Scope of Practice Laws and Anesthesia Complications

No Measurable Impact of Certified Registered Nurse Anesthetist Expanded Scope of Practice on Anesthesia-related Complications

Brighita Negrusa, PhD, Paul F. Hogan, MS, John T. Warner, PhD, Caryl H. Schroeder, BA, and Bo Pang, MS

Background: Scope of practice (SOP) laws governing Certified Registered Nurse Anesthetists (CRNAs) vary by state and drive CRNA practice and reimbursement.

Objective: To test whether the odds of an anesthesia complication vary by SOP and delivery model (CRNA only, anesthesiologist only, or mixed anesthesiologist and CRNAs team).

Methods: Anesthesia claims and related complications were identified in a large commercial payor database, including inpatient and ambulatory settings. Logit regression models were estimated by setting to determine the impact of SOP and delivery model on the odds of an anesthesia-related complication, while controlling for patient characteristics, patient comorbidities, procedure and procedure complexity, and local area economic factors.

Results: Overall, 8 in every 10,000 anesthesia-related procedures had a complication. However, complications were 4 times more likely in the inpatient setting (20 per 10,000) than the outpatient setting (4 per 10,000). In both settings, the odds of a complication were found to differ significantly with patient characteristics, patient comorbidities, and the procedures being administered. The odds of an anesthesia-elated complication are particularly high for procedures related to childbirth. However, complication odds were not found to differ by SOP or delivery model.

Conclusions: Our research results suggest that there is strong evidence of differences in the likelihood of anesthesia complications by patient characteristics, patient comorbidities, and the procedures being administered, but virtually no evidence that the odds of a complication differ by SOP or delivery model.

Key Words: scope of practice, anesthesia complications, anesthesia delivery model, CRNA, anesthesiologist

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Reprints: Paul F. Hogan, MS, The Lewin Group, 3130 Fairview Park Drive, Suite 500, Falls Church, VA 22042. E-mail: paul.hogan@lewin.com.
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BACKGROUND

Advance Practice Registered Nurses (APRNs) are an important resource to the health care system; however, barriers to full APRN practice limit the full utilization of the APRN workforce.[1,2] According to the 2008 APRN Consensus Model, APRN professional activities are overseen by state nursing boards, which determine their legal scope of practice (SOP).[3] Both the APRN Consensus Model and the Institute of Medicine expressed the value of APRNs being able to practice to the full extent of their training.[3,4]

Both Certified Registered Nurse Anesthetists (CRNAs) and anesthesiologists are trained to provide the full range of anesthesia-related care. CRNAs face barriers similar to other APRNs, and state SOP restrictions play a crucial role in how anesthesia is delivered.

The issue regarding CRNA SOP entails restrictive language specifying the extent of physician involvement in the delivery of anesthesia. A restrictive SOP for CRNAs is a scope containing a requirement for physician involvement (at facility level or in the state law). Examples of such restrictions include supervision, immediate presence, timely onsite consultation, and physically present and available on the premises. A nonrestrictive SOP is a scope containing no or minimal requirements for physician involvement. In this case, minimal involvement may come in the form of requirements for collaboration and/or direction.

The rationale for CRNA SOP restrictions often focuses on years of training and anesthesia quality outcomes. Several studies have compared anesthesia-related complications or mortality by anesthesia delivery model.[5–9] These studies explored the implications of anesthesia provider type on inpatient outcomes in subsets of the population, including Medicare beneficiaries or women of child-bearing age. With 1 exception,[9] the current literature suggests no difference in quality based on anesthesia provider type.[5–8] Nevertheless, many states still maintain restrictive CRNA SOP.

PURPOSE

The purpose of this study is to determine whether there are differences in anesthesia-related complications across delivery models and CRNA SOP among inpatients and outpatients of all ages in a commercial payor database. No existing studies have examined whether anesthesia complications are related to SOP laws. We test whether states with SOP laws allowing CRNAs to practice independently experience the same risk of anesthesia complications as states that require supervision or direction/collaboration. We also test whether risk varies across anesthesia delivery models, which include anesthesia delivered by CRNAs acting alone, anesthesiologists acting alone, and teams of anesthesiologists and CRNAs.

