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The Effect of "Opt-Out" Regulation on Access to Surgical Care for Urgent Cases in the United States: Evidence from the National Inpatient Sample

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BACKGROUND: In 2001, the Center for Medicare and Medicaid Services issued a rule permitting states to "opt-out" of federal regulations requiring physician supervision of nurse anesthetists. We examined the extent to which this rule increased access to anesthesia care for urgent cases.

METHODS: Using data from a national sample of inpatient discharges, we examined whether opt-out was associated with an increase in the percentage of patients receiving a therapeutic procedure among patients admitted for appendicitis, bowel obstruction, choledocholithiasis, or hip fracture. We chose these 4 diagnoses because they represent instances where urgent access to a procedure requiring anesthesia is often indicated. In addition, we examined whether opt-out was associated with a reduction in the number of appendicitis patients who presented with a ruptured appendix. In addition to controlling for patient morbidities and demographics, our analysis incorporated a difference-in-differences approach, with additional controls for state-year trends, to reduce confounding.

RESULTS: Across all 4 diagnoses, opt-out was not associated with a statistically significant change in the percentage of patients who received a procedure (0.0315 percentage point increase, 95% confidence interval [CI] −0.843 to 0.906 percentage point increase). When broken down by diagnosis, opt-out was also not associated with statistically significant changes in the percentage of patients who received a procedure for bowel obstruction (0.511 percentage point decrease, 95% CI −2.28 to 1.26), choledocholithiasis (2.78 percentage point decrease, 95% CI −6.12 to 0.565), and hip fracture (0.291 percentage point increase, 95% CI −1.76 to 2.94). Opt-out was associated with a small but statistically significant increase in the percentage of appendicitis patients receiving an appendectomy (0.876 percentage point increase, 95% CI 0.194 to 1.56); however, there was no significant change in the percentage of patients presenting with a ruptured appendix (−0.914 percentage point decrease, 95% CI −2.41 to 0.582). Subanalyses showed that the effects of opt-out did not differ in rural versus urban areas.

CONCLUSIONS: Based on 2 measures of access, opt-out does not appear to have significantly increased access to anesthesia for urgent inpatient conditions. (Anesth Analg 2016;122:1983–91)

Anesthesia in the United States is provided by anesthesiologists and nurse anesthetists. There are broad differences in how the 2 groups are used, with nurse anesthetists being more likely to practice in rural areas and more likely to provide monitored anesthesia care, as opposed to general anesthesia.[1,2] Generally, nurse anesthetists are supervised by an anesthesiologist, but occasionally they are supervised by a proceduralist (e.g., the surgeon performing the case). Concerns over access to anesthesia care, as well as predicted future shortages of anesthesiologists,[1] have led policy makers to consider loosening the degree to which nurse anesthetists must be supervised, up to and including independent practice.

The degree to which nurse anesthetists in the United States require supervision is influenced by several entities including hospitals, state laws, and insurer regulations. Until 2001, the United States Centers for Medicare and Medicaid Services (CMS) required nurse anesthetists to be supervised by a physician (either an anesthesiologist or the proceduralist) in order for providers to receive payment from Medicare for the case. That year, in an effort to increase access to anesthesia care, CMS issued a rule allowing states to "opt-out" of this requirement. Specifically, the rule allows health care providers to receive Medicare payments without requiring physician supervision of nurse anesthetists in states where the governor has issued a letter attesting that: (1) s/he has consulted with the state medical and nursing boards about access to and quality of anesthesia services in the state, (2) it is in the interests of the state's citizens to opt-out of the federal requirement, and (3) opt-out is consistent with state law. By 2013, 17 states had decided to opt-out of the Medicare regulations requiring supervision of nurse anesthetists, which could, in theory, allow for independent nurse anesthetist practice.[3]

Debate over the merits of opt-out has focused on 2 issues: whether it has affected quality and whether it has affected access to care. Although a larger literature has explored the

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issue of quality,[4–13] we are unaware of studies examining whether opt-out has improved access to care. This omission is surprising since proponents of opt-out argue that it increases access to care[a] in underserved or rural areas, by expanding the pool of anesthesia providers. Moreover, the CMS rule states that governors must consider the availability of anesthesia care before opt-out, and in choosing to opt-out, governors have typically cited the necessity of improving access to critical services in rural areas. In theory, opt-out could increase access by facilitating nurse anesthetists' independent practice and thereby directly increasing the pool of available anesthesia providers. Whether it has done so in practice remains an open question.

