

Advocacy, Research, and Anesthesia Practice Models: Key Studies of Safety and Cost-Effectiveness

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Abstract

The practice of anesthesia includes multiple competing practice models, including services delivered by anesthesiologists, independent practice by certified registered nurse anesthetists (CRNAs), and team-based approaches incorporating anesthesiologist supervision or direction of CRNAs. Despite data demonstrating very low risk of death and complications associated with anesthesia, debate among professional societies and policymakers persists over the superiority or equivalence among these models. The American Society of Anesthesiologists uses published findings as evidence for claims that anesthesia is safer when anesthesiologists lead in providing care. The American Association of Nurse Anesthetists cites its own research on safety and cost-efficiency outcomes to defend against these claims. We review and critique studies of the safety outcomes and cost-effectiveness of anesthesia delivery that have been cited in the Federal Trade Commission comment letters related to competition in health care, where each profession has laid out their case for how they ought to be recognized in the market for anesthesia services. The Federal Trade Commission has a role in protecting consumers from anticompetitive conduct that has the potential to impact quality and cost in health care. Thus, it is important to evaluate the evidence used to make claims about these topics. We argue that while research in this area is imperfect, the strong safety record of anesthesia in general and CRNAs in particular suggest that politics and professional interests are the main drivers of supervision policy in anesthesia delivery.

Keywords

nurse anesthetists, anesthesiology, anesthesia, perioperative care, politics, research

Anesthesia is safe. Modern anesthesia techniques, medications, and superior training have reduced the rate of anesthesia mortality risk to approximately one death per 100,000 anesthetic administrations (Li, Warner, Lang, Huang, & Sun, 2009). In 1990, the Centers for Disease Control and Prevention (CDC) proposed research on morbidity and mortality in anesthesia (American Association of Nurse Anesthetists [AANA], 2009). However, after reviewing preliminary data by Klaucke, Revicki, and Brown (1988), the CDC concluded that the morbidity and mortality rates in anesthesia were too low to warrant a multimillion-dollar study. Essentially, they found that anesthesia has become extremely safe, and its mortality risk is too difficult to gauge precisely. Mortality and complication rates are not the only or

best indices of the quality of anesthesia services, but they are the easiest to measure and therefore among the most investigated outcomes. Despite the rarity of deaths and anesthesia-related complications, political and economic influences still drive significant debate among anesthesia professionals and policymakers over the types of anesthesia practice models that should be permitted in operating rooms.

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There are two leading providers of anesthesia services in the United States, anesthesiologists and certified registered nurse anesthetists (CRNAs), who compete in the market for anesthesia service delivery. Both are active in political advocacy related to professional practice and federal reimbursement regulations.

The purpose of this analysis is to examine some of the key studies used to advocate and defend one provider type's position or oppose the other side. We examine the background and history of the anesthesia professions, including the relationship between anesthesiologists and CRNAs, the development of each profession's advocacy organization, and how each type of clinician practices anesthesia today. Next, we review research findings on the outcomes for safety and cost and the underlying assumptions of studies that the AANA and the American Society of Anesthesiologists (ASA) have cited in their comment letters to the Federal Trade Commission (FTC). We critically evaluate these findings and assess how they have been used for advocacy. Finally, we explore the implications of basing policy decisions on the claims of superiority or equivalence among CRNAs and anesthesiologists and try to offer insight into additional forces driving the contentious arguments over anesthesia practice models.

Background

History of Anesthesia Professions

The first public demonstration of anesthesia was conducted in 1846 by a dentist at Massachusetts General Hospital (Ray & Desai, 2016). The earliest providers of anesthesia were typically medical students, junior physicians, nurses, and even orderlies. Initially, physicians were generally not drawn to anesthesia other than as a means to learn surgical techniques, yet many surgeons saw a need for a trained specialist solely focused on the safety and comfort of the anesthetized patient (Bankert, 1989). Due to the relatively lower pay and status compared with surgery or other medical specialties, many came to rely on trained nurses as providers of anesthesia (Bankert, 1989). Nurses, including many Catholic nuns, were instrumental in spreading knowledge and developing training programs around the country during the late 19th and early 20th centuries. As a result, hospital-based anesthesia training programs for nurses proliferated during the late 19th and early 20th centuries, in addition to some programs for physicians (Gunn, 1991). Major centers of research and training for early nurse anesthetists included the Mayo Clinic and Lakewood Hospital in Cleveland, where open drop ether and nitrous oxide techniques, respectively, were pioneered (Bankert, 1989).