Past studies find that the incidence of anesthesia-related complications is very low. Power tests (available from the authors upon request) indicate that the sample must contain at least 1 million observations to detect an actual difference in the odds of a complication of 10% (or more) between 2 SOP classifications or 2 delivery models with a high degree of confidence (probability of a type II error of ≤ 0.1). Our 5.7 million observation database is over 5 times larger than the largest sample used in previous studies. It is national in scope, covers patients of both sexes and all age ranges, and contains procedures performed in all settings. By contrast, previous studies were limited to specific states or regions[6–9] or to Medicare patients,[5] and none have studied anesthesia-related complications in the outpatient setting.

METHODS

Study Sample

This study is based on 2011–2012 data from the Optum Research Database, a database of deidentified health care claims of individuals insured by United Healthcare, a major US health insurer, and other claims processed by Optum. Our database includes approximately 4.6 million covered lives associated with an anesthesia-related claim and 5.7 million anesthesia-related claims. Anesthesia-specific Current Procedural Terminology (CPT) codes (ie, 00100–01999) along with modifier fields were used to identify anesthesia claims. Place of service codes were used to classify outpatient, inpatient, and emergency room settings. The anesthesia base units (BU) identified by CMS corresponding to each anesthesia CPT code were attached to each claim.[10] BUs reflect procedure difficulty and skills necessary to perform a procedure; higher BUs reflect increasing complexity.[10]

Our database contains 5,740,470 anesthesia-specific procedures in 2011–2012. About 75% of them occurred in an outpatient setting (4,273,122) and the rest (1,467,348) were in the inpatient setting. The mean age of the study population was 52 and 60% of the patients were female. The average BUs for anesthesia procedures was 6.7 in the inpatient setting and 4.7 in the outpatient setting. Approximately 6% (355,103) procedures were administered in rural areas (Table 1).

Key Variables

The dependent variable in the logit regression models described below is an indicator for whether the procedure had an anesthesia-related complication. The key explanatory variables in these models are indicators for anesthesia delivery model and state SOP classification. Furthermore, to mitigate bias in the estimated effects of the key variables, the models controlled for (1) the patient's age and sex, (2) the patient's health as measured by 6 comorbidity indicators, (3) procedure and BUs, and (4) local area economic factors, including a rural indicator, local area poverty rate, and median income. Summary statistics for the key variables other than procedure are shown in Table 1. Procedures are discussed in more detail below.

Anesthesia Delivery Model

Anesthesia delivery models were defined by the procedure modifiers on the claim (Supplementary Table 1, Supplemental Digital Content 1, http://links.lww.com/MLR/B181). Using these modifiers, 5 delivery models were identified: CRNA only, Anesthesiologist only, Medical Direction 1:1, Medical Direction 1:2–4, and Supervision 1:>4. The latter 3 models are characterized as "team" models where the notation 1:1, 1:2–4, and 1:>4 refer to the anesthesiologist-to-CRNA ratio (Supplementary Table 2, Supplemental Digital Content 1, http://links.lww.com/MLR/B181).

In both settings combined, the distribution of the anesthesia procedures by delivery model was as follows: 21.7% by CRNAs only, 49.9% by anesthesiologists only, 3.8% under Medical Direction 1:1, 24.4% under Medical Direction 1:2–4, and 0.3% under Supervision 1:>4. Table 1 shows that the distribution varies somewhat by setting, with relatively more outpatient procedures administered by CRNAs acting alone and relatively more inpatient procedures administered by anesthesiologists acting alone.

State SOP Classification

CRNA SOP laws vary by state as well as by setting or facility type within the state. An analysis conducted by the AANA classified states into 3 categories: (1) supervision in state nursing or facility statutes, rules, or regulations; (2) direction/collaboration in state nursing or facility statutes, rules, or regulations; and (3) no supervision or direction in nursing or facility statutes, rules, or regulations. Table 2 displays AANA's classification of states by SOP.

"Supervision" SOP means supervision by a physician such as an anesthesiologist, but it can also be by another physician, typically a surgeon. Hence, in states that require "supervision" a CRNA-only delivery model is possible when, for example, the surgeon agrees to accept the responsibility of supervision. "Direction/collaboration" means that there must be an anesthesiologist involved at some level in the procedure. This can range from direction of the CRNA(s) by an anesthesiologist, but it can also mean that the CRNA is simply affiliated with an anesthesiologist practice, and collaborates with that practice. In this case, the "collaboration" does not necessarily imply that the anesthesiologist will be present for any part of the procedure. Finally, "no supervision" means that an anesthesiologist is not required to be involved in any part of the anesthesia procedure, nor is a physician required to accept supervisory responsibility for the CRNA. Note that none of the SOP categories necessarily define or eliminate the types of