In this article, we use data from the National Inpatient Sample (NIS), a nationally representative sample of inpatient discharges, to examine whether opt-out was associated with increased access to anesthesia care for urgent procedures by considering 2 measures of access. First, we examine whether opt-out was associated with an increase in the percentage of patients admitted for appendicitis, intestinal obstruction, choledocholithiasis, and hip fracture (conditions often requiring urgent access to anesthesia care) who received a procedure requiring anesthesia. Many factors, such as surgeon and patient preferences, will affect the number and percentage of patients who ultimately receive surgery for these conditions, particularly since there are nonoperative alternatives in some cases (e.g., intestinal obstruction). Nonetheless, the percentage of patients receiving surgery is typically used as a proxy for access to surgery.[14,15] Second, we examine whether opt-out was associated with a decrease in the number of acute appendicitis patients presenting with a ruptured appendix, because the incidence of ruptured appendicitis has also been used to measure access to surgery.[16]

METHODS

Data and Sample Selection

This study used deidentified data and did not require IRB approval. We used data from the 1998 to 2010 NIS, produced by the Healthcare Cost and Utilization Project. The NIS is a nationally representative sample of inpatient visits drawn from community hospitals in the United States.[b] Each year, community hospitals from participating states are classified into strata based on rural/urban location, number of beds, region, teaching status, and ownership. A 20% random sample of hospitals is then selected from each stratum, and all admissions to these hospitals in the given year are recorded. The NIS provides detailed patient-level data for each admission, including demographic variables such as age, sex, and insurance status, as well as *International Classification of Diseases, Ninth Revision* (ICD-9) procedure and diagnosis codes obtained from the discharge abstract. The diagnoses can be the admitting diagnosis, as well as diagnoses present on discharge. In addition, the NIS provides data on the hospital, such as its state and whether it is located in a rural or urban area. The NIS has been extensively used to examine trends in health care utilization,[17] as well as the effect of policies at the state level.[18,19]

We extracted all patients with a diagnosis code (either primary or secondary diagnosis), indicating appendicitis, bowel obstruction, choledocholithiasis, or hip fracture. Our inclusion/exclusion criteria for each condition were adopted from previous studies and are shown in Table 1.[15,17,20–23] In all, we identified 802,892 cases of appendicitis, 724,475 cases of bowel obstruction, 293,863 cases of choledocholithiasis, and 808,888 cases of hip fracture. We then excluded patients younger than 18 years, patients with more than one of these diagnoses, and patients with missing data on our covariates of interest (see below). With these exclusions, our final sample consisted of 574,807 cases of appendicitis, 693,257 cases of bowel obstruction, 286,196 cases of choledocholithiasis, and 798,870 cases of hip fracture. Of note, the methods used to identify choledocholithiasis exclude chronic biliary obstruction (a nonurgent scenario), while the methods used to identify hip fracture include low-velocity hip fractures and exclude high-velocity hip fractures, such as those associated with polytrauma.

Outcomes

Our outcomes consisted of 2 measures of access. The first was whether an individual patient underwent a procedure (typically a surgery), which we inferred by the presence of the ICD-9 procedure codes listed in Table 1. Using these codes, we generated a dummy variable, which equaled 1 if a patient underwent a procedure and 0 otherwise. For choledocholithiasis, patients could receive 3 types of procedures (i.e., surgery, endoscopic procedures, and percutaneous procedures), and we considered any of the 3. It is important to note that the NIS does not follow a patient across hospitals, so if a patient was admitted and then transferred to another hospital for the procedure, we would have no record of the subsequent admission. However, we would observe that the patient did not receive a procedure at the initial hospital. Since transfer represents a lack of access, both in terms of patient inconvenience and because it delays the receipt of a potentially urgent procedure, our approach counted these transferred patients as not having received a procedure. Our second outcome, limited to patients with appendicitis, was a dummy variable equaling 1 if the patient presented with a ruptured appendix (ICD-9 540.0 or 540.1) and zero otherwise.

Variables

Our analysis included 2 independent variables of interest. The first indicated whether opt-out was in effect. Specifically, a dummy variable equaled 1 in the opt-out states starting the year following the opt-out year (Table 1). For non-opt-out states and for opt-out states in the years before and including the opt-out year, the variable equaled zero. It is important to note that the number of states participating in the NIS has grown over time from 22 in 1998 to 46 in 2010. Therefore, our analysis of the NIS characterized the experience of opt-out states that (a) reported data to the NIS and (b) chose to opt-out at least 1 year after initially providing data to the NIS. For example, Colorado opted-out in 2010 and so was not examined. Table 2 provides a list of opt-out states, the year they chose to opt-out, and the year they began providing data to the NIS.

[a]See "February Marks 10-Year Anniversary of Landmark Decision Ensuring Nebraskans Access to Safe, Cost-Effective Anesthesia Care," available at http://www.aana.com/newsandjournal/News/Pages/022412-February-Marks-10-Year-Anniversary-of-Landmark-Decision-Ensuring-Nebraskans.aspx.

[b]In essence, "community hospitals" exclude Federal hospitals (e.g., hospitals run by the United States Veterans Administration or the military), as well as hospitals that are part of an institution (e.g., a prison hospital).

Table 1. ICD-9 Diagnosis and Procedure Codes for Appendicitis, Bowel Obstruction, Choledocholithiasis, and Hip Fracture