By the late 1910s, anesthesia was largely considered a nursing activity in the physician psyche (Bankert, 1989);

however, physician advocates led by Ralph Waters and Francis McMechan worked diligently in this era to establish anesthesia as a medical specialty. Their tactics included establishing state and regional professional societies, lobbying state medical boards and hospital trustees for the exclusion of nurses from anesthesia practice, and questioning the ethics of surgeons working with nurse anesthetists (Bankert, 1989). These efforts culminated in the first legal challenges by physicians to the practice of anesthesia by nurses in Ohio in 1916, Kentucky in 1917, and California in 1934 (Ray & Desai, 2016). In each case, anesthesia practice rights for nurses prevailed.

Ralph Waters established the first medical anesthesia residency program at the University of Wisconsin in 1927. Over time, graduates of that program started other programs around the country (Ahmad & Tariq, 2017). The New York Society of Anesthetists began certifying fellows in 1936 (Betcher, 1982). That same year, it changed its name to the American Society of Anesthetists, becoming a national organization in compliance with requirements of the Advisory Board for Medical Specialties. Despite some initial resistance, the American Medical Association approved anesthesia as a medical specialty in 1940, and in 1944, the American Society of Anesthetists name was changed again to the ASA (Betcher, 1982).

The National Association of Nurse Anesthetists was founded in 1931 and later renamed as the AANA in 1939. The organization finalized the first formal educational standards for anesthesia programs in 1935 and implemented program accreditation standards by 1952 (Ray & Desai, 2016). In 1956, the first credentialed nurse anesthetists began practicing, and the profession adopted the title *certified registered nurse anesthetist*.

The AANA and the ASA developed a pattern of bitter conflict and ardent disagreement over independent practice for nurse anesthetists and the relationship between the two anesthesia professions. In the post-World War II era, the ASA made several moves to undermine the nurse anesthesia profession. Among them were a public relations campaign focused on anesthesia as the domain of medicine and an ethics code prohibiting members from participating in the training of nurse anesthetists (Bankert, 1989). In the 1960s, relations between the AANA and ASA briefly thawed as the ASA realized that physicians alone could not support the rapidly growing anesthesia workload. In 1972, the AANA and ASA released a joint committee statement acknowledging a collaborative relationship as the ideal, although conceding it would remain challenging (Bankert, 1989). Things deteriorated quickly after the ASA used this statement to lobby the Office of Education for greater control of the accreditation program for CRNAs. In a letter to Congress in 1975, the AANA president

suggested that there was no evidence of differences in the quality of practice between CRNAs and anesthesiologists, a point that has ever since remained highly contentious. The ASA subsequently withdrew from the joint statement in 1976 and endorsed a new Anesthesia Care Team (ACT) model that placed an anesthesiologist in a leadership role (Bankert, 1989).

Current Policy and Practice

As of 2018, there were approximately 39,000 CRNAs and 37,000 medical doctor anesthesiologists (MDAs) actively practicing and billing Medicare (Quraishi, Hoyem, & Jordan, 2018) in three predominant models of anesthesia care. These include an ACT utilizing a ratio of one MDA for a variable number of CRNAs, an MDA practicing solo, or a CRNA practicing autonomously.

Clinical autonomy means having the authority to make patient care decisions using one's own knowledge and training within the full scope of practice in accordance with existing rules and regulations (Weston, 2008). Additional providers include anesthesiologist assistants (AAs), who are trained to work exclusively in a directed care model, and registered nurses who provide sedation for procedures such as endoscopy. Unlike AAs and sedation nurses, CRNAs may practice without medical supervision where allowed.

In 1982, Congress passed the Tax Equity and Fiscal Responsibility Act with an amendment establishing the current policy governing billing regulations for the direction and supervision of Medicare anesthesia service provider reimbursement. For an anesthesiologist to bill Medicare for the medical direction of anesthesia services, seven requirements must be met: (a) perform a preanesthetic evaluation; (b) prescribe an anesthesia plan; (c) participate in the most demanding procedures, including induction and emergence; (d) ensure that anesthesia procedures, if not personally performed, are performed by a qualified anesthetist (CRNA, AA, or resident); (e) monitor at frequent intervals; (f) remain physically present and available in case of emergencies; and (g) provide postanesthesia care.

The Omnibus Budget Reconciliation Act of 1986 made nurse anesthetists the first nursing specialty that was allowed direct reimbursement rights under the Medicare program. Thus, a CRNA may provide care and bill Medicare directly for anesthesia services, similar to an anesthesiologist. Reimbursement amounts for anesthesia services are determined using *base units*, which are associated with anesthesia Current Procedural Terminology codes in accordance with the complexity of the procedure, and *time units* delineated by the duration of the anesthesia procedure. The sum of the base and time units multiplied by an anesthesia conversion factor specific to the locality of the anesthesia service determines the allowable charge.