TABLE 1. Summary Statistics for Optum Data

	Inpatient (N = 1,467,348)		Outpatient (N = 4,273,122)	
Variables	**Mean**	**SD**	**Mean**	**SD**
Complication	0.002	0.044	0.0004	0.021
Age 0–4	0.011	0.102	0.027	0.163
Age 5–14	0.016	0.124	0.034	0.181
Age 15–24	0.057	0.231	0.046	0.210
Age 25–34	0.198	0.398	0.069	0.253
Age 35–44	0.128	0.334	0.115	0.319
Age 45–54	0.113	0.316	0.189	0.391
Age 55–64	0.155	0.362	0.215	0.411
Age 65–74	0.158	0.364	0.179	0.383
Age 75–84	0.117	0.321	0.102	0.302
Age 85+	0.049	0.216	0.0246	0.155
Female	0.660	0.474	0.567	0.495
CRNA only	0.130	0.336	0.247	0.431
AA only	0.558	0.497	0.478	0.500
Medical direction 1:1	0.050	0.217	0.033	0.180
Medical direction 1:2–4	0.259	0.438	0.239	0.426
Supervision 1:1 > 4	0.004	0.060	0.002	0.048
Direction/collaboration	0.363	0.481	0.306	0.461
Supervision	0.394	0.489	0.436	0.496
Arrhythmia	0.234	0.424	0.126	0.332
Aortic stenosis	0.056	0.231	0.027	0.161
Diabetes	0.222	0.415	0.183	0.387
Cancer	0.256	0.436	0.249	0.433
Hypertension	0.502	0.500	0.464	0.499
COPD	0.226	0.418	0.179	0.383
Rural indicator	0.052	0.222	0.065	0.247
Base units	6.668	3.293	4.723	1.222
Percent below poverty	15.941	5.041	15.712	5.069
Median family income (in “000s”)	67.680	16.058	68.101	17.182

Data on percent in poverty and median family income at the 3-digit zip code level were obtained from the American Community Survey and are available at https://www.census.gov/programs-surveys/acs/data/summary-file.2012.html.

TABLE 2. Classification of Scope of Practice State Laws or Regulations by Setting

No Supervision or Direction		Direction/Collaboration in Nursing Statute or Hospital Rules		Supervision in Either Nursing or Hospital Statute, State Rules or Hospital Rules, or Both	
Inpatient and ER	**Ambulatory**	**Inpatient and ER**	**Ambulatory**	**Inpatient and ER**	**Ambulatory**
Alaska	Alaska	Arizona	Arizona	Alabama	Alabama
California	California	Connecticut	Connecticut	Arkansas	Arkansas
Colorado	Colorado	Delaware			Delaware
Hawaii			District of Columbia	District of Columbia	
Idaho	Idaho	Georgia	Georgia	Florida	Florida
Iowa	Iowa	Illinois	Illinois		Hawaii
Kansas	Kansas	Indiana			Indiana
Montana	Montana	Kentucky	Kentucky	Louisiana	Louisiana
New Hampshire	New Hampshire	Maryland	Maryland	Maine	Maine
New Mexico	New Mexico	Massachusetts	Massachusetts	Michigan	Michigan
North Dakota	North Dakota	Mississippi			Mississippi
Oregon	Oregon	Minnesota	Minnesota	Missouri	Missouri
Tennessee	Tennessee	Nebraska	Nebraska	New Jersey	New Jersey
Texas	Texas	Nevada	Nevada	New York	New York
Vermont	Vermont	North Carolina	North Carolina	Ohio	Ohio
Washington	Washington		Pennsylvania	Oklahoma	Oklahoma
		South Dakota	South Dakota	Pennsylvania	
		Wisconsin	Wisconsin	Rhode Island	Rhode Island
				South Carolina	South Carolina
				Utah	Utah
				Virginia	Virginia
				West Virginia	West Virginia
				Wyoming	

delivery models observed in the state. However, in states with "no supervision" we do observe a higher proportion of cases with a CRNA-only delivery model, compared with the mix of models in the other 2 categories.

In our data, about 32% of all anesthesia procedures were identified as "direction/collaboration," 43% "supervision," and 25% "no supervision."