	Inclusion ICD-9 diagnosis codes	Exclusion codes	ICD-9 codes used to indicate whether patient received a procedure
Appendicitis	540.0,[a] 540.1,[a] 540.9, 541, 542	ICD-9 procedure codes 47.1, 47.11, 47.19	47.01, 47.09, 54.21, 54.51, v64.4
Bowel obstruction	560.9, 560.81		54.11, 54.21, 54.50, 54.51, 54.59, 45.61, 45.62, 54.61, 54.62
Choledocholithiasis	574.3, 574.31, 574.4, 574.41, 574.5, 574.51, 574.60, 574.61, 574.70, 574.71, 574.80, 574.81, 574.90, 475.91, 577.0, 576.1	ICD-9 diagnosis codes 576.2, 996.82, 577.1, 577.2; ICD-9 procedure codes 50.59, 50.5, 50.51; CCS groups 16–18	Endoscopic: 51.10, 51.11, 51.64, 51.84, 51.85, 51.86, 51.87, 51.88 Surgical: 51.02, 51.03, 51.04, 51.05, 51.31, 51.32, 51.33, 51.34, 51.35, 51.36, 51.37, 51.39, 51.41, 51.42, 51.43, 51.49, 51.51, 51.59, 51.61, 51.62, 51.63, 51.69, 51.71, 51.72, 51.79 Percutaneous: 51.01, 51.96, 51.98
Hip fracture	820, 733.14	800–819, 821–829, 830–839, 840–848, 850–854, 860–887, 925–929, E800-E807, E810-E838, E840-E848	00.7, 79.15, 79.25, 79.35, 81.40, 81.51–81.53

ICD-9 diagnosis codes used to identify patients admitted for appendicitis, bowel obstruction, choledocholithiasis, and hip fracture, as well as the ICD-9 procedure codes used to identify whether patients underwent a corresponding procedure for their condition. Patients were determined to meet the criteria for appendicitis, bowel obstruction, choledocholithiasis, or hip fracture if they had at least one of the associated ICD-9 diagnosis codes list under “Inclusion ICD-9 Diagnosis Codes” and none of the ICD-9 codes listed under “Exclusion ICD-9 Diagnosis codes.” In the case of choledocholithiasis, the table shows the codes for 3 types of procedures: endoscopic, surgical, and percutaneous procedures. The codes above were adopted from previous studies as discussed and referenced in the methods section.

ICD-9 = *International Classification of Diseases, Ninth Revision.*

[a]Codes used to identify a ruptured appendix.

Table 2. List of Opt-Out States

State	Opt-out date	Year entered NIS
Iowa	December 2001	1998
Nebraska	February 2002	2001
Idaho	March 2002	N/A
Minnesota	April 2002	2001
New Hampshire	June 2002	2003
New Mexico	November 2002	2009
Kansas	April 2003	1998
North Dakota	October 2003	N/A
Washington	October 2003	1998
Alaska	October 2003	2010
Oregon	December 2003	1998
Montana	January 2004	2009
South Dakota	March 2005	2002
Wisconsin	June 2005	1998
California	June 2009	1998
Colorado	September 2010	1998
Kentucky	April 2012	2000

The list of states opting-out of federal regulations requiring physician supervision of Certified Registered Nurse Anesthetists. The second column provides the date the opt-out decision took effect, and the third column shows the first year the state began providing information to the Nationwide Inpatient Sample (NIS). “N/A” means that the state did not provide data to the NIS during the study period.

We also obtained additional control variables including patient age and sex. In addition, we controlled for comorbidities using a version of the Charlson Index that has been modified for use with administrative databases.[24] Although the NIS does record race, we did not include controls for race in our analysis because it was inconsistently reported across states in the NIS, and indeed was missing for 23% of our sample.

Statistical Analyses

Our analysis used a difference-in-differences approach to further minimize confounding.[25] Even after controlling for the various patient factors listed above (e.g., Charlson Index and age), a simple comparison of outcomes between opt-out and non-opt-out states is likely to face additional confounding due to unobservable differences between patients in these 2 groups of states. With a difference-in-differences approach, state-specific controls are used to adjust for unobservable state-level factors. Therefore, rather than comparing outcomes across states, the difference-in-differences approach identifies the effect of opt-out by comparing outcomes in the pre- and post-opt-out period within the opt-out states. The difference-in-differences approach also controls for year effects to control for secular trends at the national level, such as general changes in surgical practice.

We implemented our difference-in-differences approach by using a multivariable linear regression. Our dependent variable in this regression was an indicator variable indicating whether the patient received a procedure/presented with a ruptured appendix. Our independent variable of interest was a dummy variable indicating whether opt-out is in effect. The coefficient on this variable can be interpreted as the difference in the percentage of patients undergoing a procedure/presenting with appendiceal rupture following opt-out in urban areas. For example, if the coefficient equaled 0.0500, this would imply that opt-out was associated with a 5.00% (absolute) increase in the probability of surgery/appendiceal rupture.

Our baseline analysis combines patients with appendicitis, bowel obstruction, choledocholithiasis, or hip fracture when examining how opt-out affected the probability of receiving a procedure. In addition, we analyzed the effect of opt-out on each diagnosis separately. In the case of appendiceal rupture, our analysis was necessarily limited to patients presenting with appendicitis. In addition to the difference-in-differences approach described above, we incorporated the use of state-specific linear and quadratic year trends to further reduce confounding by controlling for secular time trends at the state level. For example, these trends would control for changes in surgical practice occurring at a state level. Since the NIS is a multistage, stratified sample of admissions, all our analyses incorporate appropriate sampling weights (the TRENDWT variable), and our standard errors are adjusted for clustering by state.[26] We performed our analyses with STATA 13.0 (College Station, TX). We adjusted our confidence intervals for each of the 4 individual procedures composing our composite end point using the Bonferroni method. Further details are found in Appendix 1.