Medicare payment rules vary depending on the type of practice model. An anesthesiologist or a CRNA practicing autonomously can bill for 100% of the anesthesia services they provide. Anesthesia services that are medically directed, meaning provided by both an anesthesiologist and a CRNA or an AA working in an ACT, are reimbursed at a rate of 50% for each provider as long as the ratio of anesthesiologists to CRNAs is no greater than 1:4. Accordingly, anesthesiologists directing four concurrent cases collect 200% of the revenue compared with performing a single case. In ACT models where the ratio of anesthesiologists to CRNAs is greater than 1:4, the CRNA requests reimbursement for 50% of the fee, but the anesthesiologist may only request reimbursement for two or three base units. A modifier attached to each claim indicates the type of provider or practice model. The QZ modifier designates a CRNA practicing without medical direction, and the AA modifier designates an anesthesiologist practicing alone. Direction modifiers include QY for anesthesiologists directing one procedure and QK for two to four procedures. An anesthesiologist uses the AD modifier when supervising more than four concurrent procedures. The directed CRNA or AA also submits a claim for the service with the modifier QX. Documentation to comply with Medicare billing regulations for supervision and direction may be onerous. While the total billing revenue may be similar for directed and undirected cases, the inefficiency and administrative complexity associated with Tax Equity and Fiscal Responsibility Act compliance means that financial officers and clinical administrators must weigh the associated risks and labor costs of lower ratios of anesthesiologists to CRNAs, the potential for case delays, the likelihood of lapses in supervision, and the potential for Medicare billing fraud if anesthesiologists do not fulfill all the requirements of medical direction. Some anesthesiologists discourage billing Medicare using the QZ modifier claiming that it diminishes their contributions to the ACT (Byrd, Merrick, & Stead, 2011).

While the Medicare anesthesia provider reimbursement policy allows for fully independent or autonomous CRNA practice, facilities must still comply with Medicare Part A Conditions of Participation to receive Medicare facility reimbursement. Physician supervision of nurse anesthetists is one of these requirements, but the physician need not be an anesthesiologist. However, the federal government allows states to opt out of this requirement with 17 state governors formally taking this action as of 2019 (AANA, 2019). Each state further develops its own scope-of-practice regulations, influenced by their respective medical and nursing state organizations and state politics.

Hospitals, ambulatory surgical centers, and individual provider organizations also implement their own policies

through bylaws and management decision-making. These decisions are based on a range of other factors beyond state and federal policy and include patient acuity and type of surgery (Penn & Ruthman, 2005; Rosenbach & Cromwell, 1989) and non-Medicare reimbursement regulations, which may allow provider discrimination. Finally, local norms and preferences of organization leadership, which may be dominated by a physician perspective, can also be very influential.

Geography affects the service model because the availability of anesthesia providers differs across states and in rural versus urban areas (Daugherty, Fonseca, Kumar, & Michaud, 2010; Dunbar et al., 1998; Fallacaro & Ruiz-Law, 2004; Grundy et al., 1987; Seibert, Alexander, & Lupien, 2004). The ability to hire or contract with anesthesiologists or CRNAs depends on their presence in the local labor force and a facility's capacity to financially support a given mix of providers. If a hospital cannot maintain the availability of an anesthesiologist or chooses to be less restrictive, then often a surgeon or other physician may supervise a CRNA if required under state law. Lower volume hospitals typically cannot support multiple concurrent surgical procedures challenging the economic viability of an ACT model. Particularly in rural areas, independent CRNA practice supports access to surgical and other diagnostic services by enabling hospitals to provide anesthesia care when an anesthesiologist is unavailable (Grundy et al., 1987; Seibert et al., 2004).

Safety and Efficiency in Anesthesia Practice

Opposing Views

The major issue dividing the two anesthesia professions is the role of the anesthesiologist in supervising or directing the work of the CRNA. The ASA releases a *Statement on the Anesthesia Care Team* (ASA, 2018), which is updated every 5 years. The statement lays out the ASA's philosophy of how anesthesia ought to be practiced, including who is and is not considered a member of the team and the specific responsibilities of the anesthesiologist. The ASA contends that the anesthesiologist is the leader responsible for managing all anesthesia-related care, including evaluating the patient, prescribing the anesthetic plan, treating complications, and delegating routine tasks to subordinate qualified personnel. Conversely, the AANA staunchly claims that CRNAs should be permitted to practice to the full scope of their training and expertise, which includes supplying the full range of anesthesia care services (AANA, 2013), whether or not an anesthesiologist is on staff.