Comorbidities and Procedures

We used all International Classification of Diseases, 9th Revision (ICD-9) diagnosis codes reported on patients' claims to identify comorbid conditions for patients undergoing anesthesia procedures. Following the literature,[9] we identify and control for the following comorbidities: arrhythmia (ICD-9 code 417), aortic stenosis (ICD-9 code 424.1), hypertension (ICD-9 codes 401, 405), cancer (ICD-9 codes 140–209, 230–239), diabetes (ICD-9 codes 250, 357.2, 362.0, 366.41, 648.0), and chronic obstructive pulmonary disease (COPD) (ICD-9 codes 490–496, 500–505, 506.4).

Comorbidities are similarly represented in both settings with the exception of arrhythmia and aortic stenosis, which are almost twice as prevalent in the inpatient setting (Table 1). Hypertension is a condition that affects half of our inpatient sample and 46% of our outpatient sample. Cancer is a comorbid condition for around 26% of observations in both settings, whereas the incidence of diabetes and COPD ranges from 18% (outpatient) to 22% (inpatient).

There are 280 currently active anesthesia-specific CPT codes, and our database contains all but 2. The codes contain descriptions of the reason for the anesthesia. Codes were analyzed to determine the frequency of each procedure overall as well as their frequency by delivery model and setting. Table 3 shows the top 60 procedures in each setting. Frequency of all procedures by delivery model and setting are available in the Supplemental Digital Content 2 (see Supplementary Tables 6, 6a, and 6b, Supplemental Digital Content 2, http://links.lww.com/MLR/B182).

The most frequently performed inpatient procedure is normal child delivery, which accounts for 15.6% of all inpatient procedures. The most frequent outpatient procedure is "lower intestine scope," which accounts for 19.5% of all outpatient procedures. The supplementary tables referenced above show that all delivery models perform all procedures and that the frequency (and ranking) of procedures by delivery model does not vary significantly. That is to say, it is not the case that delivery models specialize in select procedures.

Table 3 indicates that the top 60 procedures performed in each setting account for over 90% of all procedures performed in that setting. Furthermore, the same 60 procedures account for 89%, or more, of the procedures performed by each delivery model. Therefore, we controlled for procedure risk using indicators for the top 60 procedures performed in that setting. Each procedure effect thus estimates the average difference in the odds of a complication between the given procedure and the omitted procedures.

Anesthesia-related Complications

Li et al[11] constructed a list of anesthesia-related complications using ICD-10 codes for medical conditions that we matched to ICD-9 codes in the Optum research database (Supplementary Table 3, Supplemental Digital Content 1, http://links.lww.com/MLR/B181). Matched ICD-9 codes were grouped into major categories according to Li et al[11]: (1) overdose of anesthetics; (2) complications of anesthesia during pregnancy, labor, and puerperium; and (3) other complications of anesthesia (Supplementary Table 4, Supplemental Digital Content 1, http://links.lww.com/MLR/B181). We also used ICD-9 codes from AHRQ's Experimental Quality Indicator #1 for rate of complications of anesthesia[12] (Supplementary Table 5, Supplemental Digital Content 1, http://links.lww.com/MLR/B181).

Patients who underwent an anesthesia procedure in the calendar year were linked to all identified anesthesia complications, except complications from spinal and epidural anesthesia, which occurred at or before 3 days post-procedure. Complications resulting from spinal and epidural anesthesia procedures were assessed for complications up to 7 days postoperatively since, unlike the majority of complications, a spinal and/or epidural complication may not be recognized within 72 hours.

Regression Methodology

A complication occurring during or after a medical procedure is a binary outcome. Consistent with past studies, we use logistic regression to analyze whether a complication occurred during or after a procedure involving anesthesia delivery. In our models, the probability of an anesthesia complication is based on the key variables of interest (3 state SOP classification indicators and 5 delivery model indicators) plus control variables to account for other observable factors that might affect the risk of an anesthesia complication. The reference category for SOP classification is "no supervision" and the reference category the delivery model categories is "Anesthesiologist only." The controls for procedure risk include (1) indicators for patient age group and sex, (2) BUs, (3) 6 patient comorbidity indicators, (4) indicators for the top 60 most frequent procedures, and (5) 2 measures of local area economic conditions (% below poverty and median family income in the provider's 3-digit zip code). Models were estimated separately by setting.

Models were estimated by setting separately. The model specification includes the following key variables: (1) indicators for delivery model, (2) indicators for state SOP classification, (3) patient age and sex, (4) 6 patient comorbidity indicators, (5) indicator variables for the top 60 most frequent procedures, and (6) BUs. The reference category for the delivery model categories is "Anesthesiologist only" and the reference category for SOP classification is "no supervision."