Subanalyses

The baseline analyses we described above examined the degree to which opt-out affected outcomes at across the entire state. However, these analyses may understate the effect of opt-out if its effects were limited to particular parts of the state. For example, suppose that, as a result of opt-out, more hospitals were opened in rural areas so that, instead of being transferred to an urban hospital, rural patients now received their procedure closer to home. Then at the statewide level, there would be no change in the overall number of procedures (or probability of receiving a procedure). Procedures that had been done in urban areas would now be done in rural areas. However, this finding would underestimate the true effect of opt-out because rural patients are now able to receive their procedure closer to home, and access has increased.

To address this scenario, we tested for the possibility that opt-out had differential effects in urban and rural areas. Our approach was built on the baseline analyses described above by incorporating a second independent variable of interest consisting of an interaction term between our opt-out variable and a dummy variable that equaled 1 if a hospital were located in a rural area and 0 otherwise. Our interaction term was produced by multiplying our opt-out variable by our variable indicating rural status. Thus, it equaled 1 if opt-out were in effect and the hospital were located in a rural area, and 0 otherwise. By adding this interaction term, the interpretation on our original opt-out variable now changes slightly, because it now represents the effect of opt-out in urban areas, while the coefficient on this new interaction term represents the effect of opt-out in rural areas, relative to its effect in urban areas. For example, suppose that the coefficient on our opt-out variable were 0.0500 and the coefficient on our interaction term −0.0200. In tandem, these results would indicate that opt-out was associated with a 5.00% (absolute) increase in procedure rates/appendiceal rupture in urban areas and that the effect of opt-out was 2.00% lower in rural areas, relative to urban areas. This, the effect of opt-out in rural areas overall would be a 3.00% (=5.00% − 2.00%) increase. In short, the coefficient on the interaction term is a test of the hypothesis that opt-out had a different effect in rural areas.

We used the NIS variable HOSP_LOCATION to identify rural hospitals. Before 2004, the NIS defined urban hospitals as those located in a Metropolitan Statistical Area (MSA) as delineated by the United States Office of Management and Budget (OMB). Hospitals not located in an MSA were defined as rural.[c] In defining an MSA, the OMB first looks for an urban area with a population of at least 50,000 people. The MSA is then defined as the set of counties containing the urban area, as well as the set of counties with close economic and social ties to the urban area, as measured by commuting patterns. In 2004, the definition of "rural" used by the NIS changed slightly primarily because it now defined rural counties based on a newer OMB entity, the metropolitan Core-Based Statistical Area (CBSAs). Functionally, metropolitan CBSAs and MSAs are similarly defined. However, in identifying metropolitan CBSAs, the NIS used data from the 2000 United States census, while it had used data from the 1990 United States census to define MSAs. This change resulted in a slight decrease in the number of hospitals classified as rural, with a corresponding increase the number of hospitals classified as urban.

RESULTS

Table 3 shows summary statistics for our sample. With regard to age, sex, and Charlson Index, there were some differences between the opt-out and non-opt-out states that were small in magnitude (standardized differences scores <0.05) and generally always of no statistical significance. There were no significant differences in the percentage of patients receiving a procedure in the case of hip fracture, choledocholithiasis, and appendicitis. We found that a slightly smaller percentage of patients with bowel obstruction received a procedure in opt-out states (27.1% vs 28.9%, $P = 0.029$).

Figure 1 plots trends in surgical rates for patients with bowel obstruction, appendicitis, choledocholithiasis, and hip fracture. The figure demonstrates 2 important facts. First, as indicated from previous literature, the percentage of patients undergoing a procedure was smaller in rural areas. Second, while the percentage of patients undergoing a procedure overall declined during this period, the decline qualitatively "looks" sharper among the opt-out states, particularly in rural areas. While this result provides a basis for suggesting that opt-out did not increase access to surgery, the goal of our difference-in-differences approach is to analyze this result more rigorously by imposing additional controls for case mix, patient characteristics, and secular time trends at the national and state level. Similar to Figure 1, Figure 2 plots the percentage of patients with appendicitis who presented with a ruptured appendix. Overall, there appears to have been a downward trend in the incidence of appendiceal rupture during this period. Qualitatively, the trend does not appear to be different in opt-out versus non-opt-out states, again providing some basis to suggest that opt-out did not decrease rates of appendiceal rupture.

Table 4 presents the results of our analysis in 3 columns. The first column presents our baseline results, which show the effect of opt-out at the state level. Across all 4 diagnoses (bowel obstruction, appendicitis, choledocholithiasis, and hip fracture), opt-out was not associated with a significant increase in the percentage of patients who received a procedure in urban hospitals (0.0315 percentage point increase, $P = 0.926$). From the confidence interval, there could be an (absolute) increase as large as 0.906%. When considered by procedure, opt-out was associated with statistically insignificant changes in the percentage of patients undergoing a procedure for bowel obstruction (0.511 percentage point decrease, $P = 0.455$), choledocholithiasis (−2.78 percentage point increase, $P = 0.144$), and hip fracture (0.291 percentage point increase, $P = 0.713$).

[c]See https://www.hcup-us.ahrq.gov/db/vars/hosp_location/nisnote.jsp.

