Capstone Project Proposal

Safe Epidural Administration and Management in the Obstetric Population Anna Kadeg, RN, BSN, SRNA & Megan Cooper, RN, BSN, SRNA Nurse Anesthesia Program 2016: Adventist University of Health Sciences

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Safe Epidural Administration and Management in the Obstetric Population

## Abstract

Safe administration and management of epidurals in the obstetric population is a skill that anesthesia providers perform and are responsible for. Unfortunately, mistakes can and do occur in this setting due to the effect of human error. The purpose of this project was to evaluate the common errors that can occur in this setting and to educate first year Student Registered Nurse Anesthetists (SRNAs) on how best to provide the safest care possible. By reviewing the most current literature available regarding common medication errors and causative factors as well as case studies related to the topic, the project aimed to provide a thorough educational experience for the SRNAs that would be preparing to provide care to the obstetric patient population through the administration and management of epidural anesthesia.

In conclusion, the goal of the project was to raise awareness among the SRNAs of the potential for errors in the obstetric setting. Safety of the patient is a standard of care that all anesthesia providers must be accountable for in order to allow safe practice and overall highquality patient care.

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## Problem

The problem this Capstone project aimed to address is that of human error in the administration and management of obstetric epidural anesthesia and analgesia. Renowned English poet Alexander Pope once penned the now-common adage "To err is human" (Pope, 2008, p. 25). In an increasingly fast-paced and technologically advanced healthcare setting, Pope's sentiment from 1711 rings true now more than ever. James (2013) estimates the number of premature deaths associated with preventable harm to patients at upwards of 400,000 per year. There is an apparent paucity of statistical evidence regarding the incidence of preventable harm in obstetrics (OB) specifically, though countless qualitative studies as well as public record of OB malpractice lawsuits suggest that this specialty is far from immune to human error. Evidence to this effect will be further discussed in "Literature Review."

Epidural anesthesia and analgesia is a major contributor to these human-error statistics, seeing as it is one of the most specialized procedures performed by anesthesia practitioners. Konrad, Schupfer, Wietlisbach, & Gerber (1998) tracked the progress of anesthesia residents, and identified epidural administration as the most difficult to learn of the manual anesthesia skills. Administration and maintenance of epidural anesthesia and analgesia requires interdisciplinary collaboration, communication with and cooperation from the patient, knowledge of complicated anatomical and pharmacologic concepts, as well as refined dexterity and mastery of the physical skill. The involvedness and complexity of the procedure lends to its propensity for inviting errors.

Having established that human error on behalf of healthcare providers is one of the most detrimental threats to patient outcomes, that anesthesia in obstetrics is a specialty in which these errors are highly likely to occur, and that the complexity of epidurals specifically make them a culprit, one can deduce that to address epidural safety is integral to resolving the issue of human error leading to poor patient outcomes. A population at high risk for making these mistakes is Student Registered Nurse Anesthetists (SRNAs). Many factors contribute to this risk, such as lack of experiential knowledge, being unacquainted with the equipment, the pressure of being "in the spotlight," and countless other stressors associated with being a student.

In summary, the problem this Capstone project aims to address is that of human error (specifically by SRNAs) in the administration and management of obstetric epidural anesthesia and analgesia. The intended approach does not focus on didactic information and textbook instruction, as SRNAs tend to be rich in that form of knowledge. This project instead emphasizes improvements that can be made to existing protocols, processes, and practices to promote safety on a deeper level than simply knowing the facts. At the first National Summit on Medical Errors and Patient Safety Research, American Psychological Association member and PhD, David Woods, eloquently described the merit of this approach. "Human errors in medicine, and the adverse events that may follow, are problems of psychology and engineering, not of medicine," said Woods. "Where you are puzzled by erratic people, we see common patterns in problem-solving and cooperative work" (Kogan, 2000, p. 29).

## **Review of Literature**

A review of the literature reveals a plethora of studies conducted by both the private and governmental sectors concerning medical errors. While this research has resulted in a broad wealth of knowledge concerning medical errors in general, information specifically pertaining to medical errors involving epidurals is limited; furthermore, data concerning medical errors involving epidurals predominantly identifies the error event and its resulting financial loss without addressing other contributing elements.

