Southern California CSU DNP Consortium
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TRACKING AND MANAGEMENT OF POST-DURAL PUNCTURE HEADACHE

A DOCTORAL PROJECT
Submitted in Partial Fulfillment of the Requirements
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DOCTOR OF NURSING PRACTICE

By

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ABSTRACT

Post-dural puncture headache (PDPH) can occur with neuraxial procedures commonly used in obstetric anesthesia and analgesia. Both spinal and epidural analgesia are performed using special needles that are designed to cause minimal or no injury to the dural membrane surrounding lumbar neuronal structures. Occasionally, disruptions to this protective membrane can result in a loss of the cerebral spinal fluid (CSF) surrounding the brain and spinal cord. A decreased volume of lost CSF can result in significant symptoms (e.g., severe headache, nausea, vomiting, visual/auditory disturbances). Most debilitating is the impairment for parturients to care for themselves or their newborn. Relief of symptoms can be obtained through various interventions depending on the degree of symptom severity. Limited activity, bedrest in a supine position with the head-of-bed low, analgesics, caffeinated beverages and fluids are often successful to minimize discomfort. However, marked debilitation is treated with an autologous epidural blood patch (AEBP) to alleviate symptoms; AEBP demonstrates high rates of efficacy and patient satisfaction.

The purpose of this Doctor of Nursing Practicew project was to implement a uniform reporting and follow-up system for known unintentional dural punctures (UDPs) and PDPH. Such a system would guide clinicians to identify and track incidents of PDPH more effectively, thereby facilitating ongoing efforts to improve management of these potentially serious events.
This quality improvement project focused on implementation of a systematic surveillance and reporting system for suspected PDPH cases. Complaints of headache, UDPs, confirmed PDPH cases, treatment strategies, and AEBP procedures were prospectively tracked. Additionally tracked were descriptions of symptom resolution, whether additional evaluation, intervention, or patient referral was needed, and whether cases resulted in hospital readmission. Hospital staff provided daily surveillance, with monthly and quarterly reporting to anesthesia/obstetric staff and primary stakeholders. Headache, UDPs, and AEBP incidents occurring in 2014 were compared to annual Quality Assurance data dating back to 2010. Analysis was via descriptive statistics.

A total of 14 cases were identified as confirmed or potential for PDPH during surveillance (January 1 through December 31, 2014). Nine cases were related to epidurals and five to spinal anesthetics for cesarean section. There were a total of 6 UDPs among the nine epidural cases. A total of nine AEBPs were performed (4 spinals; 5 epidurals). Two patients were readmitted to the hospital. The median patient age was 28 years.

The results of this project verified low rates of PDPH at the facility and appropriate use of evidence-based practices in their management. Because PDPH presents clinicians with a problem that must be resolved quickly, anesthesia practices that serve a high number of parturients should adopt some form of tracking and management reporting methods to document positively identified cases, ensure subsequent reevaluation, and ensure patient needs are addressed.
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BACKGROUND

Many women in the United States receive neuraxial anesthesia and analgesia as a means to reduce or eliminate the pain associated with labor and delivery. In 2008, three out of five women received epidural analgesia or spinal anesthesia for labor pain control, according to figures published by the U.S. Department of Health and Human Services (Osterman & Martin, 2011). During 2012, nearly 33% of births in the United States were surgically delivered by cesarean section, usually under neuraxial anesthesia (Martin, Hamilton, Osterman, Curtin, & Mathews, 2013). The recent Listening to Mothers Survey (Childbirth Connection, 2013), reported to be representative of the nation, supported the above rate for epidural usage in women delivering in U.S. hospitals, while documenting a slightly lower rate for cesarean sections (21%). Spinal anesthesia is preferred over general anesthesia for cesarean surgery due to concerns of safety for the parturient and fetus (Bucklin, Gambling, & Wlody, 2009). Appropriately administered neuraxial analgesia is considered safe for maternal and fetal outcomes and has some physiologic advantages, despite the potential prolongation of the second stage of labor during vaginal delivery (Wong, 2009).

Neuraxial procedures are invasive techniques performed with special needles and can cause deliberate or inadvertent puncture of the outer layer of the meninges (dura), which is a protective membrane surrounding the spinal cord and underlying neuronal structures (Stendell, Fomsgaard, & Olsen, 2012). When this membrane is punctured, leakage of cerebral spinal fluid (CSF) may result. When CSF is lost, the brain and associated structures sag or sink within the cranial vault (Bezov, Lipton, & Ashina, 2010a). If a large enough volume of CSF leaks through the normally intact meninges,
nerve irritation occurs, leading to a severe frontal or occipital headache (Ghaleb, 2010). Symptoms commonly develop within the first 24 to 72 hours after a neuraxial procedure (Bezov, Lipton, & Ashina, 2010). The diagnosis for this condition is post-dural puncture headache (PDPH).

When PDPH occurs in women following delivery, these debilitating symptoms impair the postpartum experience, including the ability of new mothers to tend to their own needs and those of their newborn infants (Apfel et al., 2010). Bezov, Lipton, et al. (2010) reported that nearly 40% of patients diagnosed with PDPH may develop a severe impediment to activities of daily living. For the postpartum woman attempting to care for herself, a newborn, and perhaps other children in her family, the consequences can be devastating in terms of physical, psychological, and perhaps even economic impact (Tohomo et al., 1998, as cited in Bezov, Lipton, et al., 2010).

**Risks and Complexity of PDPH**

PDPH can occur after intended or unintended puncture of the dura. With spinal anesthesia, intended dural puncture occurs (by nature of the procedure) and the risk of PDPH is 1.5% to 11.2% (Macarthur, 2009). Incidence of unintended or unintentional dural puncture (UDP) during epidural placement occurs at a rate of about 1.5%. The term *wet-tap* is often used in the literature (Bezov, Lipton, et al., 2010; Gaiser, 2013; Ghaleb, 2010; Kuczkowski, 2004), referring to the same occurrence as an UDP and to the witnessed leakage of CSF from the needle hub. Patients may report an immediate headache or dizziness if enough fluid is lost acutely. Subsequently, the risk of developing symptoms of PDPH when the dura is unintentionally punctured by an epidural needle is 52.1% (Macarthur, 2009). Overall, the incidence of reported PDPH is
highly variable and can be influenced by patient factors such as gender, age, body mass index, and predisposition to headaches. Technical and procedural factors such as needle size, shape, design, operator experience, and number of procedure attempts also affect the likelihood of PDPH (Davigon & Dennehy, 2002). The presence of multiple risk factors in any one case contributes to increased risk of PDPH (Kuczkowski, 2004).

Anesthesia providers receive intensive training on neuraxial methods and techniques in order to become proficient and minimize complications. The use of smaller-gauge, specially designed noncutting spinal needles decreases trauma to the dural sheath at the time of needle penetration and has resulted in decreased risks for developing PDPH during subarachnoid block (Kuczkowski, 2004). However, untoward events do happen, even when procedures are performed in a standardized manner, using appropriate techniques, and without experiencing any known difficulties. Therefore, each neuraxial procedure has the potential for a complication such as UDP or PDPH to occur.

PDPH can result in problems beyond the symptoms of headache. Delayed hospital discharges can occur, as well as hospital readmissions for treatment of PDPH, both of which increase health care costs (Apfel et al., 2010). Although symptoms of the condition can be self-limiting, in cases left untreated or undiagnosed, PDPH can lead to significant associated comorbidity, including death. In a case report described by Aziz (2009), a 26-year-old postpartum patient presented with and was treated for symptoms of PDPH but eventually died of subarachnoid hemorrhage, which is very rare (1 to 5 per 10,000 pregnancies).

Patients who develop PDPH should not suffer needlessly. Many options for conservative treatment of PDPH exist, such as hydration, caffeine, and analgesics or
other pharmacologic approaches, each with varying degrees of efficacy (Frank, 2008; Gaiser, 2013; Ghaleb, 2010). The evidence consistently supports an autologous epidural blood patch (AEBP) as the most effective treatment for PDPH. AEBP involves injecting a freshly drawn volume of patient blood (15 to 20mL is reported as optimum) into the lumbar epidural space at, or one interspace above or below, the original epidural or spinal access point (Nelson, 2012). This technique is highly efficacious in relieving the symptoms of PDPH (Baysinger, Pope, Lockhart, & Mercaldo, 2011; Bradbury, Singh, Badder, Wakely, & Jones, 2012, Ghaleb, 2010; van Kooten, Oedit, Bakker, & Dippel, 2007).

However, there are inherent risks associated with performing a second invasive procedure, including aggravating the condition or causing other complications (e.g., backache, arachnoiditis, infection, nerve palsy, or repeated dural puncture). AEBP may not be indicated for all patients suffering from PDPH and is rarely the initial choice of treatment by most clinicians. Despite being the “gold standard” for PDPH treatment when conservative measures are unsuccessful, AEBP has not been found to be effective when used prophylactically following UDP (Agerson & Scavone, 2012).