Table 3. Summary Statistics from the Nationwide Inpatient Sample, 1998–2010

	Bowel obstruction			Appendicitis			Choledocholithiasis			Hip fracture		
	Opt-out	Non-opt-out	*P*	Opt-out	Non-opt-out	*P*	Opt-out	Non-opt-out	*P*	Opt-out	Non-opt-out	*P*
n	159,524	533,733		145,989	428,818		69,005	217,191		185,184	613,686	
Age (y)	65.1 (64.2–65.9)	64.2 (63.7–64.8)	0.093	40.8 (40.3–41.3)	40.9 (40.4–41.5)	0.708	58.2 (55.7–60.7)	59.5 (57.9–61.1)	0.353	80.5 (79.8–81.1)	79.6 (79.2–80.0)	0.019
Female (%)	58.7 (58.1–59.4)	59.2 (58.8–59.6)	0.183	46.3 (45.6–47.0)	46.2 (45.8–46.5)	0.650	66.1 (64.0–68.3)	65.0 (63.4–66.1)	0.313	71.5 (70.8–72.2)	72.5 (72.0–73.1)	0.015
Charlson index	4.22 (4.15–4.29)	4.14 (4.06–4.21)	0.086	1.68 (1.63–1.73)	1.69 (1.66–1.73)	0.599	3.15 (2.99–3.31)	3.25 (3.12–3.38)	0.328	5.17 (5.15–5.19)	5.08 (5.04–5.13)	*
Received procedure (%)	27.1 (25.7–28.6)	28.9 (28.0–29.7)	0.029	94.3 (94.0–94.6)	94.0 (93.5–94.4)	0.177	68.1 (66.0–70.3)	70.1 (68.3–71.8)	0.145	78.1 (75.1–80.1)	80.8 (79.0–82.5)	0.091

Summary statistics for the patients admitted for bowel obstruction, appendicitis, choledocholithiasis, and hip fracture. For choledocholithiasis, "Received Procedure" refers to patients who underwent surgery, endoscopy, or a percutaneous procedure (see Table 2). 95% confidence intervals are shown in parentheses. The statistical significance of differences between patients in opt-out and non-opt-out states was tested using a *t* test, and the results are shown in the column labeled "*P*."

$^*P < 0.0001$.

In the case of appendicitis, we observed a small but statistically significant increase in the percentage of patients undergoing a procedure (0.876 percentage point increase, $P = 0.008$). Opt-out was also associated with a statistically insignificant change in the percentage of appendicitis patients who presented with a ruptured appendix (0.914 percentage point decrease, $P = 0.119$).

In addition to our baseline results, Table 4 presents the results of a subanalysis examining whether opt-out had differential effects in rural and urban areas. Column 2 shows the effect of opt-out in urban areas, while column 3 shows the impact of opt-out in rural areas relative to its effect in urban areas. The values in column 3, therefore, expressed the extent to which opt-out affected rural areas separately from urban areas. Across all our outcomes, the values shown in column 3 are statistically insignificant, suggesting that the effects of opt-out were not different across rural and urban areas.

DISCUSSION

Although many states have chosen to opt-out with the stated intention of increasing access to anesthesia care, whether the decision to do so has actually increased access is an open question. Using 2 measures of access: the percentage of patients receiving surgery for 4 urgent conditions (appendicitis, small bowel obstruction, hip fracture, and choledocholithiasis) and the percentage of patients with appendicitis who presented with a ruptured appendix, we found that opt-out was not associated with increased access to anesthesia care. Our results also suggest that opt-out did not have heterogeneous effects across urban and rural areas.

These results may not necessarily be surprising. First, as previously discussed, opt-out merely means that the federal government will continue to pay providers when nurse anesthetists practice independently. This does not require states, hospitals, insurers, or surgeons to accept independent nurse anesthetist practice; each of these groups is free to restrict the scope of nurse anesthetist practice. Indeed, 14 of the 17 opt-out states do not allow true independent nurse anesthetist practice, because statutes and regulations at the state level require nurse anesthetists to work in a relationship with a physician, which may involve physician supervision, collaboration, consultation, agreement, accountability, or discretion over nurse anesthetists providing anesthesia services. Second, even if opt-out expands the supply of anesthesia providers, this expansion will not result in an increase in anesthesia services if the supply of proceduralists is insufficient. In this light, our results should not imply that opt-out could never increase the supply of anesthesia services. Rather, our results suggest that opt-out is unlikely to increase the supply of anesthesia services in the absence of policies addressing the issues outlined above. These features are not limitations of our study, however, because our goal was to examine the effects of opt-out as it was actually implemented.