The availability of two types of anesthesia providers offering largely similar services raises the stakes in the

debate over the safety and cost-effectiveness of the different care models. The ASA depends heavily on arguments of superior safety associated with anesthesiologist involvement. Attempts to curb health care costs and care for patients more efficiently without sacrificing safety puts anesthesiologists under increased pressure to rationalize their greater labor cost relative to CRNAs. Thus, the ASA's rationale for a dominant position in the market for anesthesia services requires evidence of improved outcomes relative to CRNAs.

In 2014 and 2015, the FTC solicited public comments on topics related to competition in health care. The AANA and the ASA both took the opportunity to write letters (AANA, 2014, 2015; ASA, 2014, 2015) explaining their arguments and documenting evidence to support a position on how their respective profession should be recognized in the market for delivery of anesthesia services. The letter from the AANA laid out a case for equality between the two types of providers based on equivalent safety outcomes and improved cost-efficiency. The ASA's letter supported a position of physician dominance based on improved safety and efficiency of anesthesiologist-led care. Both organizations used published research to support and defend their positions related to provider types and safety outcomes. In identifying articles for this review, we evaluated the studies cited as supporting evidence in these letters (see Table 1).

Anesthesia Safety Outcomes

The Institute of Medicine (2000), in their consensus report *To Err Is Human*, acknowledged the safety record in anesthesia care by reporting an estimated mortality of one death per 200,000 to 300,000 anesthetics. This finding is consistent with other scientific research on anesthesia safety outcomes. One study used vital statistics from 1999 to 2005 and associated multiple-cause-of-death data with up to 20 International Classification of Diseases-10 codes indicating the underlying causes of death to estimate anesthesia-related mortality (Li et al., 2009). The included complication codes represent events such as poisoning or overdose of anesthetic drugs, hypo- or hyperthermia following administration, and misplaced tube or otherwise failed intubation. They found a similar total anesthesia-related death rate of 0.82 per 100,000 surgical discharges. A pilot study conducted by the CDC in 1980 to determine the feasibility of a national surveillance study of anesthesia mortality and severe complications found a rate of 6.25 adverse outcomes per 10,000 procedures with anesthesia as a contributing factor and 1.25 per 10,000 with anesthesia as the sole contributor (Klaucke et al., 1988). Based on these data, the CDC rejected taking on a full study of anesthesia outcomes because related morbidity and mortality were too low to warrant the \$15 million

Table 1. Studies Used for This Analysis on Advocacy Related to Anesthesia Practice Model.

Cited research	Purpose/outcomes	Practice models evaluated	Data and methods	Key findings used for organizational advocacy claims
Dulisse and Cromwell (2010) [S]	Evaluation of inpatient mortality and combined complications measure incorporating seven safety measures developed by Agency for Healthcare Research and Quality by practice model and state opt-out status	CRNA solo, anesthesiologist (MDA) solo, and team models in opt-out and nonopt-out states	Medicare 5% sample from 1999 to 2005 Part A and Part B claims	No differences found in safety. Argues Medicare should eliminate supervision requirements for CRNAs as there is no measurable quality difference associated with opt-out status
Epstein and Dexter (2012) [S, C]	Study of lapses in supervision of <i>critical portions</i> (percentage of days with lapse) under various provider supervision ratios and operating room efficiency strategies	Supervision ratios of 1:1, 1:2, and 1:3	Simulation analysis of 1 year of operating room data from anesthesia information management system data	Supervision lapses highly likely to occur even at low ratios such as 1:2. AANA has cited as evidence of inefficiency and increased patient risk for providers unqualified to practice independently (i.e., anesthesiologist assistants)
Hogan, Seifert, Moore, and Simonson (2010) [C]	Comparison of labor costs associated with competing anesthesia practice model types using projected revenue, cost, and revenue minus cost	CRNA only, MDA only, four medically directed models of MDA to CRNA of 1:1 to 1:4 and a supervisory model where one MDA supervises more than four CRNAs.	Financial simulation modeling comparing practice models making assumptions around payer mix, provider salary, procedure demand, and complexity (base and time units)	CRNA provided care is more cost-effective than MDA provided or directed based on lower salary and similar quality outcomes. Some directed models not financially sustainable
Lewis, Nicholson, Smith, and Alderson (2014) [S]	Independent review by Cochrane organization of safety provided by physician and nonphysician anesthesiologists assessing safety based on strength of evidence and potential for bias	Studies included varying models of nurse and physician anesthesiologists	Review of six studies, three of which are included in the present analysis. See Pine, Holt, and Lou (2003), Silber et al. (2001), and Dulisse and Cromwell (2010). Assessed based on methodological rigor and strength of findings	Independent review finds no evidence of differences in care provided by physician and nonphysician anesthesiologists
Memtsoudis, Besculides, and Swamidoss (2005) and Memtsoudis et al. (2012) [S, C]	Similar investigations of whether patient, facility, provider, or other factors impacted disposition following surgery, that is, discharge home or to another facility for ambulatory surgery patients undergoing herniorrhaphy (2005) and knee and shoulder surgery (2012)	Anesthesiologist, CRNA, and both anesthesiologist and CRNA also included other and unknown provider types	Analyses used National Survey of Ambulatory Surgery: 1992 to 1994 used in 2005 and 1996 and 2006 used in 2012	CRNA provided care associated with greater likelihood of unexpected disposition. ASA cites as evidence of potentially greater cost associated with CRNA provided care due to worse outcomes