This Capstone presentation primarily sought to identify the origins of epidural errors, which is necessary to formulate plans to prevent or decrease medical errors in epidural administration. In the pursuit of this purpose, qualitative and anecdotal evidence becomes more valuable than quantitative, which does not address causality. A thorough review of literature including peer reviewed articles and studies within the last 10 years was be performed, focusing especially on anecdotal and qualitative evidence. Through this research, trends, common errors, and contributing factors were identified, thereby allowing for the formulation of potential solutions for medical errors commonly seen with epidural administration.

A review of literature produced a plethora of articles and studies from peer-reviewed journals. One unfortunate example mentions an anesthetist and a midwife who mistakenly connected an epidural set to a patient's IV tubing. The intended epidural dose was delivered intravenously, resulting in the patient's death ("Misconnections," 2015).

An article printed in The Official Journal of the Anesthesia Patient Safety Foundation (ASPF) titled "Reducing Risk of Epidural-Intravenous Misconnections" suggests the aforementioned story is not an isolated event and warrants further attention. The article is unique in that it provides an in-depth examination of the problem in addition to exploring potential solutions. Block, Horn, and Shlesinger (2012) set out to review sentinel events and other documented cases of error in an attempt to determine the source of medication errors..

Block, et al. (2012) reported 9 cases of tubing misconnections involving 7 adults and 2 infants, resulting in 8 deaths and one permanent loss of function. In addition, 13 case reports from the Institute for Safe Medication Practices were reviewed; one case involved the inadvertent infusion of a chemotherapeutic agent into epidural catheters. The same article quotes the US Pharmacopeia as having received 1600 reports of epidural to central or peripheral intravenous connections between 1999 and 2011. (Block, Horn, & Schlesinger, 2012).

Strengthening the case against epidural misconnection as a common event, the ASPF expounds further on a few accounts with unfortunate outcomes. Accessory devices such as blood pressure cuffs, enteral feeding systems, and even a bladder irrigation system were found to have been mistakenly connected to epidural tubing. Magnesium sulfate in the Labor and Delivery setting was, in one report, accidentally administered through the epidural route twice within a period of just two months, and a bag of epidural anesthetic, being mistaken for an antibiotic, was administered intravenously (Block, Horn, & Schlesinger, 2012).

In response to these findings, a product was developed by Smiths Medical in a noteworthy attempt to decrease the likelihood of epidural misconnections. The CorrectInject<sup>®</sup> epidural safety system consisted of syringes, catheters, and needles not compatible with the widely used Luer connection. Following FDA approval, a study was designed to examine both

the system's clinical usability and perceived effectiveness in preventing wrong-route epidural drug administration. The controlled, prospective study used a 9-question survey composed of a numeric rating scale, yes/no questions, and an open-ended invitation for comments.

The findings of the study were mixed. A total of 202 anonymous surveys were collected. Though a promising 96% of respondents, when asked in yes-or-no format, agreed the system was likely to prevent misconnections, in practice 15 (7%) reported having technical difficulties using the system (Block et al., 2012). In 2 of those cases participants were even compelled to circumvent the system, swapping CorrectInject<sup>®</sup> connections for standard Luer connections in an emergent situation. To have 7% of epidural administrations prove technically problematic is clinically unacceptable and likely unsafe. To support this premise, over half of respondents rated the CorrectInject<sup>®</sup> system as a 3 or greater on a scale of 5, with 5 being "very complicated" to use. The study proclaims that over the 10-month course of the study, ease of use scores improved by over 50%, allegedly demonstrating a promising learning curve (Block et al., 2012).

The CorrectInject<sup>®</sup> system provided a hopeful answer to a very real problem. Unfortunately, though the study was conducted in a reliable fashion and with an acceptable sample size, the analysis of data is poor and demonstrates a rather suspect optimistic bent in its interpretation. The authors offer a broad summary stating, "The findings of this clinical trial demonstrate the perceived safety benefits and clinical suitability of the device..." largely ignoring the 15 cases reporting technical difficulties (Block, Horn, & Schlesinger, 2012, p. 5).