Our study should be viewed in light of its limitations. We cannot exclude the possibility that unobserved factors, such as changes in patient population or surgical practice, could explain our results. However, our difference-in-differences approach does minimize the possibility of confounding. For a factor to confound our results, it would have to be

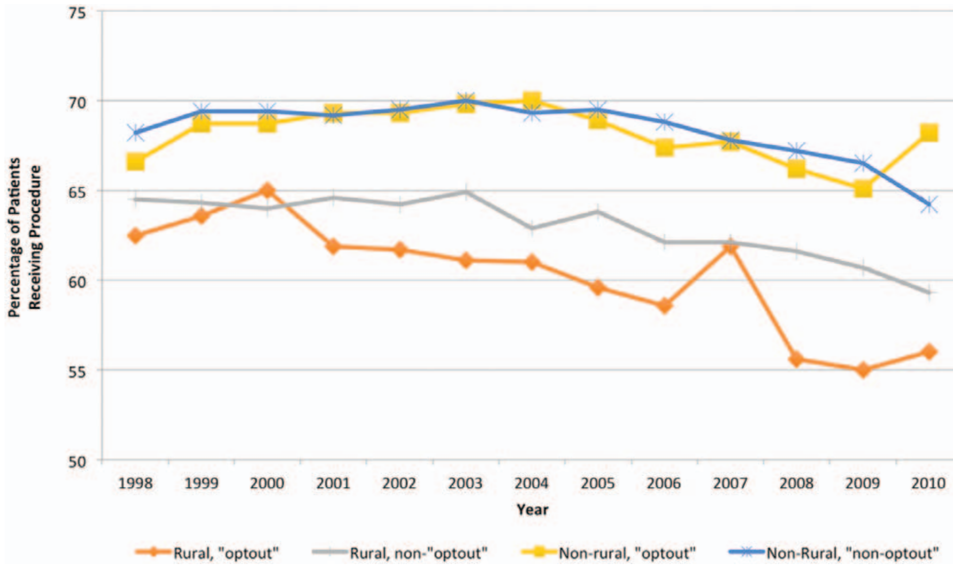

Figure 1. Trends in percentage of patients with bowel obstruction, appendicitis, choledocholithiasis, and hip fracture who received a procedure, 1998–2010.

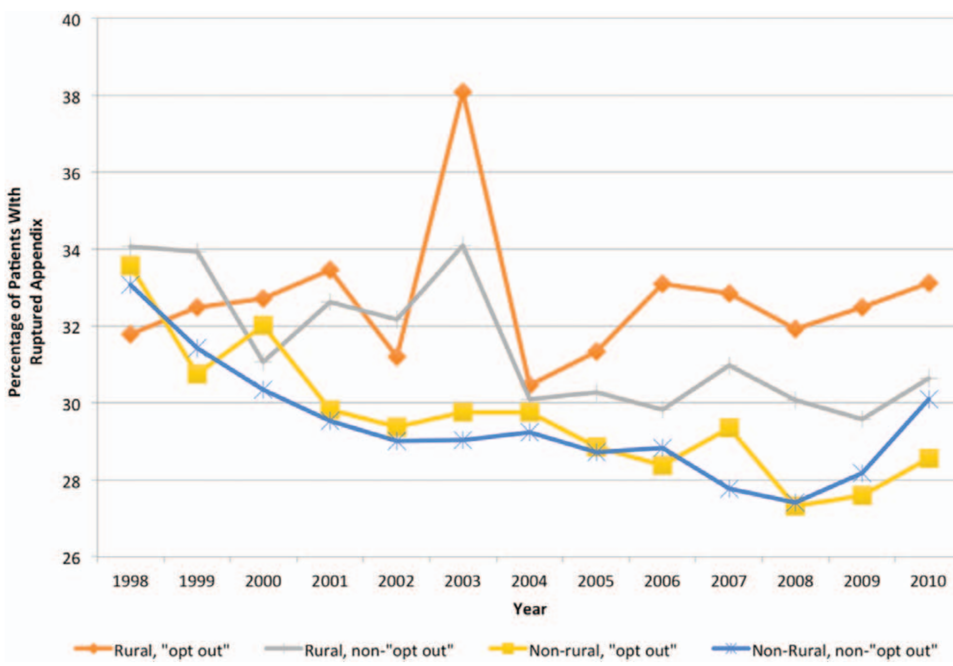

Figure 2. Percentage of patients with appendicitis presenting with a ruptured appendix, 1998–2010.

associated with the timing of opt-out among each opt-out state and be independent of yearly effects at a national level, as well as secular time trends at the state level. In addition, as previously noted, our analysis does not cover the entirety of opt-out states, because not all states submitted data to the NIS. In addition, our findings only address the issue of whether opt-out has affected access to care; whether it has affected quality remains an area for further study. Finally, our study is limited to the case of urgent surgery for 4 conditions. As previously noted, nurse anesthetists and anesthesiologists tend to practice anesthesia in different settings. It is possible that opt-out could have increased access to other types of anesthesia care, such as monitored anesthesia care for elective cases. Whether it may have done so, and the social value of these increases, are subjects for further research, using a dataset different from the NIS that we used.

In sum, our results suggest that opt-out has not significantly increased access to anesthesia care for urgent inpatient procedures. Although we did not consider elective and/or outpatient procedures, presumably one of the primary goals of opt-out would have been to increase access to urgent inpatient procedures, both because of their acuity and because, as demonstrated here, rates of surgery are markedly lower in rural areas, with potential implications for patient health.