Logit model coefficients show how each variable affects the natural logarithm of the odds of the outcome, where odds equal $p/(1-p)$ and p is the probability of an anesthesia-related complication. Following past studies, our logit model coefficient estimates are presented in Table 4 as odds ratios (OR). An OR estimate larger (smaller) than 1.0 and statistically significant indicates that the variable in question increases (reduces) the odds of a complication. A coefficient insignificantly different from 1.0 indicates that the variable

TABLE 3. Top 60 Inpatient and Outpatient Procedures for All Delivery Models

	Inpatient				Outpatient			
Rank	CPT Description	CPT Code	%	Cumulative %	CPT Description	CPT Code	%	Cumulative %
1	Analg, vag delivery	01967	0.156	0.156	Low intestine scope	00810	0.195	0.195
2	Surg lower abdomen	00840	0.071	0.227	Upper GI visualize	00740	0.101	0.296
3	Surg upper abdomen	00790	0.068	0.295	Lens surgery	00142	0.100	0.396
4	Cs delivery	01961	0.068	0.363	Knee joint surgery	01400	0.040	0.436
5	Knee arthroplasty	01402	0.057	0.420	Surg lower abdomen	00840	0.030	0.467
6	Upper GI visualize	00740	0.052	0.472	Skin, ext/per/atrunk	00400	0.028	0.495
7	Spine, cord surgery	00670	0.037	0.509	Lower arm surgery	01810	0.026	0.521
8	Hip arthroplasty	01214	0.029	0.539	lower leg bone surg	01480	0.026	0.547
9	Analg cs deliv add-on	01968	0.024	0.562	N block/inj, prone	01992	0.026	0.573
10	Skin, ext/per/atrunk	00400	0.022	0.584	Procedure on mouth	00170	0.025	0.598
11	Low intestine scope	00810	0.021	0.605	Surg upper abdomen	00790	0.024	0.622
12	Spine, cord surgery	00630	0.016	0.622	Hysteroscope/graph	00952	0.021	0.643
13	Surgery of femur	01230	0.015	0.636	Surgery of shoulder	01630	0.020	0.663
14	Lower leg bone surg	01480	0.015	0.651	Head/neck/ptrunk	00300	0.018	0.681
15	Neck organ, 1 and over	00320	0.013	0.664	Nose/sinus surgery	00160	0.017	0.698
16	Bladder surgery	00910	0.012	0.676	Bladder surgery	00910	0.017	0.715
17	Hrt surg w/pmp ag > 1	00562	0.011	0.687	Repair of hernia	00830	0.013	0.728
18	CAT or MRI scan	01922	0.010	0.697	Anorectal surgery	00902	0.012	0.739
19	Hip joint surgery	01210	0.010	0.707	Tympanotomy	00126	0.012	0.751
20	CABG w/pump	00567	0.010	0.717	Lower arm surgery	01830	0.011	0.762
21	Cranial surg nos	00210	0.009	0.725	procedures on eye	00140	0.010	0.772
22	Head/neck/ptrunk	00300	0.008	0.733	Neck organ, 1 and over	00320	0.010	0.782
23	Neck vessel surgery	00350	0.008	0.741	Vaginal procedures	00940	0.009	0.791
24	Surgery for obesity	00797	0.008	0.749	CAT or MRI scan	01922	0.009	0.799
25	1 lung ventilation	00541	0.008	0.757	Perc img tx sp proc	01936	0.008	0.808