**Risks of Litigation**

Despite a decrease in U.S. obstetric anesthesia malpractice claims for maternal death and newborn brain damage in the 1990s and early 2000s (as compared to those previous to 1990), claims for back pain and nerve injury increased (Gaiser, 2013). Headache continued to rank third in reasons for litigation during both of these time periods (Schwalbe, 2000). The American Society of Anesthesiologist (ASA) Closed Claim database analysis published in 1991 for claims related to obstetric anesthesia
resulted in a median payment awarded of $77,500 in 45% of cases filed (Chadwick, 1996). Closed claim events for PDPH occurring from 2003 to 2013 are currently being evaluated by the ASA; the process is in the data analysis phase and publication will most likely occur in 2015 (J. Quraishi, Research Analyst, American Association of Nurse Anesthetists, personal communication, April 2, 2014). Guidelines for treatment protocols may reduce the incidence of lawsuits and promote continuity of care for all patients experiencing PDPH (Gaiser, 2013).

**Statement of the Problem**

At the intended project site, during annual performance of several hundred labor epidurals and spinal anesthetics by both experienced clinicians and students of anesthesia, a confirmed diagnosis of PDPH requiring treatment was rarely reported (0.04% for 2013; see Appendix A). This unusually low rate was thought to be the result of a lack of reporting. At that time, there was no systematic, regularly reviewed process to document the prevalence of PDPH, track treatment and outcomes, or monitor follow-up at the project institution. Implementation of such a process was suggested during an anesthesia department staff meeting in October 2013.

Since PDPH reportedly occurs infrequently and no definitive treatment regimen is in place to guide clinicians, it is possible that there is significant inconsistency in the overall management of these cases at the hospital. Because of a perceived increased risk of additional complications, there is marked hesitation to perform AEBP immediately in cases of PDPH, despite its known efficacy (Stendell et al., 2012). If the headache occurs within 24 hours of a procedure, practitioners usually attempt conservative management
techniques (e.g., bed rest, intravenous fluids, analgesics, caffeinated beverages) to manage the symptoms. If these are unsuccessful, AEBP is done.

When PDPH related to neuraxial anesthesia occurs, patient satisfaction can be significantly impaired (Chadwick, 1996). Patients may feel ignored or mistreated when they are symptomatic, and the overall birth experience may be marred by the event. Suboptimal management of this condition results in potential for litigation. To address this quality assurance (QA) issue, a more efficient mechanism for identifying occurrences and record keeping was required, combined with timely follow-up to assess client status.

**Supporting Framework**

The process of evidence-based practice (EBP) is increasingly utilized to disseminate and bring research findings to the bedside (Gawlinski & Rutledge, 2008). EBP combines current research findings with clinical expertise to address problems or deficiencies in care delivery (Dontje, 2007). Gaps in delivering best practice may exist if nurses are hesitant to adopt this approach. However, when those in clinical practice incorporate a patient-centered model that encompasses EBP, the approach to addressing patient needs can be directed by a decision-making process guiding best-practice applications specific to patient circumstances and the clinical setting. Integrating practices based on research findings can be facilitated via a conceptual framework (Gawlinski & Rutledge, 2008). The Iowa Model of EBP to Promote Quality Care (Titler et al., 2001) is an example of such a model.

Use of the Iowa Model involves a collaborative process that includes key members in a health care setting to guide decision making and practice application (Doody & Doody, 2011). The relationships among patient, provider, infrastructure, and
research are all considered when developing solutions for identified problems. Other types of evidence are also used to guide practice (i.e., case reports, expert opinion, scientific principles and theory; Titler et al., 2001). The model follows a decision-making schematic (see Appendix B) that shows four major processes: identification of a trigger (problem or knowledge focused); identifying research that addresses the trigger; gathering, reviewing, and critiquing the relevant literature; and formulating and initiating a practice change and evaluating for effectiveness.

To achieve this process, seven steps are outlined, beginning with selecting a topic for focus that is a priority for the organization. Important questions to answer are as follows: Is the problem of significant magnitude to warrant investigation, will solving it contribute to improving care, do sufficient data exist to explore resolutions, will a multidisciplinary approach be required, and how much support will be required from the institution in terms of manpower and or financial commitment? Next to be considered are feasibility issues related to implementing change within the facility and whether the culture will be amenable to change. Despite supporting evidence, implementation requires buy-in by management, administration, and all affected stakeholders. Another factor to consider is who will implement an evidence-based change; according to Gough (as cited in Doody & Doody, 2011), “Change is more successful when implemented by frontline practitioners, rather than imposed by management” (p. 662). In any case, it may be difficult to implement practice change without support from organizational leaders.

As shown in Appendix B, retrieving the relevant evidence is the third step in the Iowa Model. Searches using all available electronic databases should be carried out. Librarians can be instrumental in obtaining resources. Once compiled, the aggregate
evidence is appraised and its level of merit determined. According to Polit and Beck (2012), research that provides good supporting evidence is appropriate. Clinicians evaluating the literature can be aided in their reviews by developing grading criteria for addressing the effectiveness, appropriateness, and feasibility of the relevant studies. Doody and Doody (2011) suggested a three-tier system—A, B, and C—to designate strong support, moderate support, and poor or no support. The application of this system of evaluating the literature can help to narrow the evidence to begin formulating the best-practice guidelines. Guideline development considers the desired outcomes, establishes baseline data, and incorporates both design and an implementation plan. The design of practice standards should be based on the evidence but cautiously avoid care that does not consider the needs of individual patients. Patient-centric guidelines are specific to the needs of the patient when implemented (Pearson et al., 2007, as cited in Doody & Doody, 2011).

The sixth step is implementation of the practice change on a small scale (pilot test). Such a test allows for evaluation of the feasibility and effectiveness of the practice change guidelines in an actual work environment where extraneous variables can influence outcomes and multiple caregivers deliver the interventions across a heterogeneous client base. This suggests whether the guidelines will perform as intended and desired outcomes will actually be achieved (Titler et al., 2001).

If the intervention achieves the desired outcome and the indication is for widespread adoption of the guidelines within the organization, then the final step is to disseminate the information and establish ongoing monitoring of the process and outcome data. Titler et al. (2001) suggest developing an algorithm that practitioners can
utilize to guide decision making. This will facilitate moving the evidence from the
literature to clinical application at the bedside.

Utilizing the methods outlined by the Iowa Model, the initial step is to determine
whether an existing problem-focused trigger can be identified. Benchmarking data and a
systematic approach to monitoring and treatment of PDPH was lacking at the project site.
The topic of PDPH and its management had been determined to be a priority for the
organization, and the literature indicated that the topic is timely and relevant (Gaiser,
2013). The team of stakeholders was identified as the anesthesia department staff and
administration, the obstetrics department staff, and, ultimately, patients suffering PDPH.

**Purpose of the Project**

The purpose of this project was to implement uniform reporting and follow-up
mechanisms for UDP and PDPH that would guide clinicians to identify and track
incidents of PDPH more effectively. Prospective improvement of reporting, cataloging,
and monitoring incidents of headache suspected to be related to neuraxial anesthetics
would occur as a result of the project, thereby facilitating ongoing quality improvement
efforts and management of these potentially serious events.
LITERATURE REVIEW

Much literature describing PDPH has been published since the phenomenon was reported in the first printed description of successful spinal anesthesia by August Bier in 1898 (Davignon & Dennehy, 2002). Having cocaine injected intrathecally by an associate and then confirming sensory blockade by applying burning cigars or striking the shin with an iron hammer, Bier subsequently developed a significant headache that lasted 9 days. CSF loss was considered the etiology (Macarthur, 2009). In the many decades since, PDPH remains a significant challenge for practitioners and correctly identifying and managing cases require appropriate guidance. Polit and Beck (2012) indicated that scholarly literature should be used to guide EBP, and Titler et al. (2001) specified that evidence should be sought during implementation of a quality improvement project.

A variety of databases and websites was searched for literature published in the past 10 years (2004 through 2014). Current anesthesia texts were used as resources. Systematic reviews and meta-analyses assessing methods for the prevention of PDPH, descriptive studies to determine current clinical practices, and a quantitative study to assess efficacy of PDPH treatments were included (see Appendix C). Case reports and qualitative studies were also reviewed in an attempt to obtain a description of the impact experienced by patients. However, contemporary qualitative studies are lacking and there are limited reports on the economic impact of PDPH. Quality review articles have been published recently (see Appendix C), providing information on trends, risk factors, treatments, and incident management of PDPH; these were helpful to determine that definitively diagnosing, treating, and monitoring PDPH are of paramount importance.
The reference lists of articles obtained generated other search pathways. Resources were delimited to those reported and published in English. Interest in the management of PDPH was refined to create an initial identification and surveillance mechanism. Keyword search of *post-dural puncture headache* and *surveillance* initially identified 81 articles.

**Incidence**

Women who choose to receive epidural analgesia for labor pain or have spinal anesthesia for cesarean sections are at risk of PDPH (Martin et al., 2013; Osterman & Martin, 2011). Ghaleb (2010) reported relatively low incident rates of PDPH (0.16% to 1.30%) in the hands of experienced clinicians. Kuczkowski (2007) cited rates of 0.19% to 4.40%. During a spinal anesthetic procedure, needle design, size, and orientation of the tip affect the incidence of PDPH. Pencil-point needles result in a decreased risk of PDPH versus cutting needles (Bezov, Ashina, & Lipton, 2010; Bradbury et al., 2012; Kuczkowski, 2007).

