by 45 CFR 46.102(f): as presented, the activities described above do not meet the definition of research involving human subjects as cited in the regulations issued by the U.S. Department of Health and Human Services which state that "human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information."

The project listed above does not require oversight by the University of Arizona.

If the nature of the project changes, submit a new determination form to the Human Subjects Protection Program (HSPP) for reassessment. Changes include addition of research with children, specimen collection, participant observation, prospective collection of data when the study was previously retrospective in nature, and broadening the scope or nature of the study activity. Please contact the HSPP to consult on whether the proposed changes need further review.

The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).

REFERENCES

45 CFR 46 – Protection of Human Subjects. (2018). Gpo.gov. Retrieved 19 April 2018 from https://www.gpo.gov/fdsys/granule/CFR-2000-title45-vol1/CFR-2000-title45-vol1-part46

American Association of Colleges of Nursing. (2006). *The essentials of doctoral education for advanced practice nursing*. Washington, DC: Author.

Baysinger, C., Pope, J., Lockhart, E., & Mercaldo, N. (2011). The management of accidental dural puncture and postdural puncture headache: A north American survey. *Journal of Clinical Anesthesia*, *23*(5), 349-360. http://dx.doi.org/10.1016/j.jclinane.2011.04.003

Bezov, D., Ashina, S., & Lipton, R. (2010). Postdural puncture headache: Part II – prevention, management, and prognosis. *Headache: The Journal of Head and Face Pain*, *50*(9), 1482-1498. http://dx.doi.org/10.1111/j.1526-4610.2010.01758.x

Brouwers, M., Kho, M., Browman, G., Burgers, J., Cluzeau, F., & Feder, G. et al. (2010). AGREE II: Advancing guideline development, reporting and evaluation in health care. *Canadian Medical Association Journal*, *182*(18), E839-E842. doi:10.1503/cmaj.090449

Burnes, B. (2004). Kurt Lewin and the planned approach to change: A re-appraisal. *Journal of Management Studies*, *41*(6), 977-1002

Burnes, B. & Bargal, D. (2017). Kurt Lewin: 70 years on. *Journal of Change Management*, *17*(2), 91-100.

Burns, P., Rohrich, R., & Chung, K. (2011). The levels of evidence and their role in evidence-based medicine. *Plastic and Reconstructive Surgery*, *128*(1), 305-310.

Cady, R., Saper, J., Dexter, K., & Manley, H. (2014). A double-blind, placebo-controlled study of repetitive transnasal sphenopalatine ganglion blockade with Tx360® as an acute treatment for chronic migraine. *Headache: The Journal of Head and Face Pain*, *55*(1), 101-116.

Cardoso, J., Sá, M., Graça, R., Reis, H., Almeida, L., Pinheiro, C., & Machado, D. (2017). Sphenopalatine ganglion block for postdural puncture headache in ambulatory setting. *Brazilian Journal of Anesthesiology (English Edition)*, *67*(3), 311-313.

Channabasappa, S., Manjunath, S., Bommalingappa, B., Ramachandra, S., & Banuprakash, S. (2017). Transnasal sphenopalatine ganglion block for the treatment of postdural puncture headache following spinal anesthesia. *Saudi Journal of Anaesthesia*, *11*(3), 362.

Cohen, S., Trnovski, S., & Zada, Y. (2001). A new interest in an old remedy for headache and backache for our obstetric patients: A sphenopalatine ganglion block. *Anaesthesia*, *56*(6), 606-607.

Cohen, S., Ramos, D., Grubb, W., Mellender, S., Mohiuddin, A., & Chiricolo, A. (2014). Sphenopalatine ganglion block. *Regional Anesthesia and Pain Medicine*, *39*(6), 563.

Cohen, S., Sakr, A., Katyal, S., & Chopra, D. (2009). Sphenopalatine ganglion block for postdural puncture headache. *Anaesthesia*, *64*(5), 574-575. http://dx.doi.org/10.1111/j.1365-2044.2009.05925.x

Consent Templates | Research Gateway. (2018). Rgw.arizona.edu. Retrieved 19 April 2018 from https://rgw.arizona.edu/compliance/human-subjects-protection-program/HSPP-forms/consent-templates

Eccles, M. P., Foy, R., Sales, A., Wensing, M., & Mittman, B. (2012). Implementation science: Six years on our evolving scope and common reasons for rejection without review. *Implementation Science*, *7*, 1.

Fulkerson, J. (2017). A noninvasive treatment for postdural puncture headache. *CRNA Today E-Journal*, *2*(7), 3-8.

