

# “Take the Volume Pledge” may result in disparity in access to care

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**Background.** “Take the Volume Pledge” proposes restricting pancreatectomies to hospitals that perform  $\geq 20$  per year. Our purpose was to identify those factors that characterize patients at risk for loss of access to pancreatic cancer care with enforcement of volume standards.

**Methods.** Using the Healthcare Cost and Utilization Project State Inpatient Database from Florida, we identified patients who underwent pancreatectomy for pancreatic malignancy from 2007–2011. American Hospital Association and United States Census Bureau data were linked to patient-level data. High-volume hospitals were defined as performing  $\geq 20$  pancreatic resections per year. Univariable and multivariable statistics compared patient characteristics and utilization of high-volume hospitals.

Classification and Regression Tree modeling was used to predict patients at risk for losing access to care. **Results.** Our study included 1,663 patients. Five high-volume hospitals were identified, and they treated 1,056 (63.5%) patients. Patients residing far from high-volume hospitals, in areas with the highest population density, non-Caucasian ethnicity, and greater income had decreased odds of obtaining care at high-volume hospitals. Using these factors, we developed a Classification and Regression Tree-based predictive tool to identify these patients.

**Conclusion.** Implementation of “Take the Volume Pledge” is an important step toward improving pancreatectomy outcomes; however, policymakers must consider the potential impact on limiting access and possible health disparities that may arise. (Surgery 2016;■:■-■.)

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IN THE UNITED STATES, >46,000 people are diagnosed with pancreatic malignancy each year. The number of cases has been increasing and is projected to continue to rise. Because of the aggressive nature of the disease, pancreatic cancer incidence rates nearly equal mortality rates, making it the fourth leading cause of death by cancer in the United States (US).<sup>1</sup> Furthermore, because pancreatic malignancies tend to be diagnosed late in the natural history of the disease process, pancreatic resection, the standard of care and only potentially curative treatment, is only an option for a limited number of patients, ranging from 5–22%.<sup>2</sup>

The number of patients undergoing pancreatectomy continues to increase, with a corresponding rise in the proportion of patients undergoing this complex operative procedure at high-volume centers.<sup>3–5</sup> This trend has been accompanied by a continuous reduction in the overall perioperative mortality, from about 25% in the 1960s to <5% today.<sup>2–4,6,7</sup> Multiple factors explain this decrease, including changes in hospital resources, better patient selection, new operative techniques, and improved care coordination.<sup>4</sup> Another proposed factor is the increase of patients undergoing care at high-volume centers.<sup>8</sup>

The association between greater operative volume and improved outcomes has been described broadly in the literature and is especially strong for complex operative procedures.<sup>3–6,8</sup> The “Take the Volume Pledge” effort is a policy campaign announced in May 2015 by leaders of 3 large health systems aimed at addressing this substantial body of evidence. The campaign encourages the use of specific volume thresholds for several operations, including a minimum of 20 pancreatectomies per year per hospital for pancreatic malignancy.<sup>9</sup> Additionally, hospitals within these 3

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health systems that perform less than this number would not be permitted to perform that procedure, and their patients would be forced to seek care at high-volume centers within the system.

Although the intention of this limitation is to provide patients with the best possible operative care, it is unclear if the volume restrictions in this proposal will lead to access of care issues that ultimately could lead to a delay in patients' procedures and reduce continuity of postoperative care.<sup>10,11</sup> Previous experience with volume standards imposed for bariatric operation among Medicare beneficiaries has shown that access to care can be affected negatively by such measures.<sup>12</sup>

The purpose of this study was to identify the socioeconomic and geographic factors that characterize patients currently being treated at low-volume hospitals who might be at risk of losing access to pancreatic cancer care with enforcement of the proposed volume threshold. In addition, this study attempted to develop a predictive tool to allow policymakers to identify patients vulnerable to losing access if such restrictions initially proposed for these 3 health care systems were put in place in an entire state.

## METHODS

**Data sources.** To conduct this retrospective study, the Healthcare Cost and Utilization Project (HCUP) State Inpatient Database (SID) from Florida was used to extract patient-level data. HCUP-SID was developed through sponsorship by the Agency of Health Research and Quality, and it includes all patient discharge records, regardless of payer, for the states that participate in the project.<sup>13</sup> Florida was chosen because it offers a diverse network of hospital-led health systems and is a rich source of administrative patient-level data.

