Exploring Production Pressure and Normalization of Deviance and Their Relationship to Poor Patient Outcomes

Marjorie Geisz Everson, PhD, CRNA, FNAP
Bryan A. Wilbanks, PhD, DNP, CRNA
Rebecca R. Boust, MSNA, CRNA

Production pressure and/or normalization of deviance contribute to poor patient outcomes. The purpose of this study was to explore the relationship between production pressure and normalization of deviance to poor patient outcomes. A team of experienced qualitative researchers conducted a metasynthesis of all qualitative closed claims studies that used the American Association of Nurse Anesthetists (AANA) Foundation Closed Claims database and were accepted for publication at the time of the study. Three central concepts emerged from the analysis: (1) impaired culture of safety, (2) violations of standards of care, and (3) impaired patient safety and outcomes. It is imperative that anesthesia providers support a culture of safety and follow AANA Standards for Nurse Anesthesia Practice.

Keywords: Normalization of deviance, patient outcomes, production pressure.

Production pressure and/or normalization of deviance (NOD) contribute to poor patient outcomes. Production pressure is both a specific type and cause of NOD. Production pressure is well known and written about in other industries such as aviation and construction. The few articles written about production pressure/NOD and anesthesia note that it occurs in the operating room and contributes to anesthesia mishaps. Gaba et al. describe production pressure as “overt or covert pressures and incentives on personnel to place production, not safety, as their primary priority.” Normalization of deviance is the gradual process in which unacceptable practice or standards become acceptable; as the deviant behavior is repeated without catastrophic results, it becomes the norm for the organization. The purpose of closed claims research is to identify patient safety issues and develop strategies to prevent them.

Production pressure can have a negative impact on many aspects of healthcare. When production pressure increases, there is a corresponding rise in the occurrence of unsafe work practices by healthcare providers. Healthcare organizations that emphasize production pressure more than patient safety can result in healthcare workers intentionally not reporting potential patient safety issues. Production pressure can also increase risk-taking behaviors, promotes communication failures between clinicians, and increases clinician workload. Overall, production pressure has a negative impact on patient safety secondary to all the factors previously mentioned.

To date, 7 qualitative studies using the American Association of Nurse Anesthetists (AANA) Foundation closed claims database have implicated production pressure and/or NOD in poor patient outcomes. The AANA Foundation closed claims researchers, in conjunction with CNA Insurance Company, created a database of 245 claims from the years 2003 to 2012 that were considered closed. Once the database was created, teams assembled and conducted various studies using the database. This study used a descriptive qualitative metasynthesis approach that integrates the findings from within a program of research conducted by the same investigators (ie, AANAF closed claims studies). The purpose of this descriptive metasynthesis was to integrate results of qualitative closed claims studies that mentioned production pressure and/or NOD to discern their relationship to patient outcomes.

Materials and Methods
A team of 3 experienced qualitative researchers was assembled to conduct a metasynthesis of all qualitative closed claims studies that were accepted for publication related to production pressure and/or NOD. These studies used the AANAF closed claims database. Eight qualitative articles that used the AANAF closed claims database and were accepted for publication were found, all of which have since been published; 7 of these articles were included in this metasynthesis because of the mention of production pressure or NOD. The team used metasynthesis guidelines outlined by Sandelowski and Barroso, which use a thematic synthesis. Table 1 depicts the steps taken for this study.

The steps of a metasynthesis includes framing, searching, rating, synthesizing, and reporting. The research...
question used to guide this study is “What are the descriptions of production pressure and NOD as they relate to patient safety and outcomes?” Since this study’s purpose was to synthesis the findings from a single program of research (ie, AANAF closed claims teams), there was no need to search the literature for other studies. The synthesizing process incorporated a qualitative thematic analysis method that first formed codes, organized codes into categories, and then formed themes from categories. The reporting phase of a metasynthesis involves reporting enough information about the study so that others can audit or replicate the process. The literature for this metasynthesis is summarized in Table 2.

Results
The qualitative analysis of the studies identified 3 overarching concepts. Central concepts that emerged included (1) impaired culture of safety, (2) violations of standards of care, and (3) impaired patient safety and outcomes. See the Figure for the conceptual relationships. These concepts and relationships are clarified here with supporting evidence identified during the metasynthesis.

- **Production Pressure and Normalization of Deviance.** Production pressure and NOD have a reciprocal relationship in which the presence of one can increase the other because these concepts are highly interrelated.