Conversely, when large bore needles are used, such as those used for epidurals, UDP can occur in up to 6% of patients (Gaiser, 2013). In fact, known UDP patients who deliver vaginally have an 85% chance of developing PDPH (Gaiser, 2013). The risk of developing a significant PDPH related to a neuraxial anesthetic in the postpartum period is highly variable: 0.2% to 85.0% (Davignon & Dennehy, 2002; Kuczkowski, 2007).

**Pathophysiology**

The complex pathophysiology associated with PDPH involves a combination of intracranial hypotension and meningeal irritation as a result of low levels of CSF. Normally, the brain and spinal cord are kept buoyant and suspended by constant levels of
CSF: about 150 mL in the average adult (Ghaleb, 2010). Any volume loss (as little as 10%) can result in headache. The resultant meningeal vasodilation and intracranial traction trigger pain responses to sensitive nerve structures. The degree of pain experienced with this condition can vary from mild to severe and incapacitating.

**Diagnosis**

Classic presentation of PDPH includes a severe throbbing cephalgia that radiates frontal to occipital and may be associated with nausea, vomiting, vertigo, diplopia, or tinnitus (Bezov, Lipton, et al., 2010). When posture changes from a sitting or standing position to supine provides relief of symptoms, this is often considered the definitive diagnostic criterion. Differential diagnoses that should be considered alternative to PDPH include nonspecific headache, migraine or lactation headache, caffeine or drug withdrawal, meningitis, sinus congestion, hypertension, pneumocephalus (trapped air in the subarachnoid space), cerebral vein thrombosis, subdural or subarachnoid hematoma, and cerebral mass or tumor (Ghaleb, 2010; Kuczkowski, 2007). Each of these conditions require specific treatment regimens and will not respond to the commonly practiced approaches to management of PDPH. Therefore, it is suggested that, before embarking on prevention or therapeutic measures specific for PDPH, alternative diagnoses should be ruled out. When a postpartum patient presents with complaint of headache, a detailed history of events preceding symptoms, evaluation of pre-existing health conditions, and a focused neurologic physical exam are required (Ghaleb, 2010; Kuczkowski, 2007).

**Risk Factors**

Parturients receiving neuraxial anesthesia have inherent risk factors such as younger age and female gender, lower body mass index, or history of previous headaches
(Bezov, Lipton, et al., 2010). Since these risk factors cannot be modified, women of childbearing age who receive neuraxial anesthesia are predisposed to increased risk for PDPH (Bucklin et al., 2009; Martin et al., 2013).

Neuraxial anesthesia or analgesia is an invasive procedure requiring practitioners to insert needles into the intrathecal or epidural space to deliver local anesthetic solutions, exposing the patient to risk of neuronal injury (Stendell et al., 2012). Mechanically, the needles vary in factors, including size, needle tip shape and design (cutting vs. pointed), and use or non-use of a stylet within the needle lumen to prevent coring (Ghaleb, 2010). Each of these variations elicits different risks related to dural puncture and CSF leakage.

Another significant variable to consider is operator experience. The risk of developing PDPH related to this variable is inversely proportional to operator experience and the number of times a procedure is attempted. Multiple attempts during a procedure can cause significant trauma to the dural membrane (Gaiser, 2013), which is more likely among inexperienced practitioners.

**PDPH Risk Reduction in Spinal and Epidural Procedures**

Mechanical contributions to the development of PDPH can be mitigated by several approaches for spinal anesthesia (Ghaleb, 2010). A mechanical variable of important consideration is needle size and orientation of the needle tip. Spinal and epidural needles come in a variety of sizes, shapes, and designs that can either reduce the occurrence of developing PDPH or potentially put patients at higher risk for PDPH (Bezov, Lipton, et al., 2010; Stendell et al., 2012). For spinal anesthesia, use of smaller-gauge needles (24 or 25) significantly reduces the size of the hole through the dural membrane. Coupled with a tip designed to pierce rather than cut, the routine use of
smaller needles can be highly effective in reducing the incidence of PDPH in spinal anesthesia. Bezov, Lipton, et al. (2010) indicated that the use of larger-size, traumatic-tip (i.e., cutting) needles increases the risk of PDPH from < 2% to 36%. Small-gauge (25–27) needles are recommended for spinal anesthesia. Atraumatic or pencil point needles reduce risk of PDPH with spinal anesthesia to 12.2%, compared to 24.4% when a cutting needle is used. However, the incidence of PDPH decreases from 25.8% to 10.9% if the orientation of the cutting needle bevel is longitudinal during placement (Bezov, Ashina, et al., 2010; Bradbury et al., 2012; Kuczkowski, 2007); in other words, adjusting the needle tip orientation parallel to the dural fibers may help to reduce tissue damage and subsequently decrease the risk of developing PDPH (Bezov, Lipton, et al., 2010; Stendell et al., 2012).

In a survey of Danish doctors practicing in neurology departments, Stendell et al. (2012) found that 74% of respondents used cutting needles when performing diagnostic lumbar puncture (not for anesthesia administration) and 18% did not know the type of needles they had used. Doctors reported that larger needle sizes (22, 20, or 18) allow for better flow of CSF when obtaining specimens for analysis and reportedly yield more accurate CSF pressure measurements. These reasons as justification for using larger needle sizes do not apply to parturients receiving neuraxial anesthesia in that no specimens nor pressure measurements are being obtained. However, several points were highlighted in response to the survey; smaller needles reduce the incidence of developing PDPH, prophylactic bed rest and fluid therapy were indicated as a primary treatment among 44% of respondents, despite questionable efficacy. Only 53% indicated that they would administer AEBP as a treatment of choice for suspected PDPH, but 100%
indicated that AEBP would be utilized if a patient had a position-dependent headache. The authors concluded that additional training was necessary regarding treatments and that use of atraumatic needles should be emphasized.

In a systematic review and meta-analysis, Bradbury et al. (2012) evaluated studies of interventions to decrease UDP and prevent PDPH in parturients receiving epidural anesthesia. Forty randomized controlled trials (RCTs) were selected from a list of 515 publications. The selected studies included a sample of 11,536 epidurals. Ten epidural variables were examined: combined spinal-epidural technique, type of medium used for loss-of-resistance (air vs. liquid), prophylactic AEBP, orientation of epidural needle bevel, special Sprotte epidural needle, ultrasound-guided insertion, acoustic device-guided insertion, continuous spinal analgesia, epidural morphine, and administration of cosyntropin. No single method of epidural insertion technique was associated with decreased risk of UDP (Bradbury et al., 2012). However, five procedural techniques were associated with decreased incidence of PDPH: prophylactic AEBP following UDP, needle bevel positioning parallel to dural fibers (thought to separate vs. cutting the dural fibers), design of the needle used (pencil point over cutting), and administration of epidural morphine or cosyntropin following UDP.

**Prevention with Pharmacologic Agents**

Basurto-Ona, Uriona-Tuma, Martinez-Garcia, Sola, and Bonfill-Cosp (2013) conducted a systematic review of RCTs evaluating the effectiveness of a variety of drugs used to prevent PDPH. Ten RCTs were evaluated ($N = 1,611$); most samples had women in the majority, most of whom were parturients in labor having received neuraxial anesthesia for pain. Drugs assessed were epidural and spinal morphine, spinal fentanyl,
oral caffeine, rectal indomethacin, intravenous cosyntropin, intravenous aminophylline, intravenous dexamethasone, and placebo. Dexamethasone was determined to increase the risk of PDPH. Spinal fentanyl, oral caffeine, and rectal indomethacin lacked conclusive evidence for effectiveness. Morphine, cosyntropin, and aminophylline had some support in preventing PDPH with lumbar puncture (Basurto-Ona et al., 2013); morphine and cosyntropin were also effective in preventing PDPH in UDP (Bradbury et al., 2012).

Pharmacologic agents other than morphine can aid in prevention of PDPH. Cosyntropin (a synthetic derivative of adrenocorticotropic hormone or ACTH), is purported to stimulate production of CSF (Basurto-Ona et al., 2013). However, optimal dosing regimens have not been established, and there are associated side effects, such as hemodynamic instability and central nervous system effects (i.e., seizure). Further research is necessary before cosyntropin is widely recommended (Bradbury et al., 2012; Gaiser, 2013; Ghaleb, 2010; Kuczkowski, 2007).

Sumatriptan, a serotonin agonist that is commonly prescribed for migraine headaches, has been suggested to relieve symptoms of PDPH. However, this medication is expensive and has potential for significant side effects. Variable effectiveness of sumatriptan is reported and additional investigation may be warranted (Bezov, Ashina, et al., 2010; Ghaleb, 2010; Kuczkowski, 2007).

Methylxanthine derivatives such as caffeine or aminophylline (theophylline) can be used for prevention of PDPH (Basurto-Ona et al., 2013). These drugs are thought to work by vasoconstriction of cerebral vasculature. The loss of CSF causes a reflex cerebral vascular dilatation as a compensatory mechanism for cerebral hypotension.
Mitigating this action through administration of methylxanthines may serve to reduce headache severity. These agents might also stimulate production of CSF (Basurto-Ona et al., 2013). Side effects (central nervous system and hemodynamic instability) can be experienced similar to those with cosyntropin; therefore, administration should be limited. Again, further research is recommended prior to widespread adoption.