Furtado, I., Lima, I., & Pedro, S. (2017). Ropivacaine use in transnasal sphenopalatine ganglion block for postdural puncture headache in obstetric patients – case series. *Brazilian Journal of Anesthesiology (English Edition)*.

Gaiser, R. (2017). Postdural puncture headache. *Anesthesiology Clinics*, *35*(1), 157-167. http://dx.doi.org/10.1016/j.anclin.2016.09.013

Gharaei, H., & Nabi, B. (2015). Sphenopalatine ganglion block: A jack of all trades block. *Journal of Anesthesia & Critical Care: Open Access, 3*(2). doi:10.15406/jaccoa.2015.03.00091

Grimshaw, J. M., Eccles, M. P., Lavis, J. N., Hill, S. J., & Squires, J. E. (2012). Knowledge translation of research findings. *Implementation Science*, *7*(1), 1.

Harrington, B. E. & Reina, M. A. (2019). Postdural puncture headache - NYSORA. Retrieved February 17, 2019 from https://www.nysora.com/foundations-of-regional-anesthesia/complications/postdural-puncture-headache/

Higgs, J., Burn, A., & Jones, M. (2001). Integrating clinical reasoning and evidence-based practice. *AACN Clinical Issues: Advanced Practice in Acute and Critical Care*, *12*(4), 482-490. http://dx.doi.org/10.1097/00044067-200111000-00005

Jones, J., Stewart, W., Darer, J., & Sittig, D. (2013). Beyond the threshold: Real-time use of evidence in practice. *BMC Medical Informatics and Decision Making*, *13*(1), 121-127.

Kent, S. & Mehaffey, G. (2015). Transnasal sphenopalatine ganglion block for the treatment of postdural puncture headache in the ED. *The American Journal of Emergency Medicine*, *33*(11), 1714.e1-1714.e2.

Kent, S. & Mehaffey, G. (2016). Trans-nasal sphenopalatine ganglion block for the treatment of postdural puncture headache in obstetric patients. *Journal of Clinical Anesthesia, 34*, 194-196.

Kwak, K. (2017). Postdural puncture headache. *Korean Journal of Anesthesiology, 70*(2), 136.

Marshall, E. & Broome, M. (2016). *Transformational leadership in nursing*, (2nd ed). New York, NY: Springer Publishing Company.

Mitchell, G. (2013). Selecting the best theory to implement planned change: Improving the workplace requires staff to be involved and innovations to be maintained: Gary Mitchell discusses the theories that can help achieve this. *Nursing Management*, *20*(1), 32-37.

Morris, Z. S., Wooding, S., & Grant, J. (2011). The answer is 17 years, what is the question: Understanding time lags in translational research. *Journal of the Royal Society of Medicine, 104*, 510-520.

Murad, M. (2017). Clinical practice guidelines. *Mayo Clinic Proceedings*, *92*(3), 423-433. http://dx.doi.org/10.1016/j.mayocp.2017.01.001

Nguyen, D. & Walters, R. (2014). Standardizing management of postdural puncture headache in obstetric patients: A literature review. *Open Journal of Anesthesiology*, *04*(10), 244-253.

Patel, P., Zhao, R., Cohen, S., Mellender, S., Shah, S., & Grubb, W. (2016). Sphenopalatine ganglion block (SPGB) versus epidural blood patch for accidental postdural puncture headache (PDPH) in obstetric patients: A retrospective observation. *The American Academy of Pain Medicine, Abstract 145*, 1.

Puledda, F., & Goadsby, P. (2016). Current approaches to neuromodulation in primary headaches: Focus on vagal nerve and sphenopalatine ganglion stimulation. *Current Pain and Headache Reports*, *20*(7). http://dx.doi.org/10.1007/s11916-16-0577-5

Robbins, M., Robertson, C., Kaplan, E., Ailani, J., Charleston, L., & Kuruvilla, D. et al. (2015). The sphenopalatine ganglion: Anatomy, pathophysiology, and therapeutic targeting in headache. *Headache: The Journal of Head and Face Pain*, *56*(2), 240-258. http://dx.doi.org/10.1111/head.12729

Schaffer, J., Hunter, B., Ball, K., & Weaver, C. (2015). Noninvasive sphenopalatine ganglion block for acute headache in the emergency department: A randomized placebo-controlled trial. *Annals of Emergency Medicine*, *65*(5), 03-510.

The International Classification of Headache Disorders, 3rd edition (beta version). (2013). *Cephalalgia*, *33*(9), 629-808. http://dx.doi.org/10.1177/0333102413485658

Waldman, S. (1993). Sphenopalatine ganglion block—80 years later. *Regional Anesthesia*, *18*(5), 274.