For example, in one case the Certified Registered Nurse Anesthetist (CRNA) had production pressure in the form of increasing the number of surgical cases per day. This production pressure resulted in abbreviated documentation and inadequate patient monitoring during a regional anesthetic in the preoperative holding area. The inadequate documentation and lack of patient monitoring was acceptable practice at this facility (ie, NOD occurred because of production pressure). In another example, NOD was represented by a facility whose management created guidelines that encouraged quicker surgical turnovers and allowed patients with major comorbidities to be operated on at a facility that was not equipped to handle them. These official guidelines represent NOD promoting production pressure.

- **Impaired Culture of Safety.** The Joint Commission defines culture of safety as “the product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the organization’s commitment to quality and patient safety.”

Production pressure and/or NOD directly impaired the culture of safety, which then directly contributed to poor patient safety and outcomes. An illustration of this involves a case in which a CRNA started a case with a pulse oximetry (SpO₂) monitor that was not registering, and the CRNA assumed it was because the patient was obese. The CRNA also noted that this particular monitor did not work sometimes, yet proceeded with the case. After induction and intubation, the CRNA confirmed endotracheal tube placement by auscultating bilateral breath sounds and chest excursion. After intubation, it was discovered that the end-tidal carbon dioxide (ETCO₂) and gas analysis monitors were not working either. The patient became bradycardic and cyanotic, requiring cardiopulmonary resuscitation and reintubation. Additional monitors were finally brought to the operating room, and the patient was successfully resuscitated; however, the patient never regained consciousness and requires permanent mechanical ventilation.

Additionally, an impaired culture of safety resulted in the occurrence of production pressure and NOD (ie, a bidirectional causal relationship exists between culture of safety and production pressure/NOD). For example, a freestanding clinic that has a policy that allows for ASA 3 or 4 patients even though it lacks the resources to appropriately manage complications creates an impaired culture of safety. A 36-year-old morbidly obese woman with several comorbidities presented for a transvaginal oocyte retrieval at a freestanding clinic that did not have the proper lithotomy positioning equipment (nurse held legs over her shoulders), no difficult airway equipment, and no method for continuously measuring ETCO₂. The patient experienced a compromised airway that the nurse anesthetist was not able to secure. The patient died shortly after emergency medical services delivered the patient to the emergency department. In this example, the culture of safety was impaired by the organizational policy that allowed sedation of patients with substantial comorbidities and the performance of the procedure without adequate equipment (including patient positioning, required physiologic monitors, and difficult airway supplies).

- **Violations of Standards of Care.** The standards of care for nurse anesthetists are defined by the AANA and are intended to assist with assessing the quality of care provided to patients, create a common base for nurse anesthetists to inform their own clinical practices, educate the general public in what to expect from nurse anesthetists.

![Table 1. Steps Taken in Metasynthesis](image-url)
A regional anesthetic was appropriate documentation that accurately outlined the history was normal), did not preoxygenate the patient with a pencil-sized stoma from a previous laryngectomy was scheduled for a lower-extremity orthopedic procedure. The CRNA did not conduct an appropriate preanesthesia assessment (ie, did not recognize that the patient had a stoma and documented that the patient's medical history was normal), did not preoxygenate the patient before induction of general anesthesia, did not formulate an appropriate anesthesia plan, and did not have appropriate documentation that accurately outlined the sequence of patient care events. A regional anesthetic was an appropriate choice for the case; however, the CRNA chose to provide a general anesthetic and attempted to orally intubate the patient, which was unsuccessful after numerous attempts. Finally, a small endotracheal tube was inserted into the stoma, and the patient was able to be ventilated. Despite the eventual stoma intubation, the patient sustained anoxic encephalopathy.

**Impaired Patient Safety and Outcomes.** The impaired patient safety and outcomes identified in this metasynthesis were associated with production pressure and/or NOD. Examples of identified issues that were associated with impaired patient safety include the failure to use appropriate physiologic monitoring equipment, unavailability of difficult airway equipment, failure to adequately assess the patient before anesthesia services, failure to appropriately monitor the patient during the delivery of anesthesia services, providing intravenous medications without assessing the patient's need for them (eg, “It is the way I always do it”), and inappropriate transfer of care (eg, inappropriate location or premature discharge home). Some examples of poor patient outcomes included nerve damage (eg, permanent neurologic deficit from an epidural anesthetic), respiratory compromise requiring endotracheal intubation, cardiopulmonary arrest, anoxic encephalopathy (ranging from mild cognitive impairment to brain death), and death.