Inviting even more scrutiny is the proposed solution to the two cases, which necessitated switching out the connectors for standard Luer locks. The authors states "...molding of the non-Luer adapter into the infusion tubing during manufacturing would achieve incompatibility with intravenous tubing without required attachment by the clinician" (Block, Horn, & Schlesinger,

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2012, p. 5). While this would indeed prevent the provider from reverting to standard Luer connections it sidesteps the real issue: the equipment difficulty necessitating the swap in the first place. Failing to address the root cause and simply preventing the action could prove disastrous to patient care, expressly in emergent circumstances. Finally, the claim that ease-of-use scores improved over time is dubious. Evidential support of this assertion would mandate identification of specific practitioners' progression over time. The study simply examined mean scores and had no way of isolating if, and how many, subjects were repeat users and over what timeframe.

It is commonplace for product studies to be funded by the manufacturing company, but results must be examined through an inquisitive lens nonetheless, bearing bias in mind. This caveat in concert with questionable data analysis and interpretation preclude surprise when, in 2013, Smiths Medical released a statement that they were abandoning the epidural safety system and redirecting their efforts.

In addition to misconnections, further accounts implicate wrong-route and wrongmedication errors as a common threat. At St. Mary's Hospital in Wisconsin, such an error proved fatal when a nurse mistakenly gave Bupivacaine, an epidural anesthetic, intravenously. Within minutes the patient suffered from a seizure and expired (Medical Ethics Advisor, 2007). The unfortunate theme repeated itself when, in Sydney, Australia a 37-year-old woman suffered the tragic fallout from an epidural medication error. The anesthetist mistakenly used a loss-ofresistance syringe filled with chlorhexidine and alcohol instead of normal saline. It was injected into the patient's epidural space resulting in an acute inflammatory condition necessitating surgery, the clinical consequences of which were various neurologic deficits and paraplegia (Smetannikov, 2011).

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At the 2012 annual meeting of the International Anesthesia Research Society an anesthesiologist, Dr. Santosh Patel, presented results he had compiled from an extensive review of literature. His findings concerning epidural and intrathecal medication administration errors mimic the aforementioned stories, and demonstrate the extensive scope of this problem.

In addition to wrong route, wrong medication, and misconnection errors, the comprehensive review of literature unearthed multiple human and environmental factors as healthcare safety pitfalls. In 2013, the Pennsylvania Patient Safety Advisory examined the issue of distractions as they relate to practitioners involved in complex and rapidly changing healthcare settings. The purpose of this study was to evaluate distractions that may lead to errors, identify instances in which errors are more likely to occur, and recognize key risk reduction strategies to help prevent future errors from occurring. A patient safety database was examined for documented incidents that may have been attributed to distraction. A total of 1,015 reports were evaluated, demonstrating a strong sample size.

The majority of reported events were medication errors (59.6%) followed by errors that related to a procedure, treatment, or test (27.8%). Key terms were identified from the report database revealing that forgetfulness (80.8%), distraction (14.1%) and interruptions (7.3%) account for many of the incidents or events (Feil, 2013).

The study also examines several risk reduction strategies proposed to ameliorate the effect distractions can have in the healthcare setting. These strategies include education for clinicians regarding distractions, promoting vigilance, and implementing effective communication strategies. In summary, distractions have been implicated in the form of both internal and external stimuli, and can have a major impact on patient safety. Clinicians can take

steps toward eliminating distraction as a causative factor in errors by recognizing the common sources of distraction, educating to improve awareness, and taking steps to eliminate the source.

An article published by the American College of Obstetricians and Gynecologists presented a thorough literature review explaining the topic of fatigue and the effect it can have on cognitive and physical function. The importance of minimizing error and confusion is paramount for a safe and effective health care system. The review uncovered multiple studies demonstrating the negative effect of fatigue on the abilities of healthcare providers. In a field such as obstetrics, which does not adhere to standard working hours, it may be assumed that practitioners are at high risk for fatigue. As this study suggests, this could be potentially hazardous when performing technical skills such as epidurals, which require both mental and physical acuity.

The National Sleep Foundation recommends 8 hours of sleep per night. Reviews of medical literature have shown that with less than 5 hours of sleep numeric skills, short-term memory, and concentration all decrease (Fatigue and patient safety, 2012). Problem-solving skills and decision-making have shown to be negatively affected with a lack of sleep.

The implications of quality care being enhanced by increased rest needs additional research. Inevitably, the patient's safety must come first and that this safety is compromised by fatigue or even partial sleep deprivation. Future studies should focus on the direct correlation between patient outcomes and provider fatigue, especially in relation to complex mental and physical skills such as epidural administration.