Table 4. Effect of Opt-Out on Probability of Surgery for Bowel Obstruction, Appendicitis, and Choledocholithiasis and Probability of Appendiceal Rupture

	n	(1) Entire State	(2) Urban	(3) Rural
Change in probability of receiving surgery (%)				
All (bowel obstruction, appendicitis, choledocholithiasis, hip fracture)	2,352,430	0.0315 (−0.843, 0.906)	0.0366 (−1.06, 1.13)	0.458 (−3.78, 4.70)
Bowel obstruction	693,257	−0.511 (−2.28, 1.26)	−0.839 (−2.96, 1.28)	2.97 (−2.18, 8.11)
Appendicitis	574,107	0.876* (0.194, 1.56)	0.804 (−0.272, 1.88)	0.448 (−2.08, 2.97)
Choledocholithiasis (any procedure)	286,196	−2.78 (−6.12, 0.565)	−3.22 (−6.36, −0.0816)	1.54 (−12.3, 15.4)
Choledocholithiasis (endoscopy)		−2.76 (−6.12, 0.589)	−3.30 (−6.74, 0.142)	0.968 (−14.1, 16.1)
Choledocholithiasis (surgery)		−0.280 (−1.37, 0.803)	−0.148 (−1.71, 1.41)	−0.607 (−5.91, 4.70)
Choledocholithiasis (percutaneous)		−0.0340 (−0.628, 0.560)	0.127 (−0.421, 0.675)	−0.737 (−1.90, 0.427)
Hip fracture	798,870	0.291 (−1.76, 2.34)	0.806 (−1.73, 3.34)	−0.967 (−8.35, 6.41)
Change in probability appendiceal rupture (%)				
Appendicitis	693,257	−0.914 (−2.41, 0.582)	−1.45 (−3.30, 0.401)	3.21 (−1.17, 7.59)

The results of a multivariable linear regression in which the dependent variable indicates whether a patient with the given diagnosis received surgery (top half of the table) or whether the patient presented with appendiceal rupture (bottom half of the table). In the case of choledocholithiasis, we considered three possible procedures: surgery, endoscopy, and percutaneous intervention. Column (1) shows the absolute (percentage point) difference in the probability of receiving surgery/appendiceal rupture associated with opt-out across the entire state (rural and urban areas combined). Column (2) shows the absolute (percentage point) difference in the probability of receiving surgery associated with opt-out in urban areas. Column (3) shows the change in rural areas *relative* to *urban areas*. Thus, the total change in rural areas is the sum of columns (2) and (3). 95% confidence intervals are shown in parentheses. Standard errors clustered at the state level. Analyses above include controls for state, year, state-specific year trends, age, sex, and Charlson index. Bonferroni-corrected *P* values shown;
*$P < 0.05$.

While increasing access to surgery, particularly in underserved areas, is a laudable goal, our results suggest that opt-out alone is unlikely to address this issue.

APPENDIX 1

In this technical appendix, we describe in detail the implementation of our difference-in-differences approach. As discussed in the main body of the paper, a simple comparison of outcomes between opt-out and non-opt-out states may suffer from confounding due to differences in observable and unobservable factors between the 2 groups, such as patient type and surgical practice patterns. Although we did control for many plausible differences—such as Charlson scores, race, and sex—these controls might not fully account for all plausible confounders.

The difference-in-differences approach, which has been extensively used to evaluate the effects of policy,[25] provides one way to minimize confounding. At heart, the difference-in-differences approach estimates the effect of opt-out by performing 2 calculations. First, it evaluates the change in outcomes among "opt-out" states following the decision to opt-out rather than simply comparing opt-out states to non-opt-out states. By focusing on the changes in outcomes before and after opt-out *within* a given state, the difference-in-differences approach eliminates much of the confounding that may occur due to differences in patients, surgeons, and hospitals across states. However, this simple "before-after" comparison can also be confounded by secular trends (such as changes in practice patterns) at the national level. The difference-in-differences approach addresses this issue by including year-specific controls to control for year-to-year variability in surgical rates at the national level.

We can implement a basic difference-in-differences approach using the following linear regression:

$$surgery_{ijt} = f_i + d_t + \Gamma X_i + \beta opt\text{-}out_{jt} + \varepsilon_{ijt} \quad (1)$$

where $surgery_{ijt}$ is an indicator variable indicating whether patient i received surgery in state j in year t. $surgery_{ijt}$ was set to equal 1 if the patient received surgery and 0 otherwise. f_i is a state effect for state i and d_t is a year effect for year t. Γ_i is a vector of patient characteristics: age, sex, and Charlson score. The year effects d_t, state effects f_i, age, and Charlson scores were modeled as categorical variables. In other words, they were composed of vectors of indicator variable equaling 1 if the patient met the relevant criteria and 0 otherwise. For example, the state effects f_i consisted of a vector of indicator variables, one for each state in our analysis, equaling 1 if the hospital was located in the given state and 0 otherwise. Similarly, for age, we incorporated a vector of indicator variables equaling 1 if the patient was of the given years of age (e.g., age = 62 years) and 0 otherwise. $opt\text{-}out_{ijt}$ is an indicator variable which equals one if opt-out was in effect in state j during year t and 0 otherwise. ε_{ijt} is the error term in the regression. Our coefficient of interest is β, which represents the absolute (percentage point) change in the percentage of patients who received a procedure associated with a state's decision to "opt-out."