(continued)

Table 1. Continued.

Cited research	Purpose/outcomes	Practice models evaluated	Data and methods	Key findings used for organizational advocacy claims
Miller, Abouleish, and Halzack (2016) [S]	Study of whether an anesthesiologist was affiliated with hospitals exclusively billing with QZ modifier	Identified hospitals billing exclusively under the QZ modifier used for nonmedically directed CRNA services	Used Medicare 5% sample to assess whether anesthesiologists associated with hospitals billing QZ	47% of QZ only hospitals had affiliated anesthesiologists; ASA uses to undermine QZ modifier as indicator of CRNA only practice
Pine, Holt, and Lou (2003) [S]	Evaluation of in-hospital mortality by practice model including anesthesiologist only, CRNA only, and team models	Anesthesiologist alone, CRNA alone, and anesthesia care team	Risk adjusted analysis of 1995 to 1997 Medicare claims from 22 states for eight surgical procedures	No significant differences across care models. AANA cites in regulatory comments as evidence of safety.
Silber et al. (2000) [S]	Evaluation of 30-day mortality and failure to rescue (i.e., deaths among those who experienced complication) for anesthesiologist-directed and undirected cases	Anesthesiologist-directed and undirected cases were determined using billing records	Used billing records from Medicare from Pennsylvania in 1991 to 1994 and complications rate	Odds of death and failure to rescue were higher for undirected cases. Complication odds were similar. ASA cites to support claim that anesthesiologist-directed is safer than not directed
Wiklund and Rosenbaum (1997); findings are from Fischer (1996) [C]	Assessment of advances in anesthesiology that cites data from an evaluation of anesthesiologist-led outpatient perioperative care clinic including number of requested consultations, day-of-surgery cancellations, and cost of preoperative testing	Anesthesiologist-led clinic staffed by nurses and residents requesting medical consultations as necessary	Fischer study assessed outcomes from evaluation of perioperative care clinic run by anesthesiologists compared with a prior state when surgeons performed evaluations	Improvements in operating room efficiency were observed after implementation of anesthesiologist-led preoperative clinic

Note. [S] = safety oriented; [C] = cost-efficiency oriented; CRNA = certified registered nurse anesthetist; MDA = anesthesiologist; AANA = American Association of Nurse Anesthetists; ASA = American Society of Anesthesiologists.

cost of a controlled study (AANA, 2009). More recently, researchers (Negrusa, Hogan, Warner, Schroeder, & Pang, 2016) used 5.6 million commercial claims from 2011 to 2012 and a complication identification methodology based on Li et al. (2009) and found unadjusted anesthesia-related complication rates of 2 per 1,000 inpatient procedures and 4 per 10,000 outpatient procedures. Despite the laudable safety record in anesthesia, available research has not resolved the questions about safety and anesthesia providers. While the quality of the studies and data sets present one factor, professional politics also has an important role.