**Risk Reduction for PDPH after UDP**

When performing neuraxial anesthesia with larger needle sizes, specifically epidural anesthesia for labor pain management, the practitioner may inadvertently puncture the dura, resulting in UDP. Immediate approaches to reduce risk of developing PDPH include injecting preservative free saline or other solutions into the epidural or intrathecal space, threading an epidural catheter into the subdural space, or removing the needle and applying direct pressure to the site.

When UDP occurs, practitioners may thread the epidural catheter through the hole in the dura and into the subarachnoid space and leave the catheter in place (Apfel et al., 2010; Baysinger et al., 2011). The rationale for this action is that the catheter will cause an inflammatory response of the dural membrane and hasten the sealing process. Apfel et al. (2010) and Kuczkowski (2007) reported histological confirmation of this inflammatory response. However, there is insufficient data to recommend this practice (Agerson & Scavone, 2012).

Use of an indwelling subarachnoid catheter has several risks and requires precise incremental dosing of anesthetic solution volumes. Deliberate intrathecal catheter placement can be useful to provide access for analgesia in cases where epidural placement is difficult (Gaiser, 2013). To avoid potential widespread migration of the
anesthetic solution, resulting in significant problems, such as an inadvertent high spinal blockade that could have devastating consequences, this approach should be used cautiously and only by experienced practitioners (Bezov, Ashina, et al., 2010; Ghaleb, 2010; Kuczkowski, 2007).

Apfel et al. (2010), Bezov, Ashina, et al. (2010), Gaiser (2013), Ghaleb (2010), and Kuczkowski (2007) reported the instillation of a variety of solutions to quell further leakage of CSF or to replace lost CSF and can include saline, morphine, and Dextran, or even fibrin glue. Use of these techniques adds risks to patient safety. For example, Dextran (a colloid solution) can cause anaphylaxis. Also, the solutions have varying degrees of efficacy in terms of stopping CSF leakage. Saline injections were found to be only temporarily effective (Apfel et al., 2010). Epidural morphine was shown to be useful in preventing PDPH in the presence of a wet tap (Gaiser, 2013) but has associated side effects, such as nausea and vomiting or pruritus. Morphine can cause respiratory depression for up to 24 hours after administration, which may lead to prolonged hospitalization for monitoring. Because of these side effects and potential associated increased costs, use of morphine to prevent PDPH after UDP has not been widely adopted (Basurto-Ona et al., 2013; Gaiser, 2013). Further research is needed on the efficacy of the other solutions.

**Conservative Treatment**

There is an abundance of literature on a variety of suggested treatments for PDPH. Usually a multimodal approach in the form of intravenous fluids, analgesics, anti-inflammatory medications, headache specific remedies, and even the unconventional pharmacologic interventions as described above has been explored and reported (Apfel et
al., 2010; Basurto-Ona et al., 2013; Bezov, Ashina, et al., 2010; Gaiser, 2013; Ghaleb 2010; Kuczkowski, 2007). Other measures have been attempted as treatment. Firm abdominal pressure may provide temporary relief by offsetting intracranial hypotension (Frank, 2008). Nearly all evaluation reports include hydration and nonsteroidal anti-inflammatory medications as recommended treatment for PDPH. However, little evidence supports these practices as significantly efficacious (Stendell et al., 2012).

Even though these noninvasive interventions have modest effectiveness at best, most are tried before initiating the one intervention with demonstrated effect: AEBP (van Kooten et al., 2007). This is most likely due to the potential additional risks from this treatment; AEBP can be associated with other complications such as radiculopathy, neuropathy (e.g., back pain, acute or chronic), infection (arachnoiditis), and additional trauma to the dural membrane (Ghaleb, 2010).

**Autologous Epidural Blood Patch**

The literature suggests that the most effective management of severe symptoms of PDPH can be accomplished using AEBP (Bezov, Ashina, et al., 2010; Frank, 2008; Gaiser, 2013; Ghaleb, 2010; Van Kooten et al., 2007). AEBP is a procedure involving phlebotomy of at least 20 ml of blood from the patient in aseptic fashion and injection of the blood into the epidural space at the area of the original puncture site. Subsequent formation of a blood clot plugs any dural defects and prevents further loss of CSF (Gaiser, 2013).

A complimentary mechanism for effectiveness of this intervention is increased pressure exerted on the spinal canal and thecal sac, which relieves cranial hypotension as a result of lost CSF volume. The procedure typically involves two clinicians and is not
without risks; however, the likelihood of relief of symptoms is high. In a randomized, observer-blinded, controlled clinical trial with 40 participants receiving diagnostic lumbar puncture (no parturients), Van Kooten et al. (2007) found that 19 of those who received AEBP treatment had superior relief of symptoms, compared with the 21 participants who received conservative therapy (e.g., bed rest for 24 hours, fluid intake of 2 liters). The AEBP treatment group had an 84% reduction of symptoms after 1 week, compared to 14% improvement in the comparison group.

Timing of AEBP placement appears to affect efficacy (Bezov, Ashina, et al., 2010). Prophylactic administration immediately after known UDP with large-gauge (17 or 18) epidural needles was found to be less effective than waiting 24 hours. Serial dilution of the injected blood by subsequently administering anesthetic solution may prevent formation of adequate clotting and likely prevents effective sealing of the dural defect (Ghaleb, 2010). While complications related to AEBP are rare, problems typically arise from using increased blood volumes for the procedure (Nelson, 2012).
METHODS

Ethical Considerations

In this project, personal information was removed from all records. Patient confidentiality was maintained by eliminating any demographic information that could be linked to clients. The only such tool that would contain confidential information would be a headache tracking tool (see Appendix D) used to identify potential or actual cases of PDPH. These tools have become part of the daily post-anesthesia evaluation form, which is housed in the anesthesia department office in a locked file with limited access. Only the primary investigator directly involved in this project or administrators have access to these forms. Information required for the project does not include personal information and was copied to a password-protected data file before removal from the work site.

Project Implementation

This project involved implementation of a systematic surveillance and reporting system for suspected PDPH cases. In order to compare pre and post system implementation, baseline reporting of the occurrences of PDPH cases, known wet taps, and AEBP procedures for calendar years 2010 to 2013 were available (Appendix A). Beginning April 2014, complaints of headache, known UDPs, confirmed cases of PDPH, treatment strategies, and AEBP procedures were tracked prospectively; this allowed determination of whether there was an increase in the number of cases reported and tracked. The 2014 data also allowed description of resolution of symptoms or whether additional evaluation, intervention, or patient referral was needed and whether any cases were hospital readmissions. Surveillance was done daily, with monthly reviews and quarterly reporting disseminated to the staff and primary stakeholders.
Sequence of Activities

At the project site, patient follow-up occurs within 24 hours for all patients who receive neuraxial anesthesia, in part to meet regulatory standards (Anesthesia Services Interpretive Guidelines issued by the Centers for Medicare and Medicaid Services, 2011) and to assess for related post-anesthetic complications, including headache. Vague complaints of headache determined to be unrelated to neuraxial anesthesia (e.g., caffeine withdrawal, dehydration, dietary restrictions) are not tracked but can mimic or mask PDPH. These symptoms may or may not be recorded in the patient record at the discretion of the evaluator, usually depending on symptom severity. These cases have the potential for symptoms to progress and may be eventually diagnosed as PDPH requiring treatment. Cases deemed at risk to develop PDPH were forwarded to the department secretary to be flagged and reevaluated within 24 hours as outlined below. Patients found to be asymptomatic on subsequent visits \( n = 4 \) were not followed further.

Changes in Documentation Forms and Processes

As part of the daily follow-up process, the 2014 (April) post-anesthesia documentation sheet was amended to include a tracking tool called Follow-Up for Evaluation of PDPH and Possible PDPH (Appendix D), prompting providers to flag cases for reevaluation. Beginning in April 2014, flagged cases were automatically added to the next day’s list for recheck by a Certified Registered Nurse Anesthetist (CRNA) within the next 24 hours, or sooner if severity of symptoms worsened. Anesthesia staff members were trained by the investigator during two staff meetings and via email at the beginning of implementation regarding use of Appendix D. Criteria were added to the
follow-up tool, listing specific questions to be addressed when evaluating patients to determine diagnosis; these criteria were discussed during the staff meetings.

During the project, reports of headache automatically triggered an occurrence report and a QA form was generated. These QA forms had normally been reviewed by the Department Chief but, until this project, had not been categorized for future reference or retrieval. Prior to April 2014, only patients presenting with significant symptoms of PDPH received formal tracking and follow-up of these patients occurred sporadically.

This project was designed to capture reliably all patients suspected of having PDPH, including those tolerating their condition and who never received treatment. This required closer inquiry and monitoring of cases by staff other than the investigator. Clients who developed symptoms after the initial or subsequent follow-up visits or following hospital discharge ($n = 2$) were referred back to the anesthesia service by their primary care providers.

**Capturing Event Occurrence and Comparison**

A tally of incidents via the QA forms (January through December 2013) in which known dural punctures (wet-taps) occurred ($n = 7$) or AEBPs were administered ($n = 9$, of which 3 were also known wet-taps) was compiled. These incidents were used as baseline data for comparison.