We expanded the basic regression shown in Equation (1) in 2 ways. First, d_t, our year effect, was used to control for secular time trends at the national level. In our final regression model, we incorporated additional controls for secular time trends occurring at the state level, leading to the following regression equation:

$$\begin{aligned} surgery_{ijt} = f_i + d_t + \alpha_1\left(year \times f_j\right) + \alpha_2\left(year^2 \times f_j\right) \\ + \Gamma X_i + \beta_1 opt\text{-}out_{jt} + \varepsilon_{ijt} \end{aligned} \quad (2)$$

Equation (2) is similar to Equation (1), except that we included the terms $year \times f_j$, which controls for secular linear trends occurring at the state level, and $year^2 \times f_j$, which controls for secular quadratic trends occurring at the state level. Equation (2) formed the basis for our baseline analyses, which examined how opt-out affected our outcomes at the state level. As we noted, however, it is also important to test the potential that opt-out may have affected urban and rural areas differentially. To test this hypothesis, we used the following regression equation:

$$surgery_{ijt} = f_i + d_t + \alpha_1\left(year \times f_j\right) + \alpha_2\left(year^2 \times f_j\right) + \Gamma X_i + \beta_1 opt\text{-}out_{jt} + \beta_2\left(opt\text{-}out_{jt} \times rural_{it}\right) + \varepsilon_{ijt} \quad (3)$$

Equation (3) is similar to Equation (2), except that we included the term $opt\text{-}out_{jt} \times rural_{it}$, which was our interaction term. This term was obtained by multiplying our opt-out variable, $opt\text{-}out_{jt}$, by another indicator variable, $rural_{it}$, equaling one if the patient was seen in a rural hospital and zero otherwise. Thus, our interaction term, $opt\text{-}out_{jt} \times rural_{it}$, equaled one only if opt-out was in effect and if the patient was seen in a rural hospital. As can be seen from Equation (3), β_1 represented the effect of opt-out in urban areas, while β_2 represented the effect of opt-out in rural areas *relative to its effect* in urban areas. Therefore, testing the hypothesis that opt-out had a different effect in rural areas was a test of the hypothesis that $\beta_2 = 0$. In addition, note that the total effect of opt-out in rural areas was $\beta_1 + \beta_2$. Although not shown in Equation (3) for the purposes of exposition, in estimating Equation (3), we also interacted $rural_{it}$ with each of the other covariates (e.g., f_i, d_t, ($year \times f_j$), ($year^2 \times f_j$), and X_i) to allow for the possibility that the effects of these variables could differ in urban and rural areas. Given the large number of terms in our regression, we only reported the results for β_1 and β_2. Results for the other regression coefficients are available upon request.

Because the National Inpatient Sample employs a complex sampling strategy, we incorporated sampling weights (the TRENDWT variable) in our analyses. In addition, we clustered our errors at the state level. Our sample consists of 2,353,130 observations, each with a corresponding sampling weight. A simple ordinary least squares regression would tend to underestimate our standard errors (and therefore overestimate the statistical significance of our regression coefficients) because these observations were not independent, since observations within a given state were likely to be correlated. Calculating clustered standard errors is an appropriate approach to deal with this issue.[27] In essence, clustering adjusts the standard errors based on the observed level of correlation within a given unit (cluster) defined by the investigator. Since we were primarily concerned with correlation within a given state, we clustered our standard errors at the state level.[28]

By using a linear regression, we estimated a linear probability model, in contrast to a probit or logistic regression. We chose a linear probability model for several reasons. First, implementing our difference-in-differences model, along with the controls for linear and quadratic trends, required the use of numerous indicator variables, which can lead to computational difficulties with logistic or probit regression.[29] Second, the coefficients from the linear probability model are easier to interpret and directly correspond to the increase in probability that a patient received surgery. By contrast, it is harder to translate the coefficients from a logistic or probit regression into the change in probability for receiving surgery. For example, odds ratios are easily estimated from a logistic regression and are an unbiased estimator for changes in probability for rare events.[30,31] However, since around 50% of patients receive a procedure, odds ratios would be a biased measure of probability changes in our case. Finally, since our analysis incorporated an interaction term between 2 dummy variables to estimate how opt-out affects the probability of surgery in rural areas, we chose a linear probability model as the interpretation of this interaction term is more straightforward.[32]

DISCLOSURES

Name: Eric Sun, MD, PhD.
Contribution: This author helped design the study, conduct the study, analyze the data, and write the manuscript.
Conflicts: Eric Sun reported no conflicts of interest.
Attestation: Eric Sun has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files.
Name: Franklin Dexter, MD, PhD.
Contribution: This author helped design the study, analyze the data, and write the manuscript.
Conflicts: Franklin Dexter reported no conflicts of interest.
Attestation: Franklin Dexter has reviewed the analysis of the data and approved the final manuscript.
Name: Thomas R. Miller, PhD, MBA.
Contribution: This author helped design the study and write the manuscript.
Conflicts: Thomas R. Miller is employed by the American Society of Anesthesiologists.
Attestation: Thomas R. Miller has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

RECUSE NOTE

Applicable as of the accept date of this article (November 20, 2015), Dr. Dexter is the Statistical Editor for *Anesthesia & Analgesia*. This manuscript was handled by Dr. Jean-Francois Pittet, Incoming Editor-in-Chief, and Dr. Dexter was not involved in the editorial process or decision.

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