Because the rates of anesthesia complications and deaths are so low, the data sources available for such studies are generally restricted to administrative data, such as medical claims or vital statistics, and general-purpose national surveys such as the National Survey of Ambulatory Surgery. Medicare claims, in particular, have served as the data source in multiple studies of patient safety and anesthesia providers (Dulisse & Cromwell, 2010; Pine et al., 2003; Silber et al., 2000), despite limitations in their ability to adequately measure both the outcomes and independent predictors in these models. First, claims data do not reference specific causes of death. This limits investigators to identifying potential surgery-related deaths based on occurrence during a specified period in the claim history. To maximize the likelihood of anesthesia as a cause, quality experts recommend a window of 48-hours postsurgery for measuring anesthesia-related safety indicators (ASA, 2009; Haller, Stoelwinder, Myles, & McNeil, 2009). A wider window encompasses a substantial part of postoperative care, including additional hospital, medical, and nursing factors that potentially mask the impact of anesthesia care. Likewise, claims-based measures of surgical complications depend on the reliability of coding processes. Substantial discrepancies with more accurate clinical registry data sources have been documented (Lawson et al., 2015). In addition to the limitations of measuring safety outcomes, patient and provider characteristics are also problematic. Patient risk adjustment limited to only the comorbidities and severity of conditions present in the claims may offer an incomplete assessment of the patient's condition. Finally, using the billing modifier (e.g., QZ, QK, etc.) as the only indicator of whether a case involved an anesthesiologist's medical direction or supervision does not capture the true level of involvement of each participating anesthesia provider. Miller et al. (2016) find that even facilities exclusively billing CRNA services without medical direction (QZ) often have affiliated anesthesiologists. However, the contribution, if any, of anesthesiologists in these cases is unclear based on the claims. Notably, in Miller et al., QZ only hospitals with affiliated

anesthesiologists had a median of only 0.5 anesthesiologists, suggesting rather limited availability in those facilities.

Provider Safety Comparison Studies

Despite the limitations of claims data, two studies cited by the AANA (Dulisse & Cromwell, 2010; Pine et al., 2003) and one by the ASA (Silber et al., 2000) in the reviewed letters to the FTC specifically address provider comparisons of the safety in anesthesia care using Medicare claims data.

Silber et al. (2000) used Pennsylvania Medicare claims from 1991 to 1994 to investigate anesthesiologist-directed and undirected anesthesia cases. Outcome measures included death rate within 30 days, a broad measure of in-hospital complications, and mortality rates among patients experiencing complications (failure-to-rescue). They found higher mortality and failure to rescue rates among undirected patients. However, their outcome measures departed significantly from established approaches for anesthesia quality measurement, including mortality at 30 days instead of 48 hours and an expansive complications measure that included conditions (e.g., psychosis) that have not been established as anesthesia related. An unadjusted overall death rate of 3.5% across both groups, which is thousands of times greater than established estimates of anesthesia-related mortality risk, such as in Li et al.'s (2009) research, suggests that this is not actually a study of anesthesia-related outcomes. Practice model attribution also presents problems. Directed cases were assigned based on a submitted claim from an anesthesiologist, while undirected cases included a mixture of 39% claims from billed cases for supervised or independent CRNAs or other providers and 61% unbilled cases. There are multiple potential sources of bias in this classification approach that limit the study's ability to draw conclusions about the quality of care delivered by undirected CRNAs, including (a) no determination of the share of CRNA cases in the undirected group; (b) inclusion in the undirected group of all cases with any undirected procedures, even if a directed procedure was also performed during the same hospital stay (e.g., an emergency reoperation where an anesthesiologist was unavailable); and (c) an assumption that death or complications did not affect the likelihood of submitting a bill in directed cases. Despite these flaws, this study represents the primary evidence for anesthesiologists' claims of improved safety associated with medical direction during the last two decades.

The AANA has also supported studies comparing safety outcomes across anesthesia providers and practice models (Dulisse & Cromwell, 2010; Pine et al., 2003). In one study of safety outcomes, Pine et al. (2003) calculated inpatient mortality rates for eight procedure types

across 22 states for anesthesiologist only, CRNA only, and team models. Unadjusted mortality rates ranged from 0.11% in mastectomy procedures to 1.2% in cholecystectomy. They controlled for patient risk, hospital, and geographic variables. The results indicated no statistically significant differences in mortality among practice model types. Dulisse and Cromwell (2010) also used Medicare claims to examine inpatient mortality and combined complications consisting of seven patient safety indicators (PSI) developed by the Agency for Healthcare Research and Quality (2019) including anesthesia complications (PSI 1), death in low-mortality diagnoses (PSI 2), failure to rescue from a complication (PSI 4), iatrogenic pneumothorax/collapsed lung (PSI 6), postoperative physiologic and metabolic derangement (PSI 10), postoperative respiratory failure (PSI 11), and transfusion reaction (PSI 16). Comparing anesthesiologist solo, CRNA solo, and team models by whether a state had opted out of Medicare's supervision requirement, they found lower mortality rates for CRNA than anesthesiologist solo cases and no evidence of improved quality associated with required medical supervision in nonopt-out states based on either mortality or complication outcomes. The ASA charges that this study is invalid due to ambiguous identification of providers, an all-cause mortality measure that could be related to many other factors outside of the anesthesia practice model, and insufficient risk adjustment (Miller, 2013).