In Summary, the review of literature has produced recognizable patterns in terms of common epidural-related errors. These themes include human error as a result of multitasking, distraction, or fatigue, errors such as incorrect medication or route, and equipment design flaws contributing to misconnections. This information is helpful as a foundation for promoting change and refining methods in order that patient safety in epidural administration and maintenance may be improved.

## **Project Description**

The focus of this Capstone Project was four-fold and consisted of defining the problem at hand, determining causative factors, addressing ways to improve practice, and compiling this information into an informative presentation. The first aspect (defining the problem) was achieved through in-depth research and analysis of literature. Case studies of known incidents and their outcomes were reviewed as well as articles and studies addressing the weak-points in existing systems and areas where there is the potential for errors to be made. A thorough review of existing literature aided in defining the most common errors made.

The processes and actions leading up to their occurrence were examined. In order to avoid future errors and construct methods to improve safety, there must be a comprehensive understanding as to what factors contributed to the mistakes in the first place. Environmental factors can be physical such as noise and lighting, or conceptual in regards to hospital culture and staff or patient expectations. Individual factors may vary from fatigue and emotional stress to multitasking or knowledge deficit. The elements of existing protocols and devices were also evaluated to determine if they were in any way causal to the error being examined.

The third phase in this venture involved delineating methods for potentially reducing the incidence of the aforementioned epidural errors. The information gleaned from step two (determining causative factors) was used to formulate recommendations for avoiding each

specific error in the future. Every suggested precaution or change in practice correlates specifically with an identified causative factor. For example, if an environmental element is to blame for an error, the recommendation addressed this as well as a proposed method for altering the detrimental environment.

The final stage of the Epidural Safety Capstone Project was centered on educating first year student nurse anesthetists, and can be viewed in three segments. First, a PowerPoint presentation was constructed compiling the wealth of knowledge obtained regarding epidural errors and recommended solutions. This PowerPoint presentation was then used as an aid in teaching the freshman SRNA class. The third segment aimed at evaluating teaching goals. A tenquestion pre-test was administered before the presentation to establish a baseline level of knowledge, and the same test was given afterwards to assess whether the intended subject matter was retained.

## **Evaluation**

The ultimate goal of this Capstone Project was to educate SRNAs on epidural safety in order to reduce the likelihood of future errors, consequently increasing patient safety, avoiding mental and emotional distress on behalf of the SRNA, and potentially protecting their careers in anesthesia. The effects of the education provided may be far-reaching and thus difficult to quantify, but the immediate success of the presentation can be effectively measured through comparison of pre and post-tests. Said testing has provided a concrete, measurable method of evaluating whether the goal was met.

It can be assumed that the target population (first year student nurse anesthetists) has, at best, a very basic understanding of epidural safety. As Registered Nurses, even if they had labor and delivery experience, placing epidurals was not within their scope of practice, and expectations as to epidural management was minimal. The presentation was given before the SRNAs had completed their Anesthesia in Obstetrics and Pediatrics course, and before they had completed their obstetric clinical specialty rotation. The pre-test aimed at assessing this level of understanding, and gave a numeric value that could be compared to the post-test.

Prior to administering the pre-test or presenting any educational material, the objective and evaluation process was clearly explained to the students, and their written consent was obtained. The multiple-choice pre and post-tests were identical, and were returned anonymously. The students were instructed not to identify themselves on the tests. A student volunteer distributed the pre-tests, and collected them upon completion, placing them back in the "pre" envelope, which was returned to the presenters. The same procedure was followed with the posttests once the presentation was been completed.

Data was analyzed based on total numeric scores before education, and after. Successful completion of the intended education was determined by a gross increase of post-test scores. As all SRNAs are required to be proficient in reading, and understand basic multiple-choice test-taking skills, this pre and post-testing method provides an unbiased approach for accurate evaluation of information retention.