26	Vaginal hysterectomy	00944	0.008	0.764	Kidney stone destruc	00873	0.008	0.816
27	Kidney/ureter surg	00862	0.008	0.772	Spine, cord surgery	00630	0.008	0.824
28	Removal of prostate	00865	0.007	0.779	Vitreoretinal surg	00145	0.008	0.832
29	Electroshock	00104	0.007	0.786	Surgery of breast	00402	0.006	0.839
30	Cardiac electrophys	00537	0.006	0.792	Blepharoplasty	00103	0.006	0.845
31	Vascular access	00532	0.006	0.799	Genitalia surgery	00920	0.006	0.851
32	Thigh arteries surg	01270	0.006	0.805	Lower leg surgery	01470	0.006	0.858
33	Knee joint surgery	01400	0.006	0.810	Inc/missed ab proc	01965	0.006	0.864
34	Chest procedure	00520	0.006	0.816	vascular access	00532	0.006	0.870
35	Surgery of abdomen	00860	0.005	0.821	Stone removal	00918	0.006	0.876
36	Tx interv rad hrt/cran	01926	0.005	0.826	Surgery of shoulder	01610	0.006	0.882
37	Stone removal	00918	0.005	0.831	Surgery of abdomen	00860	0.005	0.887
38	Shoulder replacement	01638	0.005	0.835	Electroshock	00104	0.005	0.893
39	Surgery of breast	00402	0.004	0.840	ear surgery	00120	0.005	0.898
40	Anorectal surgery	00902	0.004	0.844	Repair of hernia	00750	0.004	0.902
41	Surgery of shoulder	01630	0.004	0.848	Bladder tumor surg	00912	0.004	0.906
42	Spine, cord surgery	00600	0.004	0.852	Removal of prostate	00914	0.004	0.910
43	Pacemaker insertion	00530	0.004	0.856	Spine, cord surgery	00670	0.003	0.913
44	Revise hip repair	01215	0.004	0.860	Repair of hernia	00752	0.003	0.916
45	Removal of prostate	00914	0.004	0.864	Cardiac electrophys	00537	0.003	0.919
46	Correct heart rhythm	00410	0.004	0.867	Elbow area surgery	01710	0.003	0.922
47	Lower arm surgery	01830	0.004	0.871	Correct heart rhythm	00410	0.003	0.925
48	Lower leg surgery	01470	0.003	0.875	Vascular shunt surg	01844	0.003	0.928
49	Procedure on mouth	00170	0.003	0.878	Lower arm procedure	01820	0.003	0.931
50	Repair of hernia	00752	0.003	0.881	Vag hysterectomy	00944	0.003	0.933
51	Heart surg w/o pump	00560	0.003	0.884	chest procedure	00520	0.003	0.936
52	Vascular shunt surg	01844	0.003	0.887	Tubal ligation	00851	0.003	0.939
53	Vaginal procedures	00940	0.003	0.889	Nerve block/inj	01991	0.003	0.941
54	Intrcrn nerve	00220	0.003	0.892	Upper arm surgery	01740	0.002	0.943
55	Chest surgery	00540	0.003	0.895	Repair of hernia	00832	0.002	0.945
56	Surgery of shoulder	01610	0.003	0.897	Perc img dx sp proc	01935	0.002	0.947
57	Knee area surgery	01392	0.003	0.900	Ther interven rad, vei	01930	0.002	0.949
58	CABG w/o pump	00566	0.003	0.903	Kidney/ureter surg	00862	0.002	0.950
59	Perc img tx sp proc	01936	0.002	0.905	Knee arthroplasty	01402	0.002	0.952
60	Repair of hernia	00830	0.002	0.907	Surgery of breast	00404	0.002	0.954