Staff use of Appendix D allowed documentation of complaints of headache and more accurately identified the incidence of PDPH in 2014. Used in conjunction with the existing QA forms, these provided a redundant method for identifying, reporting, and ensuring follow-up for incidents of UDP and/or PDPH. The tool also documented AEBP, its success rate, and details of any treatments.
Time Line of Activities

During 2014, the method to track all clients identified with and referred for headache received by the anesthesia department was developed (Appendix D) and piloted, along with the current QA form. Incident rates from 2014 were compared to rates for the previous 4 years. Surveillance utilizing the newly developed Follow-Up for Evaluation of PDPH and Possible PDPH (Appendix D) on the daily postoperative patient list began in spring 2014 and was managed by the author throughout the project.

To promote engagement in reporting PDPH by anesthesia providers in the department, educational sessions were held at two weekly anesthesia staff meetings in March 2014. These sessions focused on use of the Follow-Up Tool for Evaluation of PDPH and Possible PDPH (Appendix D). Training emphasized that use of the tracking tool and findings elicited from the tool were not intended to be punitive but rather were aimed at finding and treating potential PDPHs, thereby leading to enhanced patient satisfaction and improved outcomes. Staff members who were unable to attend these sessions ($n = 6$) received an e-mail notification following the first training session, outlining project goals and providing instructions on use of the tool. Follow-up to assess utilization of the tool was conducted at the start of implementation (April 1, 2014) and re-evaluated for a 10-week period (compliance check).

Organizational Setting

The setting for the project was a county hospital in a semi-rural southern California area that serves a moderately high-risk obstetric population. Total births for 2013 were more than 3,200; more than 700 spinal anesthetics for cesarean section
delivery were performed and nearly 900 epidurals were administered to control labor pain.

**Stakeholders Involved**

Key stakeholders of the obstetrics and anesthesia departments included the postpartum directors and anesthesia administrators, as well as patients who develop PDPH. Reports from the Follow-Up Tool for Evaluation of PDPH and Possible PDPH were generated quarterly and disseminated to both departments. Beneficiaries of this project are anesthesia and nursing staff who gain knowledge about the incidence of PDPH at the hospital and future patients who receive improved care.

**Patient Selection**

The patients of interest in this project were those who received neuraxial anesthesia associated with labor and delivery. Specifically targeted were those who developed symptoms of PDPH or had known UDP during epidural placement. Patients who developed PDPH symptoms were identified through the daily post-procedure evaluation process and from referrals from the postpartum unit and associated clinics or the emergency department. Rarely, the anesthesia department receives a referral for consultation of a patient suffering symptoms of PDPH as a result of diagnostic lumbar puncture used to obtain CSF. Treatment information of these patients was not included in this project.

**Evaluation**

This project allowed description of PDPH rates and treatment information pre- and post-implementation of a new tracking system for potential/actual PDPH at this institution. Descriptive statistics (frequencies, percentages) were used to describe
prevalence of known UDP, PDPHs, and treatment strategies (including prophylactic treatment). De-identified copies of Appendix D collected for 2014 were tallied and evaluated \( n = 5 \) to determine (a) measures taken to prevent PDPH when known UDP occurred, and (b) when PDPH developed, what treatments were rendered, and what were the clinical outcomes. The data collected via the Follow-up Tool for Evaluation of PDPH and Possible PDPH was evaluated for reported incidents during 2014 (April through December), as compared to the prior years.

A review of provider utilization of the tracking tool was conducted quarterly (number and percentage of staff users). This assisted in identifying whether improvements or modifications to the tool were necessary. Overall effectiveness of the project would be reflected if no patients or a decreased number of patients were readmitted to the hospital for evaluation of treatment of PDPH and if the number of identified PDPH cases was aligned with expected occurrences for the number of neuraxial procedures performed among obstetric patients. Effective early identification and intervention measures should significantly reduce or eliminate PDPH readmissions. For 2013, three patients were treated for PDPH as readmissions.
RESULTS

Fourteen cases were identified as confirmed or potential for PDPH during the surveillance period of January 1 through December 31, 2014, compared to nine cases during the previous year. Of the cases identified for 2014, the median age was 28 years, nine were patients who elected to have epidurals for labor pain management, and five had spinal anesthesia for cesarean section. Among the nine epidural patients, six were known UDPs, three of whom never developed significant symptoms of PDPH. Of these, one received a prophylactic injection of saline (5 mL) in the epidural space at the time of the initial procedure and the other two required no treatment. Obesity may have contributed to prevention of PDPH in at least one of these cases. Another two of the known UDP patients had mild symptoms prior to hospital discharge but elected to forego invasive treatment, specifically AEBP. Both were subsequently readmitted within a few days for debilitating headaches; each received AEBP, which was effective in eliminating symptoms.

The five patients suffering from PDPH after spinal anesthesia received either AEBP (n = 4) or conservative treatment (n = 1) to resolve their symptoms. Nine AEBP procedures were performed among both groups (n = 5 for the epidurals). Not all of the cases were detected utilizing the PDPH survey tool as a part of the daily postoperative patient rounds. The known UDP cases were automatically flagged for follow-up at the time of occurrence. Three cases (two epidurals and one spinal anesthetic) were identified via referrals from the postpartum department as complaining of headache. Two of these received AEBP with relief and one was later determined to have a probable case of pneumocephalus based on clinical evaluation, symptoms, and response to treatment
(oxygen therapy). None of these referral cases revealed any indication of difficulty during the procedures that could increase the risk for developing PDPH (Davigon & Dennehy, 2002; Kuczkowski, 2004). This highlights the potential for regional anesthesia procedures to develop problems, regardless of absence of known complications during the intervention. A telephone follow-up of one of the known UDP cases revealed that the patient developed PDPH after discharge, although not to a degree to prompt her to seek treatment. Self-management at home (drinking caffeinated beverages) relieved the symptoms.
DISCUSSION

The Iowa Model (Titler et al., 2001) describes four major processes used to implement change to practice based on evidence. Initially, a trigger (problem or knowledge focused) is identified and research that addresses the trigger is identified; incidence of PDPH below anticipated published rates was the trigger that led to this project. Once the potential problem was identified, per the Iowa Model, the relevant literature was gathered, reviewed, and critiqued. In this project, the focus was to develop a clinical tool to identify cases of PDPH in the target population to determine true incidence rates. As a result of staff education and utilization of the tool, more accurate incidence rates were established. A secondary effect may have been increased vigilance for PDPH events.

The final process in the Iowa Model is formulating and initiating a practice change, and then evaluating for effectiveness. As a result of this project, staff members were better prepared to make inquiries specific to symptoms of PDPH and possibly more apt to intervene when cases were positively identified as PDPH. The PDPH tool (Appendix D) lists specific treatment options that are readily available and easily implemented. Utilization of the tool will likely continue. Also generated as a result of this project was a much more accurate internal QA report on PDPH incidents, as requested by the Department Chief. The findings were presented to staff members on January 21, 2015.

Post-Dural Puncture Headache Findings

The overall findings of this project confirm data on PDPH incidence at this facility. Prior to the start of the project, the investigator anticipated higher actual
incidence rates than those in prior reports at the institution (e.g., 9 for 2013). In fact, intended dural puncture occurs with spinal anesthesia and the risk of developing PDPH is 1.5% to 11.2%, while UDP during epidural placement could result in a 52.1% chance of PDPH when the dura is unintentionally punctured by the larger epidural needle (Macarthur, 2009). Consistent with anticipated rates, only half of the known UDP incidents developed PDPH symptoms that required treatment. The total numbers of spinal anesthetics and epidurals for labor pain management during the survey period were 499 and 571 cases, respectively. This places the 2014 documented institutional risk of developing PDPH after spinal at < 1.5% and the risk of developing PDPH as a result of epidural analgesia at 1.6%. Thus, prospectively determined incidence rates for both spinal and epidural cases were lower than typically reported in the literature. Gaiser (2013) indicated the incidence of PDPH as high as 6% with epidurals. These extremely low incidence rates for PDPH cases are desirable, especially given the fact that many of the parturients cared for at this institution have inherent risk factors, such as female gender and younger age, as identified by Bezov, Lipton, et al. (2010). Gaiser (2013) noted increased risks when the practitioner is inexperienced. Students contributed to two incidents of UDPs, neither of which developed PDPH. Late in the survey period, two new graduates were added to the staff and an increase of PDPH cases was anticipated. However, only two incidents occurred after their hire dates and neither of these less-experienced staff members was involved with those cases.

**Prosp ective Surveillance for PDPH Using the Survey Tool**

Following implementation of the PDPH tool, 1-year surveillance for PDPH cases identified an overall higher annual number of actual and at-risk cases (15 for 2014 vs. 9
for 2013) and identified two cases of PDPH prior to discharge that may have benefitted from early intervention.