Normalization of deviance represents a break in the

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<thead>
<tr>
<th>Author, y</th>
<th>Topic</th>
<th>Major factors contributing to adverse outcomes</th>
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<tr>
<td>Clayton et al, 2018</td>
<td>Obstetric patients receiving anesthesia</td>
<td>(1) Delayed recognition, diagnosis, and treatment of adverse events; (2) interdisciplinary communication failures; (3) poor documentation quality; (4) unrecognized/delayed treatment of hemorrhage; and (5) lack of vigilance</td>
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<td>Geisz-Everson et al, 2019</td>
<td>Cardiovascular complications in noncardiac surgeries</td>
<td>(1) Normalization of deviance, (2) poor preanesthetic evaluations, (3) inappropriate medications, (4) hemorrhage, and (5) knowledge deficit/failed clinical reasoning</td>
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<td>Golinski &amp; Hranchook, 2019</td>
<td>Cosmetic surgery</td>
<td>(1) Normalization of deviance, (2) ineffective communication patterns, and (3) nonadherence to AANA standards of practice</td>
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<td>Hirsch et al, 2019</td>
<td>Regional anesthesia</td>
<td>(1) Errors in cognitive decision making, (2) ineffective communication patterns, and (3) production pressure</td>
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<td>Hranchook et al, 2018</td>
<td>Patient anesthesia</td>
<td>(1) Patient factors, (2) provider factors, and (3) environmental factors</td>
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<td>Kremer et al, 2019</td>
<td>Preventable anesthesia complications</td>
<td>(1) Communication failures, (2) violations of AANA standards, and (3) errors in judgment</td>
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<td>Wilbanks et al, 2016</td>
<td>Role of documentation quality in closed claims</td>
<td>Because documentation is assumed to be equal to provider competence, poor documentation (1) increases legal liability, (2) impairs patient safety because incorrect information is used to make clinical decisions, and (3) allows malpractice claims that would otherwise not have been initiated</td>
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<td>Wilbanks et al, 2018</td>
<td>Role of transfer of care in anesthesia-related adverse events</td>
<td>(1) Taking patient to inappropriate level of care, (2) production pressure causing normalization of deviance, (3) providers relying exclusively on someone else’s patient assessment rather than doing their own, (4) communication failure, (5) inadequate monitoring or patient assessment, and (6) patient handovers occurring during critical events</td>
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*Abbreviation: AANA, American Association of Nurse Anesthetists.*

*Overview of the AANA Foundation closed claims program of research used in this metasynthesis.*
culture of safety. When the culture of safety results in adverse patient outcomes from NOD, it is most often the result of multiple individuals engaging in unsafe clinical practices, as opposed to a single individual. Examples of NOD due to an impaired culture of patient safety that were reported in the literature include removing physiologic monitors before emergence from anesthesia to promote efficiency in room turnover and failure to monitor neuromuscular function with use of neuromuscular blocking medications. These deviations from safe clinical practices can be minimized by continuous assessment of an organization’s current clinical practices with the standards of care, which are discussed in the next section.

Discussion

• Production Pressure and Normalization of Deviance. Production pressure is the emphasis on increasing efficiency, output, or continued productivity to increase monetary gain at the expense of patient safety. Normalization of deviance occurs when unacceptable practices gradually become acceptable over time because no immediate adverse outcomes are experienced. The studies in this metasynthesis identified that the concepts of production pressure and NOD have a reciprocal relationship in which the presence of one increased or caused the occurrence of the other. Additionally, production pressure and NOD were sometimes used synonymously. There is a great deal of overlap between the concepts of production pressure and NOD.

As previously discussed, production pressure can cause NOD. For example, an emphasis on increasing the total number of surgical cases completed in a single workday has resulted in the premature discharge of patients from the postanesthesia care unit with patients experiencing respiratory compromise at home. Also, office-based anesthesia settings can experience pressure from surgeons and patients to perform elective procedures in a timely manner without complete preoperative assessments or safety checks. Normalization of deviance can cause production pressure by the impact on an organization’s culture of safety, which is discussed in the next paragraph.