Cochrane conducted an independent review of the available studies of safety and anesthesia practice models (Lewis et al., 2014), including Pine et al. (2003), Silber et al. (2000), and Dulisse and Cromwell (2010). They determined that no definitive statement can be made concerning the possible superiority of one anesthesia care provider over another. The more recent Negrusa et al.'s (2016) study of anesthesia-related complications again failed to find significant differences in complications between practice models or providers.

Cost-Efficiency in Anesthesia Practice Models

CRNAs and anesthesiologists use different approaches and studies to argue their case about cost-effectiveness and efficiency of competing providers and practice models. The AANA cites Hogan et al. (2010) in their FTC letters to support the cost-effectiveness of the CRNA only practice model (AANA, 2014, 2015). In discussing issues of cost and efficiency, it is important to clarify whose costs one is scrutinizing. For expenses related to anesthesia practice models, the employing hospital or practice group is likely to be the most impacted by variations in labor expenses associated with different types of practice models. Anesthesiologists are paid significantly higher salaries than CRNAs, with even greater labor costs associated with directed care where multiple

providers participate in a single case. Hogan et al. (2010) employed stochastic simulation models to compare the efficiency of different anesthesia care models, including CRNA only, MDA only, and various team models under varying labor cost assumptions. They then analyzed medical claims associated with specific delivery models to compare the actual revenues and costs to the hospital. The results show that CRNAs practicing independently are the least costly while capturing the most revenue for hospitals, followed by a supervisory reimbursement model in which one MDA supervises more than four CRNAs. The sustainability of each anesthesia care model was tested under various labor cost and surgical demand assumptions. Under a scenario of reduced surgical demand, meaning that sometimes one or more operating rooms are not being used, only the CRNA practicing-independently model was self-sustaining or profitable (Hogan et al., 2010). Models that are nonself-sustaining would therefore require a subsidy from the hospital. These conclusions held after conducting sensitivity analyses around key model parameters such as provider salary. In other words, conclusions remained robust even if salaries were increased or decreased up to 10%.

The ASA uses a different approach to support the cost-effectiveness of anesthesiologists, taking the perspective of the payer instead of the employing provider in evaluating the cost. It emphasizes that for some payers, including Medicare, reimbursements for anesthesia services are the same for CRNAs and anesthesiologists and assume that additional physician services are required when anesthesiologists are not involved. The ASA has cited Wiklund and Rosenbaum (1997) in their letters to the FTC to demonstrate a reduction of 75% in additional medical consultations, 88% in cancellations, and 59% in laboratory tests (ASA, 2014) when an anesthesiologist supervises anesthesia services. However, these findings reference another study of an anesthesiologist managed preoperative evaluation clinic staffed mainly by registered nurses (Fischer, 1996). It makes no reference to CRNAs and is irrelevant to claims about the efficiency of the care they deliver.

Other studies that the ASA cited to support its assertion that CRNAs increase costs included data on unexpected disposition and associated excess costs of ambulatory surgery patients (Memtoudis et al., 2005, 2012). However, critics have identified flaws in the methodology and generalizability of these studies, including procedure selection and patient and geographic risk adjustment (Wiltse Nicely & Lynn, 2012). Earlier studies similarly used questionable claims about lower quality care provided by independent CRNAs compared with anesthesiologists to quantify potential additional costs associated with theorized excess mortality and complications (Abenstein, Long, McGlinch, & Dietz, 2004; Abenstein & Warner, 1996; Glance, 2000).

Discussion

Patient safety is of paramount concern in all health-related legislative and regulatory policy-making decisions. It is also critical that evidence used to guide these decisions accurately reflects the true risks and benefits to patients. Given the established safety record in anesthesia, we should step back for a moment and try to clarify the underlying reasons for the persistence of medical direction and supervision policy. Is the problem truly that there is no conclusive study of anesthesia provider models and safety outcomes? Or is it that the complexity of perioperative care, the low intrinsic rate of complications relating directly to anesthesia, and a multitude of potential confounding effects, all of which are nonrandom, make it exceedingly difficult to conduct such a study that would definitively answer questions about differences in provider outcomes? Or is it that professional politics surrounding anesthesia safety make it difficult to fairly assess and apply the existing research findings to health care policy? Or do we need to examine larger issues around political decision-making in health care?