Limitations to identifying all cases of PDPH or potential PDPH could have contributed to low documented incidence rates. For example, some patients may not have experienced symptoms to a degree that prompted them to notify staff of their condition during the postpartum period. A lack of probing by providers during postoperative rounds or inconsistent use of the PDPH tool could have limited case identification. The first incident identified via the tool was incomplete in documenting the patient symptoms. This led to reemphasizing, via email and one-on-one communication, to staff the importance of gathering as much information as possible related to patient condition during the initial 10-week pilot period. Thereafter, the tool forms were completed properly. The total number of cases from this point forward using the tool in 2014 was five. Staff participation was always a concern for capturing all cases. However, patients suffering from debilitating PDPH usually self-identify, which results in referral and follow-up. Although possible, it is unlikely that any case demonstrating marked symptoms was overlooked.

Of the nine cases that received AEBP, 14 mL was the median volume of blood used for the procedures. This is just below an optimum volume for AEBP (15-20 mL as reported by Nelson, 2012) but demonstrated an efficacy rate to alleviate symptoms of PDPH at 89%. The first case in 2014 received a 15mL AEBP and achieved initial relief of symptoms but subsequently required multiple follow-ups and chose to seek treatment in at least one other facility (unknown final disposition). The majority of cases that developed PDPH (82%) were treated with AEBP, suggesting that providers would
administer aggressive rather than conservative management. No single provider was responsible for a greater proportion of administering AEBP, so the decision to treat in this manner versus conservative management was probably driven by degree of symptom severity rather than by provider influence. A prophylactic AEBP was performed through the epidural catheter just prior to being removed on one of the known UDP cases. This particular intervention is interesting in that only 8 mL was used. The patient was reportedly a difficult blood draw (as noted in the anesthesia record). To compensate for the inadequate volume, the provider added 5mL of sterile water to the specimen. There is nothing in the literature that supports this practice (mixing blood and a dilutant) but apparently it worked; the patient did not develop symptoms of PDPH. Future research may show this to be effective.

The timing of AEBP is important. Administering AEBP prior to symptom onset is associated with decreased efficacy of the treatment (Bezov, Ashina, et al., 2010), as is subsequent dilution with local anesthetic when done prophylactically for known UDP (Ghaleb, 2010). In this series of cases during 1 year at a single facility, all but one of the AEBPs were performed between 23 and 96 hours after the initial procedure, indicating provider compliance with best practice. The one prophylactic AEBP (done at 8 hours after an UDP, as described in the previous paragraph) was performed just prior to epidural catheter removal after delivery. No further local anesthetic fluid dilution occurred and the patient was not reported to have developed PDPH.

Conclusion

The low percentage of risk for developing PDPH in the parturient population at the facility where this project occurred might suggest that providers are careful to avoid
complications and are quite skilled at administering regional anesthetics for this patient population, or some combination of both factors. However, limitations to identifying all cases of PDPH or patients at risk for PDPH could have contributed to the low numbers of recorded incidents. Although the tool identified only a small number of confirmed cases of PDPH overall, these might have gone unaccounted for without its use. This practice (use of the tool for prospective surveillance) should be permanently adopted and continued. The high percentage of cases receiving AEBP and subsequently obtaining symptom relief is consistent with published studies documenting the efficacy of the intervention and encourages staff to continue an aggressive approach to treatment. Further evaluation of these interventions and application to specific cases may reveal a trend that could be used to formulate a standardized approach for future case management at this institution.

PDPH presents clinicians with a problem that must be resolved in a timely manner (Bradbury et al., 2012). Anesthesia practices that serve a high number of parturients should adopt some form of tracking and management reporting methods to keep track of positively identified cases, ensure subsequent reevaluation, and ensure that these patients’ needs are addressed via observation or further treatment and intervention, as necessary.
REFERENCES


APPENDIX A

IOWA MODEL OF EVIDENCE-BASED PRACTICE

The Iowa Model of Evidence-Based Practice to Promote Quality Care

Problem Focused Triggers
- Risk Management Data
- Process Improvement Data
- Internal/External Benchmarking Data
- Financial Data
- Identification of Clinical Problem

Knowledge Focused Triggers
- New Research or Other Literature
- National Agencies or Organizational Standards & Guidelines
- Philosophies of Care
- Questions from Institutional Standards Committee

Consider Other Triggers

Is this Topic a Priority For the Organization?
- Yes: Form a Team
- No

Assemble Relevant Research & Related Literature

Critique & Synthesize Research for Use in Practice

Is There a Sufficient Research Base?
- Yes: Pilot the Change in Practice
- No

Pilot the Change in Practice
- Select Outcomes to be Achieved
- Collect Baseline Data
- Design Evidence-Based Practice (EBP) Guideline(s)
- Implement EBP on Pilot Units
- Evaluate Process & Outcomes
- Modify the Practice Guideline

Base Practice on Other Types of Evidence:
- Case Reports
- Expert Opinion
- Scientific Principles
- Theory

Conduct Research

Is Change Appropriate for Adoption in Practice?
- Yes: Institute the Change in Practice
- No

Continue to Evaluate Quality of Care and New Knowledge

Disseminate Results

Monitor and Analyze Structure, Process, and Outcome Data:
- Environment
- Staff
- Cost
- Patient and Family

REQUESTS TO
Department of Nursing
University of Iowa Hospitals and Clinics
Iowa City, IA 52242-1089

APPENDIX B

TABLES OF EVIDENCE
### Systematic Reviews and Meta-Analysis Studies to Assess Methods for the Prevention of PDPH

<table>
<thead>
<tr>
<th>Purpose (source)</th>
<th>Type</th>
<th>Sample</th>
<th>Procedures</th>
<th>Findings</th>
<th>Author conclusions, limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>To assess effectiveness and safety of drugs for preventing PDPH in adults and children. (Basurto-Ona, Uronatu, Martinez-Garcia, Soila, &amp; Bonill-Cosp, 2013)</td>
<td>Cochrane Database Systematic review. RCTs of effectiveness of any drug used to prevent PDPH.</td>
<td>10 RCTs (n = 1611), majority women with resultant lumbar puncture, mostly parturients after receiving regional anesthesia for labor pain.</td>
<td>Drugs assessed epidural and spinal morphine, spinal fentanyl, oral caffeine, rectal indomethacin, intravenous cyclosporin, intravenous aminophylline, intravenous dexamethasone, and placebo.</td>
<td>Epidural morphine and intravenous cyclosporin, and aminophylline [PDPH incidence and severity. Dexamethasone ↑ risk. Spinal fentanyl, oral caffeine, and rectal indomethacin had a lack of conclusive evidence for effectiveness.</td>
<td>Cautious interpretation of the conclusions; further studies needed with larger sample sizes. Morphine should be used with caution due to ↑ risk of side-effects (pruritus, nausea, and vomiting). Consider as adjunctive therapies to AEBP??</td>
</tr>
<tr>
<td>To identify methods to decrease UDP, and interventions to prevent PDPH in parturients. (Bradbury, Singh, Badder, Wakely, &amp; Jones, 2012)</td>
<td>Systematic review and Meta-analysis. Electronic databases were searched for studies in which interventions could result in PDPH or UDP.</td>
<td>40 RCTs were narrowed from a list of 515 publications. The final list included 11,536 epidurals. No detailed reporting of patient demographics across studies.</td>
<td>10 different epidural interventions were examined: CSE technique, type of medium used for loss-of-resistance, PAEBP, orientation of epidural needle bevel, special Sprotte epidural needle, ultrasound-guided insertion, acoustic device-guided insertion continuous spinal analgesia, epidural morphine, and administration of cyclosporin.</td>
<td>No single method of epidural insertion technique was found to demonstrate a decreased risk of UDP. However 5 techniques were found to have a decreased incidence of PDPH: performing prophylactic AEBP (high risk of infection), needle bevel positioning to lateral, type of needle used (Special Sprotte), and the administration of epidural morphine or cyclosporin.</td>
<td>Limited quality of the studies used due to poor clinical trial methodology. Suggests threats to internal validity and a significant risk of bias. Also small sample sizes and UDP and PDPH being secondary outcomes resulted in reduction of strength of conclusions that authors could draw.</td>
</tr>
<tr>
<td>A quantitative, systematic review to determine best practices for prevention of PDPH after known UDP. (Apfel, Saxena, Cakmakkaya, Gaisser, George, &amp; Radke, 2010)</td>
<td>Meta-analysis examining PDPH, PAEBP, epidural morphine, intrathecal catheter, saline.</td>
<td>17 studies (15 papers and 2 abstracts), 1264 patients. Databases searched included PubMed, EMBASE, Science Citation Index, and Cochrane Library.</td>
<td>Random effects model to determine RR for developing PDPH after a interventions compared to control groups (no intervention). Additionally, data was categorized into RCT vs. non-RCT to evaluate for heterogeneous results and to elicit potential study bias.</td>
<td>Mixed results of the four methods examined to provide reduction in development of PDPH: epidural morphine held promise but limited data to support; PAEBP was the most statistically significant for reducing PDPH but only in non-RCT trials. Intrathecal catheters show mixed results, but a larger pooling of data concluded ineffective overall; and the use of saline cannot be deemed effective as the results of publication seemed bias toward favorable outcomes.</td>
<td>No one method proved efficacious over another, although PAEBP had highest benefit ratio, further RCTs with larger sample sizes needed. No definitive clinical recommendations could be derived from this review. Two conclusions the authors did make were that some intervention regardless of type should probably be initiated if possible due to the negative impact of PDPH (e.g., mother’s ability to care for newborn), and added cost of delayed hospital discharge.</td>
</tr>
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</table>