As previously mentioned, the ultimate goal of this Capstone project was to promote safe practice in epidural administration and management. This was accomplished by identifying the most common and critical breaches in epidural safety, isolating factors that contribute to these errors, and formulating recommendations for practice changes aimed at eliminating these causal factors. The desired clinical outcome is a decreased incidence of epidural errors by the student nurse anesthetists, and consequently improved patient safety. As this outcome would be very difficult to quantify, the short-term goal of education was measured instead. Pre and post-testing took place to establish whether or not knowledge from the presentation was retained. It was the assumption that effective education with a measureable increase in knowledge regarding safe epidural administration and management would eventually translate to improvements in actual practice.

## **Results and Conclusions**

The results of the pre and post-tests were analyzed and provided a quantitative analysis of the effectiveness of the presentation provided to the first year SRNA class. The following are the results of the statistical analysis. Leven's F score was significant, therefore assumption of equal variances was not assumed. The obtained t-value (-7.910) is associated with p of <. 05, which indicated statistical significance. It, therefore, can be concluded that the mean test scores increased significantly from pre-test (2.4348) to post-test (6.0000). Refer to Appendix C for the complete statistical results.

The objectives of the presentation in regards to awareness and education were achieved and the SRNAs involved were able to improve their post-test scores based on the presentation provided. It was, however, difficult to ascertain the objective of preventing the future practice of the SRNAs in their obstetric rotations in regards to potential errors.

By providing a personal account of a medication error made by one of the presenters in the obstetric setting, the SRNAs expressed the great impact this had on them as they were preparing to embark on the obstetric rotations. The topic of medication errors was researched specifically in regards to the obstetric setting, however the subject can be applied to all avenues of anesthesia care. The presenters were told that the awareness provided through personal accounts as well as documented case studies helped the SRNAs to be reminded of the importance of protocols, vigilance, and situational awareness. Implications for practice include providing education to the future SRNA populations regarding common medication errors that can be made regarding epidural administration and management. Human error, as verified by literature review, is accountable for many mistakes that are made in medical practice and especially in the obstetrical arena. Bringing awareness to the types of errors that could occur and strategies to prevent them is imperative to create the safest environment for the patient, holding true to the standards by which SRNAs and Nurse Anesthetists are accountable.

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## Appendix A

## **Informed Consent**

Thank you for agreeing to participate in this research by Anna Kadeg, BSN, RN SRNA and Megan Cooper, BSN, RN, SRNA. This Capstone project focuses on educational research involving the safe administration and management of epidural anesthesia in the obstetric population. The project is geared towards Student Registered Nurse Anesthetists (SRNAs) as many factors of being a student can contribute to the risk of common errors. The ultimate goal of this project is to promote safe practice in epidural administration and management, from the role of an SRNA. If you agree to be a part of this study, you will be asked to take a pre-test on the subject matter before the presentation and a post-test after the presentation we provide.

All records and results of this study will be kept private. Being involved in this study is voluntary and all answers to the questions will be kept confidential. The answers you provide will not be linked to your name and will only be used for evaluation of this project. You are able to willingly withdraw from the study at any time and discontinue participation without penalty.

Statement of Consent: I have read the above information and any questions that I have asked have been answered. I hereby give my consent for the study.

Student

Name\_\_\_\_\_

Student

Signature Date

Appendix B

## **Pre and Post Test**

1) Creating a more organized work atmosphere to decrease potential risk for epidural errors includes all of the following except:

Placing IV pumps on the opposite side of the bed from the epidural pump Creating a calm environment in the room Allowing multiple family members in the room for support of the patient

Verifying the "5 Rights" of epidural medication administration

2) Which of the following are considered appropriate safe practice? (choose 3)

A) Accepting a labeled, dated, and timed syringe of local anesthetic from the off-going night shift CRNA

B) Verifying epidural pump settings with your CRNA preceptor before starting the infusion

C) Preparing the epidural administration pump and settings before placing the epidural

D) Drawing up multiple epidural bolus syringes at the start of your shift to be prepared for emergencies

E) Removal of the epidural immediately upon positive test dose administration

You are observing your CRNA preceptor as he inserts an epidural for a 63 kg, 31-year-old laboring female. He states, "I had marked loss of resistance and negative aspiration. There's no question I'm in the epidural space so there's no need for a test dose." He administers the entire bolus through the epidural needle.

3) Which of the following are potential complications of this unsafe practice?