has no statistically detectable impact on complications. To avoid potential bias in the estimation of SEs due to unobservable factors that may be correlated across observations, SEs are clustered at the state level. Hypotheses involving single coefficients are tested by z tests. ORs were determined to be significant with a P-value at the 0.10 level or lower. Joint tests involving multiple coefficients are tested by χ^2 tests with degrees of freedom equal to the number of

TABLE 4. Logistic Regressions for Likelihood of an Anesthesia-related Complication (Odds Ratio Form)

	Inpatient Procedures					Outpatient Procedures				
Variable	Parameters Estimation	SE	P	Lower 95% CI	Upper 95% CI	Parameters Estimation	SE	P	Lower 95% CI	Upper 95% CI
SOP indicators										
Direction/collaboration	0.972	0.085	0.749	0.819	1.155	0.753	0.186	0.252	0.463	1.223
Supervision	1.046	0.082	0.563	0.897	1.221	0.864	0.162	0.437	0.599	1.248
Delivery model indicators										
CRNA only	1.149	0.109	0.142	0.954	1.384	1.009	0.160	0.954	0.740	1.377
MD 1:1	1.042	0.123	0.730	0.826	1.313	1.122	0.183	0.482	0.814	1.545
MD 1:2–4	1.160	0.118	0.144	0.951	1.415	1.320	0.208	0.077	0.970	1.797
Supervision 1: > 4	1.080	0.385	0.830	0.537	2.173	1.363	0.604	0.485	0.572	3.249
Patient characteristics										
Age 0–4	0.779	0.309	0.528	0.358	1.693	1.747	0.868	0.262	0.659	4.626
Age 5–14	0.632	0.240	0.227	0.300	1.331	1.465	0.513	0.275	0.738	2.909
Age 15–24	1.089	0.225	0.680	0.727	1.631	1.098	0.308	0.738	0.634	1.901
Age 25–34	1.164	0.229	0.439	0.792	1.711	1.210	0.329	0.483	0.711	2.060
Age 35–44	1.075	0.193	0.686	0.756	1.530	1.025	0.244	0.917	0.644	1.633
Age 45–54	1.048	0.143	0.730	0.802	1.370	1.006	0.252	0.980	0.616	1.643
Age 55–64	0.997	0.131	0.980	0.771	1.289	1.009	0.232	0.971	0.643	1.582
Age 65–74	1.459	0.217	0.011	1.090	1.952	1.033	0.196	0.863	0.712	1.500
Age 75–84	1.232	0.184	0.163	0.919	1.650	1.125	0.202	0.512	0.791	1.599
Female	1.126	0.073	0.069	0.991	1.279	1.198	0.054	0.000	1.097	1.308
Geographic controls										
Rural area	1.213	0.112	0.036	1.012	1.454	1.059	0.294	0.837	0.615	1.824
Local percent below poverty	1.003	0.007	0.697	0.990	1.015	0.994	0.017	0.714	0.961	1.027
Local median income	1.000	0.002	0.777	0.996	1.003	0.990	0.006	0.105	0.977	1.002
Complexity control										
Base unit (BU)	1.008	0.017	0.618	0.976	1.042	1.026	0.033	0.424	0.964	1.092
Comorbidity indicators										
Arrhythmia	1.175	0.067	0.005	1.051	1.315	1.358	0.075	0.000	1.218	1.514
Aortic stenosis	1.021	0.084	0.804	0.869	1.199	0.939	0.123	0.632	0.727	1.214
Diabetes	0.844	0.054	0.009	0.744	0.958	1.045	0.108	0.667	0.854	1.279
Cancer	1.154	0.084	0.049	1.001	1.332	1.198	0.087	0.013	1.038	1.382
Hypertension	1.195	0.094	0.024	1.024	1.395	1.044	0.053	0.395	0.945	1.153
COPD	1.058	0.078	0.448	0.915	1.222	1.107	0.069	0.103	0.980	1.250
Top 60 procedure indicators (yes)										
Intercept	0.001	0.000	0.000	0.000	0.002	0.001	0.001	0.000	0.000	0.005
P-values for joint significance tests										
χ^2 test *P*-values										
SOP indicators	0.700					0.472				
Delivery model indicators	0.518					0.493				
Patient characteristics	0.000					0.000				
Comorbidity indicators	0.000					0.000				
Procedure indicators	0.000					0.000				

CI indicates confidence interval; CRNA, Certified Registered Nurse Anesthetists; SOP, scope of practice.

parameters being tested. The bottom panel of Table 4 contains *P*-values for groups of coefficients. In each case the joint hypothesis being tested is that the coefficients relating to the variables contained in that group all equal 0. ORs for 60 procedures included in the models are available in the Supplemental Digital Content 2 (see Supplementary Table 7, Supplemental Digital Content 2, http://links.lww.com/MLR/B182).

RESULTS

In both settings, the *P*-value for the joint hypothesis that the odds of an anesthesia-related complication do not vary with the 6 patient comorbidities included in the model is 0, indicating that the hypothesis can be rejected with a high degree of confidence. Examining the individual ORs, patients with arrhythmia are estimated to be 1.175 times more likely to have a complication than patients who do not exhibit any of the 6 comorbidities. The risk in the outpatient setting for such a patient is even higher (OR = 1.358). ORs associated with cancer are also significantly above 1.0.

In both settings, the *P*-value for the joint hypothesis of no variation in the odds of a complication by procedure is also equal to 0. In fact, the risk of a complication varies dramatically by procedure. The top 3 highest risk procedures are related to childbirth. Cesarean delivery has an OR of 4.357, normal delivery has an OR of 3.311, and cesarean delivery add-on has an OR of 3.219. Lower intestine scope is relatively safe—its OR estimate equals 0.445 in the inpatient setting and 0.576 in the outpatient setting; both estimates are statistically significant at the 0.05 level.

Another potential control for the risk of an anesthesia-related complication is the BUs for the procedure, which measure procedure complexity. The estimates in Table 4 do not indicate any relationship of BUs with risk of an anesthesia-related complication in either setting. The BU control is highly insignificant in both the inpatient setting where on average we see relatively higher BU procedures and the outpatient setting. The results indicate that the procedure controls are much better predictors of procedure risk than the BUs associated with the procedure.