• Impaired Culture of Safety and Impaired Patient Outcomes. An organization’s culture of safety is determined by its members’ overall values, attitudes, and behaviors that inform safety management practices. Some features of a culture of safety include organizational commitment of resources to address patient safety, a nonpunitive environment in which individuals are encouraged to report errors or near-misses, collaboration across ranks and disciplines to seek solutions to patient safety problems, and analysis of safety surveys to seek opportunities for safety and quality improvement. A culture of safety can include appropriate workload levels, assessment of clinician fatigue, vigilance for the occurrence of NOD, and a focus on quality improvement.

The Joint Commission and the Agency for Healthcare Research and Quality assert that inadequate organizational leadership regarding a culture of safety can lead to adverse outcomes. Not only must leaders commit to maintaining a culture of safety, they also must be consistently promoting and supporting it. A large determinant of the culture of safety is determined by the policies and procedures set by an organization’s executive leadership. Policies and procedures that explicitly support a culture of safety have been shown to mitigate the adverse
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<th>Standard (2019 revised No.)</th>
<th>Violation</th>
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<td>I (2): Perform and document a thorough preanesthesia assessment and evaluation</td>
<td>Morbidly obese patient presented for procedure using regional anesthesia. CRNA did not conduct a thorough preanesthesia evaluation and did not assess airway. Had to convert to general anesthetic, was unable to ventilate or intubate, and did not have difficult airway cart immediately available. CRNA was finally able to intubate, but patient sustained anoxic encephalopathy. Patient had previous anesthesia complications; however, the CRNA did not review the patient’s chart and did not know this.</td>
<td>Conduct thorough preanesthesia assessment and evaluation. Assess airway, even if the procedure is scheduled using regional anesthesia or MAC. Review the patient’s chart for previous anesthesia and/or medical records and notes.</td>
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<td>IV (7): Implement and adjust the anesthesia care plan based on the patient’s physiologic status. Continuously assess the patient’s response to the anesthetic, surgical intervention, or procedure. Intervene as required to maintain the patient in optimal physiologic condition.</td>
<td>Elderly patient with multiple comorbidities was scheduled for a procedure in the cardiac catheterization laboratory. The patient was connected to monitors and administered sedation. No supplemental oxygen was administered, even though the SpO2 was in the low 80s mm Hg and the patient was hypotensive and bradycardic. The CRNA thought the monitors were malfunctioning and began to troubleshoot the equipment. The cardiologist noted dark venous blood and a motionless heart via fluoroscopy. The CRNA was still troubleshooting the “malfunctioning” equipment, which showed hypotension, bradycardia, and low SpO2. Advanced cardiac life support commenced, and the patient was resuscitated but sustained anoxic encephalopathy.</td>
<td>Be vigilant. Continuously monitor patient. Use patient assessment along with monitors (palpate patient’s pulse, assess mucous membrane color, etc). Administer oxygen when sedating patient (unless contraindicated).</td>
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<td>V (9): Monitor, evaluate, and document the patient’s physiologic condition as appropriate for the type of anesthesia and specific patient needs. When any physiological monitoring device is used, variable pitch and threshold alarms shall be turned on and audible. The CRNA should attend to the patient continuously until the responsibility of care has been accepted by another anesthesia professional.</td>
<td>Patient undergoing eye procedure under general anesthesia had hypotension. Anesthesia gas was decreased and a vasoactive medication administered. Patient “bucked” and sustained permanent vision loss. A muscle relaxant was administered at beginning of case, but twitches were not monitored or documented.</td>
<td>Be vigilant. Monitor neuromuscular response when muscle relaxants are used. Be cognizant of depth of anesthesia.</td>
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<td>VII (11): Evaluate the patient’s status and determine when it is safe to transfer the responsibility of care. Accurately report the patient’s condition, including all essential information, and transfer the responsibility of care to another qualified healthcare provider in a manner that assures continuity of care and patient safety.</td>
<td>Obese patient was scheduled for ventral hernia repair. CRNA conducted a preanesthesia assessment and was told to go to lunch. The patient vomited between when the CRNA went to lunch and he or she met the relief CRNA, but this was not reported to either CRNA. A rapid-sequence induction with cricoid pressure commenced, and the patient had a copious amount of green bile in the airway that had to be suctioned before intubation. Once the patient was intubated, copious amount of green bile was suctioned from the endotracheal tube. The patient rapidly deteriorated and required resuscitation, which was unsuccessful.</td>
<td>The transfer-of-care process needs to incorporate continuous patient assessment. Standardized handoff tools should be used whenever possible.</td>
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<td>VIII (14): Adhere to appropriate safety precautions as established within the practice setting to minimize the risks of fire, explosion, electrical shock, and equipment malfunction.</td>
<td>Elderly patient was having multiple facial lesions excised. The CRNA placed a face mask on patient with 8 L/min of oxygen flowing through it. Electrocautery was used, and fire ensued. Patient sustained second-degree burns.</td>
<td>Use best practices for high-risk procedures. Use room air if possible. If not, use &lt; 30% FIO2. Make sure equipment is functioning before using on patient.</td>
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Table 3. Examples of Violated Standards of Care and Mitigation Strategies