Note. CSE = combined spinal epidural; PAEBP = prophylactic autologous epidural blood patch; PDPH = post-dural puncture headache; RCTs = randomized control trials; RR = relative risk; UDP = unintentional dural puncture.
### Descriptive Studies to Determine Current Clinical Practices

<table>
<thead>
<tr>
<th>Purpose (source)</th>
<th>Design, key variables</th>
<th>Sample, setting</th>
<th>Measures</th>
<th>Results</th>
<th>Author conclusions, limitations</th>
</tr>
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<tbody>
<tr>
<td>To determine the management of UDP and PDPH among North American obstetric anesthesiologists. (Baysinger, Pope, Lockhart, &amp; Mercaldo, 2011)</td>
<td>Descriptive study, Questionnaire: 4-part, 83-item anonymous electronic survey consisting of: Demographics, Approaches to management after UDP, Management of PDPH (prophylactic and conservative measures), and AEBP management.</td>
<td>North American (United States and Canada) members of SOAP, 160 (out of 843 members, 18.9%) responded to survey. 16 from Canada and 144 from the U.S.</td>
<td>Interventions after IDP? Management of post-dural puncture headache: prophylactic and conservative measures: oral hydration, IV crystalloid, IV or oral caffeine, NSAIDS, oral opioids, oral sumatriptan, bedrest, ambulation.</td>
<td>Most common intervention was to place epidural catheter at different level following UDP. Younger practitioners more likely to use intrathecal catheter, but not necessarily with reduced dosing. Few respondents reported using saline bolus or infusions through the catheter. Most felt prophylactic and/or conservative measures ineffective.</td>
<td>Results showed that management of UDP and the prevention of PDPH is largely anecdotal and personal experience. Even though conservative or prophylactic treatment largely ineffective, 80% of respondents used some form of. There exists a need to adopt a standardized approach to determine the best management practice for UDP and PDPH patients.</td>
</tr>
<tr>
<td>To determine the use of different types of needles among practitioners and their understanding of the risk of PDPH occurring and treatments for when performing lumbar punctures for CSF analyses. (Stendell, Fomsgaard, &amp; Olsen, 2012)</td>
<td>Descriptive study. Varying needle sizes of 22G, 21G, 20G, and 18G, and traumatic vs. atraumatic type needles. PDPH treatments surveyed were bedrest, caffeine, analgesics, fluid therapy, AEBP.</td>
<td>Questionnaire survey conducted between June to November 2010 via letter or email among doctors at 13 neurologic departments in Denmark. Participation rate 51% (n = 161) of 314 surveys distributed.</td>
<td>Frequency of use of traumatic vs. atraumatic needle type for LP. Inquiry as to types of treatments utilized for PDPH; intravenous fluids, analgesics, caffeine, bedrest, AEBP.</td>
<td>Most used traumatic type needle (74%), majority used smaller gauge needles (78%) but some practitioners still using 18 &amp; 20G. Treatment regimen for PDPH when it occurred varied with no single best intervention determined.</td>
<td>The use of smaller gauge and atraumatic needles for lumbar regional anesthesia is standard practice in Denmark. Tx and prevention of PDPH knowledge lacking. Article is of recent publication and the use of smaller, less traumatic needle types seems common practice</td>
</tr>
</tbody>
</table>

*Note. AEBP = autologous epidural blood patch; G = gauge (smaller # is larger size); IDP = inadvertent dural puncture; IV = intravenous; LP = lumbar puncture; NSAIDS = nonsteroidal anti-inflammatory drugs; SOAP = Society for Obstetric Anesthesia and Perinatology; UDP = unintentional dural puncture.*
### Quantitative Study With Intervention to Assess Efficacy of PDPH Treatments

<table>
<thead>
<tr>
<th>Purpose (source)</th>
<th>Design, key variables</th>
<th>Sample, setting</th>
<th>Measures</th>
<th>Results</th>
<th>Author conclusions, limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>To determine the efficacy of AEBP for the treatment of PDPH. (Van Kooten, Oedit, Bakker, &amp; Dippel, 2007)</td>
<td>RCT comparing AEBP to conservative Tx: 24hrs of bedrest and adequate hydration.</td>
<td>42 patients with PDPH randomized into 2 groups: G1 received EDBP ($n = 19$), G2 received conservative treatment ($n = 23$). HA was defined as moderate or severe and at least 24 hrs after initial diagnostic intervention but not longer than 1 week later. AEBP occurred via randomization within this timeframe if consented to participate. Amount of blood used was 15-20mL.</td>
<td>Primary and secondary endpoints were reports of headache 24 hours after onset of treatments, and presence/severity of HA 1 week later.</td>
<td>G1: reported ↓ from 58% at 24 hours to 16% (3 of 19) at 1 week. G2: 90% still had a HA 24hrs post-treatment; at 1 week: 86% (18 of 23).</td>
<td>“EDBP is an effective treatment for PDPH” (p. 557). This small study demonstrated that for most patients the efficacy is significant and provides marked relief of symptoms allowing them to return to activities of daily living.</td>
</tr>
</tbody>
</table>

*Note. AEBP = autologous epidural blood patch; EDPB = epidural blood patch; HA = headache; hrs = hours; PDPH = post dural puncture headache; RCT = randomized clinical trial; Tx = treatment.*
<table>
<thead>
<tr>
<th>Purpose</th>
<th>Design</th>
<th>Indications for Screening/Preventive Measures</th>
<th>Guidelines for Follow-up/Tx</th>
<th>Conclusions</th>
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<tbody>
<tr>
<td>Part I—To describe the diagnosis, epidemiology, etiology and pathophysiology of PDPH. (Besov, Lipton, &amp; Ashina, 2010a)</td>
<td>Review Article</td>
<td>PDPH can be prolonged, severe, and incapacitating. Of those Dx’d, 39% experience 1 week of inability to perform ADLs. Can result in delayed hospital discharge or readmission. Tx and prevention is optimal management approach. Other serious complications may result in a number of DDs.</td>
<td>Non-modifiable risk factors should raise clinicians’ index of suspicion for Dx of PDPH: age, gender, low BMI, previous Hx of HA or PDPH. Verification of recent procedure involving needles in the subarachnoid or epidural space within past 24-72 hrs.</td>
<td>Common complication of neuraxial anesthesia. Needs prompt recognition and Tx to avoid other significant comorbidity. Clinicians must have good knowledge of PDPH and also alternate DDs to recognize and intervene for potentially life threatening conditions.</td>
</tr>
<tr>
<td>Part II—To describe the prevention, management, and prognosis of PDPH. (Besov, Ashina, &amp; Lipton, 2010b)</td>
<td>Review Article</td>
<td>Use of larger size, traumatic tip type needles increased risk of PDPH from 2% to 36%. 25-27 gauge needles recommended for spinal anesthesia. Atraumatic needles reduce risk of PDPH after spinal anesthesia to 12.2% compared to 24.4% when cutting or traumatic needles used. Bevel orientation is recommended to be longitudinal if using cutting needle. Risk of PDPH decreases from 25.8% to 10.9% as result.</td>
<td>Comprehensive, well designed RCTs for the management of PDPH are lacking, however there are numerous RCTs for AEBP to Tx PDPH. After review of studies conducted 4 step approach to Tx: 1) conservative management, 2) aggressive medical management, 3) conventional invasive therapy, and 4) aggressive invasive treatment. A Tx algorithm is presented.</td>
<td>PDPH remains complication of neuraxial anesthesia. Should be aggressively managed, other serious conditions can mimic. If Sxs not responding to standard Tx for PDPH, practitioners need to consider other DDs and investigate accordingly. Needle type, size and orientation affect the risk of PDPH developing after neuraxial anesthesia. More RCTs needed to determine incidence and Tx efficacy.</td>
</tr>
<tr>
<td>Implications for ED Physicians Dx and Tx of PDPH. (Frank, 2008)</td>
<td>Review Article</td>
<td>Persistent, untreated PDPH can lead to worsening conditions including death. Imaging studies are rarely needed to confirm Dx: postural component and a maneuver described by Gutsche whereas firm abdominal pressure will provide relief of Sxs.</td>
<td>Describes risk factors similar to other articles such as age, gender, previous Hx of HA. Interestingly only article that mentions race (non-factor), and describes operator experience and # of attempts as not being risk factors which is contrary to other reported findings.</td>
<td>Recommends tiered level of Tx options: mild, non-debilitating Sxs should be conservatively managed with rest and medications. More severe Sxs suggests Tx with methylsulphate derivatives, and AEBP for patients in significant distress (performed by anesthesiologist).</td>
</tr>
<tr>
<td>To identify newer risk factors for developing PDPH and key points of management. (Gaiser, 2013)</td>
<td>Review Article</td>
<td>PDPH remains a common problem with neuraxial anesthesia. ASA Closed Claim database analysis for obstetric anesthesia related incidents 1990 to 2003 ranks HA as 3rd leading cause for lawsuit, resulting in payment awarded in &gt; 40% of cases filed. Known UDP patients who deliver vaginally have 85% chance of developing PDPH.</td>
<td>Recent diagnostic criteria have been established to distinguish PDPH from other types of HA by the IHS: Postural (Sxs are exacerbated or relieved by changes in positioning, at least one other accompanying Sx, neuraxial anesthesia performed, resolves untreated within 1 week or 48 hrs after AEBP). Intrathecal catheters have not been shown to be effective for preventing PDPH.</td>
<td>Evidence-based management approaches are not standard practice among providers, written guidelines should be implemented by institutions. Written guidelines for Tx protocols may reduce the incidence of lawsuits occurring. Written protocols promote continuity of care for all patients. Intrathecal catheter placement can be useful to provide access to analgesia in difficult access Pt.</td>
</tr>
<tr>
<td>Review of trends in PDPH Dx and Tx. (Ghaleh, 2010)</td>
<td>Review Article</td>
<td>Cited incidence rates: 0.16% to 1.3% among experienced operators. UDP rates 16% to 86% if large bore needle used. IHS screening tool should be used to Dx. Type and size of needle and orientation of tip during procedure has impact on risk of developing PDPH. Bloody tap (whereas bleeding occurs at puncture site) are less likely to develop PDPH.</td>
<td>Emotional support and reassurance must be provided. Recent trends shifting away from conservative Tx which have been largely shown to be only moderately effective to wider use of AEBP. ~ 20 mL has been found to the optimum volume for AEBP. Avoid placing AEBP prophylactically simultaneous to bolus of LA as high spinal block has occurred.</td>
<td>Non-invasive Tx have been less effective than AEBP. Complications t/t AEBP are rare although problems typically arise from using increased blood volumes for the procedure. Needle size, shape and tip positioning can result in risk of PDPH. Prophylactic AEBP may be indicated in cases where risk is greater. Surgical closure is another rarely used option.</td>
</tr>
<tr>
<td>Contributing factors to the development of PDPH, information for obstetricians. (Kuczkowski, 2007)</td>
<td>Review Article</td>
<td>Cited incident rates: 0.19% to 4.4%. Risk of developing PDPH after UDP with epidural needle 76—85%. Dx and Tx usually managed by anesthesia service, however earlier hospital d/c post-partum may result in presentation of symptomatic Pt at PCP f/u visit? Use of pencil-point needles results in risk PDPH than cutting needle.</td>
<td>Full explanation (in terms Pt can understand) of the cause, available therapeutic regimens, timeframe and anticipated Tx outcomes. Pt may be angry and resentful or depressed. Ability to care for newborn, herself or other family members is likely impaired. Early discussion of AEBP as Tx option indicated.</td>
<td>Operator experience inversely proportional to risk of PDPH developing. Delayed d/c or hospital readmission may occur, resulting costs associated with birth experience. PDPH 3rd most common reason for obstetric anesthesia related lawsuits. Important to consider alternative DDs prior to initiating Tx.</td>
</tr>
</tbody>
</table>