A) Intravascular injection

B) Intrathecal Injection

C) Ineffective analgesia

D) All of the above

4) The patient's mother has remained in the room for placement of the epidural and appears to be escalating the patient's anxiety. The correct action in this situation would be:

- A) Use it as a learning opportunity; performing under stress is an important skill to cultivate.
- B) Send nonverbal cues to the nurse indicating your dissatisfaction. She should interpret these and intervene on your behalf.
- C) Bring the husband into the room to help calm the patient and her mother by changing the topic of conversation.
- D) Politely ask the patient's mother to step out explaining your need to minimize distractions to ensure the safety and success of the procedure.

5) The parturient is experiencing frequent contractions during placement of the epidural and the CRNA suggests you administer a bolus of local anesthetic before threading the catheter. The appropriate action would be to:

- A) Administer the dose but only after negative aspiration
- B) Confirm a negative test dose before giving the bolus
- C) Administer the bolus and monitor for signs of toxicity
- D) Politely assert that you would rather administer the test dose and bolus through the catheter.

An actively laboring patient complains of extreme pain and upon assessing her epidural blockade you find it to be inadequate. You proceed to review her pump settings and find her catheter is open and disconnected from the tubing, which is hanging from the pump and uncapped.

6) The appropriate course of action in this case would be:

A) Thoroughly swab both the end of the tubing and the patient's catheter with alcohol, aspirate to check placement, administer a bolus, re-connect the tubing, and re-start the pump after having reviewed the settings.

B) Immediately cover the patient's catheter with sterile gauze, and remove the epidural as soon as possible.

C) Obtain a new bag and tubing. Thoroughly swab the patient's catheter with alcohol and allow it to dry. Aspirate to check placement, connect the new tubing, bolus, and start the pump.

D) Obtain new tubing, re-spike the bag to reduce waste, and after cleansing and aspirating, connect, bolus, and re-start infusion.

7) A nurse enters the room as you are navigating the disconnect issue, and states she has been looking for you. She realized after disconnecting the catheter and administering an IV medication that it was, in fact, the epidural. What measure(s) is (are) encouraged to avoid this type of error?

- A) Carefully perform the "5 rights" of medication administration
- B) Minimize distraction when administering medications
- C) Clearly label the epidural catheter
- D) Use barcode technology when available, heeding alert messages

## E) All of the above

# Appendix C

# **Group Statistics**

	Group	Ν	Mean	Std. Deviation	Std. Error Mean		
Scores	Pre-Test	23	2.4348	2.01869	.42093		
	Post-Test	23	6.0000	.73855	.15400		

# **Independent Samples Test**

		Levene's Test for Equality of Variances F	t-test for Equality of Means						
			Sig.	t	df	Sig. 2- tailed	Mean Difference	Std. Error Differe nce	95% Confidence Interval of the Difference
Scores	Equal variances assumed	32.097	.000	-7.954	44	.000	-3.56522	.44821	Lower= -4.46583 Upper= -2.66191
	Equal variances not assumed			7.954	27.786	.000	-3.56522	.44821	Lower= -4.48366 Upper= -2.64678

Appendix D

#### 2/16/16













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### 2/16/16









#### CASE SCENARIO:

- What can we take away from this tragedy, and the many others like it?
- Follow protocol, as well as your "gut"
   Pinkish tinge of Chlorhexidine was mistaken for blood left over from positive aspiration
- If there is any question, pull out and start over
   Label all medications
- Label all medications
   The "5 rights" aren't just for IV medications!
- Report all errors and near-misses • Protocols and processes can be updated to eliminate common pitfalls



### 2/16/16

• Be knowledgeable of and adhere to both AANA and institution-specific standards • Monitoring • Sterile technique a stemin technique
b Proper insertion technique
c Checking placement and test dose
"Five Rights" and proper drug dosing
temposis on "Right Route"
temposis on "Right Route"
temposis on "Right Route"
temposite relative and has technique allo report of eputant to
macconcepte, the taggest information source of tube
macconcepte, the taggest information source of tube
temposite relative and has technique allo report of eputant to
control place sources.
The start of the star • Troubleshooting

#### In Summary...

- There is no such thing as a risk-free procedure Errors will be made, but being mindful of the factors which contribute to them will decrease their severity and frequency
   Epidural administration and management is one of the more difficult responsibilities of a CRNA.
- Setting yourself up for success by eliminating risk factors has the potential to save lives and licenses