Abbreviations: CRNA, Certified Registered Nurse Anesthetist; FIO2, fraction of inspired oxygen; MAC, monitored anesthesia care; Spo2, oxygen saturation measured by pulse oximetry.
outcomes associated with production pressure. The culture of patient safety is one of the largest predictors of the occurrence of adverse anesthesia events.

- **Standards of Care.** The AANA Standards for Nurse Anesthesia Practice guide CRNA practice and are meant to “support the delivery of patient-centered, consistent, high-quality, and safe anesthesia care and assist the public in understanding the CRNA’s role in anesthesia care.” Standards of care are used to compare a provider’s actions with what is expected. Deviation from standards of care that result in patient injury is considered malpractice. Even when standards of care are followed, poor outcomes may still occur; however, the provider’s actions are more defensible. Peckham found that 58% of anesthesiologists who were involved in malpractice suits reported following standards of care. Her study found that failure to follow safety procedures, poor documentation, and improper or lack of informed consent were violated standards of care. No reasons were given for the violations. Posner found that payments were more likely and/or higher in anesthesia-related lawsuits if there was evidence of failure to follow standards of care. It is vital that CRNAs have knowledge of and follow the AANA Standards for Nurse Anesthesia Practice; this includes student registered nurse anesthetists.

### Conclusion

Production pressure can have a negative impact on many aspects of healthcare. When production pressure increases, there is a corresponding rise in the occurrence of unsafe work practices by healthcare providers. The purpose of this descriptive metasynthesis was to integrate results of qualitative closed claims studies that mentioned production pressure and/or NOD to discern their relationship to patient outcomes. Central concepts that emerged included (1) impaired culture of safety, (2) violations of standards of care, and (3) impaired patient safety and outcomes. These concepts are highly interrelated.

Production pressure or NOD directly impairs the culture of safety, which then directly contributes to poor patient safety and outcomes. Interventions that may improve a culture of safety can include assessment of appropriate workload levels, assessment of clinician fatigue, vigilance for the occurrence of NOD, and a focus on quality improvement. A culture of safety can help mitigate the negative impact of production pressure on patient safety and outcomes.

Nonadherence to the standards of care directly led to impaired patient safety and adverse outcomes in all the reviewed studies for this metasynthesis. It is vital that CRNAs have knowledge of and follow the AANA Standards for Nurse Anesthesia Practice. Production pressure may result in failure to follow the standards of care, and it is important for anesthesia providers to analyze current clinical practice routines to national standards because NOD may result in the acceptance of inappropriate clinical practices.

Examples of identified issues that were associated with impaired patient safety include the failure to use appropriate physiologic monitoring equipment, unavailable difficult airway equipment, failure to adequately assess the patient before anesthesia services, failure to appropriately monitor the patient during the delivery of anesthesia services, providing intravenous medications without assessing the patient’s need for them (eg, “It is the way I always do it”), and inappropriate transfer of care (eg, inappropriate location or premature discharge home). These issues related to impaired patient safety commonly result in preventable adverse outcomes.

### REFERENCES

graphic_11_tenets_safety_culture.pdf


AUTHORS
Marjorie Geisz Everson, PhD, CRNA, FNAP, is a faculty member of Johns Hopkins University Nurse Anesthesiology Track and a CRNA at Benefis Health System in Great Falls, Montana. Bryan A. Wilbanks, PhD, DNP, CRNA, is an assistant professor at the University of Alabama in Birmingham, Alabama. Email: bwilbanks@uab.edu. Rebecca R. Boust, MSNA, CRNA, is a CRNA at Atchison Hospital in Atchison, Kansas. Email: rebeccaboust@hotmail.com.

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