*Note. AEBP = autologous epidural blood patch; BMI = body mass index; CTs = controlled trials; d/c = discharge; DDs = differential diagnoses; Dx = diagnosis; Ddx = diagnosed; HA = headache; hrs = hours; Hx = history; IHS = International Headache Society; LA = local anesthetic; PCP = primary care provider; PDPH = post-dural puncture headache; Pt = patient; RCTs = randomized controlled trials; r/t = related to; Sxs = symptoms; Tx = treatment; Txd = treated; UDP = unintended dural puncture.*
### PDPH or Potential for Cases Identified in 2014

<table>
<thead>
<tr>
<th>Case #</th>
<th>Incident Date</th>
<th>Patient Age</th>
<th>Original Procedure</th>
<th>PDPH Survey Tool? (Y/N)</th>
<th>AEBP Performed? (Y/N)</th>
<th>Time from Procedure to AEBP (hrs)</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4/9/14</td>
<td>24yo</td>
<td>Labor Epidural → IDP → intrathecal catheter</td>
<td>Y (incomplete) initially declined blood patch and was d/c'd home.</td>
<td>Y (15mL), readmitted 4/12/14 via ED, EBP, Sx's l, released. Returned 4/15/14 for eval of continued Sx's</td>
<td>75</td>
<td>Failed to obtain adequate relief</td>
</tr>
<tr>
<td>2</td>
<td>5/29/14</td>
<td>30yo</td>
<td>Labor Epidural</td>
<td>N (post-partum referral)</td>
<td>Y (14mL)</td>
<td>23</td>
<td>Relief</td>
</tr>
<tr>
<td>3</td>
<td>6/16/14</td>
<td>28yo</td>
<td>Labor Epidural</td>
<td>Y</td>
<td>Y (18mL)</td>
<td>43</td>
<td>Relief</td>
</tr>
<tr>
<td>4</td>
<td>6/19/14</td>
<td>28yo</td>
<td>Primary C/S (spinal)</td>
<td>N (post-partum referral)</td>
<td>Y (15mL)</td>
<td>73</td>
<td>Relief</td>
</tr>
<tr>
<td>5</td>
<td>6/30/14</td>
<td>26yo</td>
<td>Labor Epidural → IDP → Primary C/S &amp; BTL</td>
<td>Y/prophylactic via catheter (15mL)</td>
<td>8</td>
<td>No Sxs</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>7/2/14</td>
<td>31yo</td>
<td>Labor Epidural → IDP (by SRNA)</td>
<td>N</td>
<td>N</td>
<td>No Sxs</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>7/15/14</td>
<td>22yo</td>
<td>Labor Epidural → IDP (by SRNA on 2nd attempt)</td>
<td>N</td>
<td>N (injected 5mL NS)</td>
<td>No Sxs</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>7/28/14</td>
<td>23yo</td>
<td>Labor Epidural</td>
<td>Y</td>
<td>Y (20mL)</td>
<td>32</td>
<td>Relief</td>
</tr>
<tr>
<td>9</td>
<td>8/12/14</td>
<td>24yo</td>
<td>Repeat C/S (spinal)</td>
<td>Y</td>
<td>Y (18mL)</td>
<td>39</td>
<td>Relief</td>
</tr>
<tr>
<td>10</td>
<td>9/21/14</td>
<td>24yo</td>
<td>Labor Epidural → IDP → Primary C/S</td>
<td>N</td>
<td>N</td>
<td>No Sxs</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>10/27/14</td>
<td>33yo</td>
<td>Repeat C/S (spinal)</td>
<td>Y</td>
<td>N (conservative Tx)</td>
<td>Relief</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>11/1/14</td>
<td>25yo</td>
<td>Labor Epidural → IDP → Primary C/S</td>
<td>N (developed headache at home)</td>
<td>N (self-managed; caffeine relieved Sx's)</td>
<td>Relief</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>11/10/14</td>
<td>30yo</td>
<td>Repeat C/S (spinal) &amp; Bilateral tubal ligation</td>
<td>Y (post-partum referral)</td>
<td>46</td>
<td>Relief</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>12/1/14</td>
<td>22yo</td>
<td>Labor Epidural (previous Hx of migraine headaches)</td>
<td>N (Post-op 12/2/14 NO complaints of headache)</td>
<td>N Given oxygen therapy (probable pneumocephalus vs. recurrent migraine)</td>
<td>Relief</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>12/5/14</td>
<td>24yo</td>
<td>Repeat C/S (spinal) 12/1/14 → Readmitted through ED on 12/5/14</td>
<td>Y (8ml, diluted /c 5mL sterile water)</td>
<td>96</td>
<td>Relief, D/C from ED to home</td>
<td></td>
</tr>
</tbody>
</table>

**Summary:** A total of 14 confirmed cases were identified as PDPH (1-yr incidence 0.013), 5 spinals and 9 epidurals from a total of 499 C/S (1-yr incidence 0.010) and 571 labor epidurals (1 yr incidence 0.016) respectively. Of the 9 epidurals, 6 were known IDP (67%). There were 9 AEBP procedures performed, 5 of the epidural cases and 4 of the spinal cases. The median volume of blood used was 14mL. Of the 4 epidurals that did not receive AEBP, the reasons varied from two patients not developing any Sx's after IDP (risk factor - obesity), one had 5mL saline injected at the time of the IDP, and one self-managed at home with caffeine. The lone spinal case that did not receive AEBP obtained effective relief from conservative management (fluids, caffeine, analgesics). One case worked-up for r/o PDPH was ultimately Dx'd as likely pneumocephalus vs migraine HA, the patient received oxygen Tx with relief. A total of 2 patients ended up as readmissions through the ED for Tx. The median age of all the cases was 28 years old. Only one patient failed to receive adequate relief initially and required multiple care session.
APPENDIX C

FOLLOW-UP FOR EVALUATION OF PDPH AND POSSIBLE PDPH

<table>
<thead>
<tr>
<th>Patient sticker here</th>
<th>Description of headache: Frontal / Occipital / Nuchal / Shoulder</th>
<th>Pain Severity Score (0-10): _______</th>
<th>Postural Y / N, Hx of Migraine or Y / N</th>
<th>Other Sxs:</th>
<th>Treatment rendered:</th>
<th>Fluids / Caffeine: ________</th>
<th>Analgesics: ___________</th>
<th>Activity: _______________</th>
<th>AEBP: mLs Relief: Y / N</th>
</tr>
</thead>
</table>

(Add additional cases here as needed)