First, consider how efforts to evaluate anesthesia quality have played out in another policy context. Based on past anesthesia safety outcomes research, it is not surprising that the discipline as a whole may be experiencing a measurement crisis. In federal quality reporting programs, such as the Merit-Based Incentive Payment System under Medicare's Quality Payment Program, many anesthesia measures are exceeding the 98% threshold used to reward excellent performance as evidenced by consistent high-performance over time (Revisions to Quality Payment Program for CY 2019, 2018). In other words, measures are topping out or losing their utility due to "extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made" (p. 59765). Given the lack of variation in anesthesia measurement and inability to further distinguish high-performing providers, some anesthesiologists concerned about quality reporting requirements for payment purposes suggest moving to jointly attributable or team-based reporting measures (Hyder et al., 2015).

The measurement challenges in anesthesia suggest that additional studies are unlikely to offer irrefutable findings related to provider differences. In the case of policies related to medical direction and supervision, however, a lack of definitive evidence is not the only relevant issue. More salient, perhaps, is the resistance of those charged with making regulatory decisions to challenge the status quo. The medical profession has a long history of cultural dominance within the American health care industry, offering it a distinct advantage in protecting and defending its economic and political

interests (Starr, 1982). Without demonstrable evidence that policy changes will lead to future improvements in patient safety outcomes or better access through lower costs or greater service availability, policymakers have little incentive to change rules that maintain the current power structure.

As independent practitioners, CRNAs represent a direct threat to anesthesiologists' revenue model. In other words, it is becoming increasingly difficult for anesthesiologists to demonstrate their value proposition outside of an ACT practice arrangement. Increasing practice consolidation has not demonstrated itself to be a means of increasing revenue through more favorable payer contracts for anesthesia providers (Sun, Dexter, Macario, Miller, & Baker, 2015), making control of labor costs and restrictions on CRNA autonomy key to the financial success of anesthesiologists' practice. Claims about safety risk associated with independent or autonomous CRNA practice represent a political tactic to preserve the economic benefits of the ACT for anesthesiologists.

Limitations of Current Analysis

There are several limitations to this analysis. First, with our extensive collective experience in nursing, research, and anesthesia, we cannot claim to be unbiased observers of the policy and politics around anesthesia delivery models. Second, the reviewed studies were limited to those used by the respective advocacy organizations for anesthesiologists and CRNAs in the specified context and are not assumed to be reflective of all literature on this topic. Third, our aim was to demonstrate how professional organizations might use research findings for policy advocacy purposes. We did not intend to assess whether the research supports any conclusive findings about provider safety or cost-efficiency. While anesthesiologists may disagree with some ideas presented in this analysis, they would likely agree that studying anesthesia safety and efficiency outcomes is challenging. Research questions, methods and data sources, and interpretations of results are all subject to an investigator's political perspective and therefore impact how their findings are incorporated into advocacy efforts.

Implications for Nursing

State regulators considering changes in scope-of-practice policy still look at safety outcomes to guide their decision-making. Despite several studies that report equivalent safety outcomes, political challenges to removing barriers to independent or autonomous practice for CRNAs still remain. Nevertheless, CRNAs are not unique among nurses in offering a quality neutral cost-efficient alternative to physicians. However, no one

should expect that evidence alone will be enough to convince legislators, state medical boards, and other health care leadership to allow nurses to practice at the full scope of their training and certification. As all advanced practice nurses (APRNs) continue to advocate for greater independence, there must be diligent and critical review of research that purports to demonstrate differences in quality among providers. Efforts to establish that physician-led or supervised care offers better outcomes for patients are likely to remain a high priority for anesthesiologists and other physicians hoping to preserve their economic advantage in state regulations and reimbursement policy. It will be critical for CRNAs and other APRN advocates to remain vigilant and critical of research that attempts to distort scientific findings toward a political end.

Conclusion

Evidence and practice trends suggest that anesthesia is safer than ever. As health care delivery and payment transitions from fee-for-service toward a value-based care model, cost-effective delivery of anesthesia services is of growing importance. A collaborative practice model that respects the clinical autonomy of all participating providers and offers patients the highest value in anesthesia services should be our priority. Because nurse anesthetists contend that CRNAs and anesthesiologists are equal in safety, while anesthesiologists contend that their profession is superior in safety to CRNAs, evidence-based guidance on the competing anesthesia practice models is likely to remain politicized.


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