The hypothesis that anesthesia-related complications do not differ with patient characteristics can be rejected for both settings (χ^2 P-value = 0). Examining the individual coefficients related to age, all but one of the inpatient model ORs associated with age are insignificant and none of the outpatient model age effects are individually significant. In the outpatient model, females are estimated to be 20% more likely than males to experience a complication in that setting (OR = 1.198, P-value = 0). The inpatient model difference due to sex is less, 13% (significant at the 0.1 level). Generally speaking, the evidence indicates that once other factors are controlled for, there is some variation in the risk of an anesthesia-related complication by patient age group and sex. However, measured by ORs, the variation does not seem to be large.

Although there is strong evidence of differences in anesthesia complications by patient comorbidities and the undergone procedure, and some evidence of variation with patient characteristics, the results in Table 4 provide virtually no evidence that complications differ by either SOP classification or by delivery model. The joint hypothesis tests involving the SOP coefficients and the delivery models are highly insignificant.

Considering first the SOP estimates found in Table 4, most of the ORs are <1.0 when compared with the reference indicator (no supervision). However, none of the estimated ORs is individually statistically significant at the P-value <0.1 level in any of the settings. Specifically, results did not indicate statistical significance in any setting for the supervision categories ($OR_{inpatient} = 1.046$, $OR_{outpatient} = 0.864$) and direction/collaboration categories ($OR_{inpatient} = 0.972$, $OR_{outpatient} = 0.753$). Finally, the P-values for the joint tests involving the SOP indicators are both quite high. Therefore, we fail to reject the hypothesis that anesthesia-related complications are unrelated to SOP classification.

Similarly, none of the delivery model ORs is individually statistically significant at P-value <0.05. The OR estimates for CRNA-only are 1.149 and 1.009 for the inpatient and outpatient settings, respectively. However, neither estimate is significant at the P-value <0.10. These results indicate that the hypothesis that the risk of anesthesia-related complications is the same whether anesthesia is delivered by a CRNA acting alone or by an anesthesiologist acting alone cannot be rejected. Furthermore, the joint test P-values of 0.700 (inpatient) and 0.472 (outpatient) indicate that the joint hypothesis that anesthesia-related complications do not vary by delivery model cannot be rejected for either setting.

Of the geographic controls included in our models, only the rural indicator is statistically significant for the inpatient setting; however, only approximately 6% of procedures were in rural areas. Inpatient procedures performed in rural areas have about 1.213 times higher (P-value = 0.04) likelihood of complications than procedures performed in urban areas. No difference was found in the outpatient setting. We find no evidence that complications vary with the poverty rate ($OR_{inpatient} = 1.003$, $OR_{outpatient} = 0.994$). Local area median family income was associated with a significantly lower likelihood of anesthesia complications for the outpatient setting (OR = 0.990, P-value = 0.10), but no difference was found for the inpatient setting.

DISCUSSION

The primary finding of this study is that there is no statistically significant difference in the risk of anesthesia complications based on the degree of restrictions placed on CRNAs by state SOP laws. Nor is there evidence that the risk of complications varies by delivery model. This evidence suggests that there is no empirical evidence for SOP laws that restrict CRNAs from practicing at levels that are below their education and training based on differences in anesthesia complication risk.

There is strong evidence of differences in anesthesia complications by patient characteristics, patient comorbidities, and the procedures for which anesthesia was administered. Depending on setting, we also find some evidence of variation with geographic factors.

In addition to being consistent with the previous literature, our findings are based on a very large commercial payor database that encompasses a wider patient population and includes data from both the inpatient and ambulatory settings. The larger sample sizes associated with this database provide a greater probability of detecting differences in complications across delivery models and state SOP categories, if differences exist.

An unavoidable limitation of this study is the possibility that small differences in risk may exist but cannot be detected even with the relatively large sample sizes of this study. Moreover, these findings are based on a privately insured population. We have no reason to believe the results would differ for other populations, but publicly insured and uninsured populations are underrepresented here. Finally, though we have controlled for a large number of factors affecting the underlying risk of anesthesia, including the procedure; the age, sex, and comorbidities of the patient; and whether the hospital or outpatient setting was in an urban or rural location, there remains a possibility that selectivity based on factors for which we do not control could have affected the results.

To the extent that state SOP limitations on CRNAs are based on the assumption that anesthesia provided by CRNAs acting alone is riskier than other delivery models, the evidence presented in this study should be considered. Potentially unnecessary restrictions can reduce patient access to high-quality anesthesia services, particularly in underserved areas, and raise the cost of providing quality care.[13,14]

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