Additionally, previous studies assessing access issues have used Florida data,<sup>14,15</sup> and the HCUP data set for Florida is one of only a few that includes patient zip codes, allowing for this kind of study. HCUP Florida is an all-payer data set, allowing for the capture of both insured and uninsured patients. For institutions that performed  $\geq 1$  pancreatic resection per year, hospital-level data were obtained from the 2011 American Hospital Association Annual Survey Database,<sup>16</sup> which is a comprehensive census of US hospitals that contains a snapshot of hospital-specific data, including organizational structure, staffing, hospital facilities and services, geographic indicators, and financial performance.

Finally, demographic data were obtained from the 2010 Census and 2011 American Community Survey collected by the US Census Bureau.<sup>17</sup> Both hospital and demographic data were linked to HCUP-SID patient-level data using each hospital's unique identification number and patient zip codes, respectively. This study was deemed exempt from Institutional Review Board approval based on the use of deidentified records.

**Patient inclusion.** All patients  $>18$  who underwent pancreatic resection for a pancreatic malignancy in Florida hospitals between January 1, 2007, and December 31, 2011, were included in this study. *International Classification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM)* procedure and diagnosis codes were used to identify our patient population.

The procedure codes used were proximal pancreatectomy (52.51), distal pancreatectomy (52.52), radical subtotal pancreatectomy (52.53), other partial pancreatectomy (52.59), total pancreatectomy (52.6), and radical pancreaticoduodenectomy (52.7).

Diagnosis codes included malignant neoplasm of head of pancreas (157.0), malignant neoplasm of body of pancreas (157.1), malignant neoplasm of tail of pancreas (157.2), malignant neoplasm of pancreatic duct (157.3), malignant neoplasm of islets of Langerhans (157.4), malignant neoplasm of other unspecified sites of pancreas (157.8), and malignant neoplasm of pancreas part unspecified (157.9).

Hospitals were classified as high-volume hospitals (HVH) if  $\geq 20$  pancreatic resections were performed per year, while those performing  $<20$  were classified as low-volume hospitals (LVH). Afterwards, 84 patients were excluded due to unavailability of a valid zip code or primary residence outside Florida to exclude medical tourists.

**Patient characteristics.** Patient demographic variables, based on availability in HCUP-SID and US Census Bureau data, included age, sex, race (Caucasian, African-American, Hispanic, other), and population density ( $<750$ , 750–2,250, 2,250–3,900, and  $>3,900$  residents/square mile) by zip code. Socioeconomic factors included median household annual income by zip code (\$0–\$39,999, \$40,000–\$49,999, \$50,000–\$65,999, and  $> \$66,000$ ), education level based on percentage of high school graduation by zip code ( $<77\%$ , 77–84%, 84–90%, and  $>90\%$ ), and primary insurance type (Medicare, Medicaid, private, self-pay, and other). Race variables that did not have a large

enough sample to be used independently in the analysis were collapsed into other variables: “Native American,” “Asian and Pacific Islander,” and patients with missing race data were collapsed into the “other” race variable. All other missing data points are reported as “unknown.”

Clinical characteristics included comorbidities assigned based on Agency of Health Research and Quality comorbidity software.<sup>18</sup> This software uses *ICD-9-CM* codes and diagnosis-related groups to identify conditions not related to the principal diagnosis and groups them into usable categories to describe patient comorbidity. Charlson Comorbidity Index was calculated as a measure of the overall severity of illness using *ICD-9-CM* codes.<sup>19</sup>

**Measurement of hospital volume.** Only institutions that performed  $\geq 1$  procedure per year for each of the 5-year study period were included. Institutions that performed  $\geq 100$  pancreatic resections for pancreatic cancer during the study period (on average  $\geq 20$  per year) were classified as HVH, and those performing  $< 100$  pancreatic resections during the 5-year period ( $< 20$  procedures on average per year) were classified as LVH.

**Distance calculation.** Distances in miles were calculated using straight lines (Euclidean) between latitude and longitude of hospital and patients’ zip code centroid latitude and longitude.

**Statistical analysis.** Baseline patient characteristics were compared between high- and low-volume centers.  $\chi^2$  tests were used for categorical variables and *t* tests were used for continuous variables. Results were presented as totals and frequencies, with percentages for categorical variables, and as means with standard deviations for continuous variables.

Multivariable logistic regression models were fit to assess patient characteristics and utilization of HVH. Multivariable regression can be used to assess the relationship between a number of predictor variables and a specific outcome, allowing independent relationships to be assessed while adjusting for potential confounders. Statistical analyses were conducted using Stata software (version 13; StataCorp LP, College Station, TX).

**Predictive modeling.** Classification and Regression Tree (CART) modeling was used to predict patients at risk for losing access to pancreatic cancer care. CART modeling is a form of machine learning that extracts relationships between the object of analysis (outcome) and  $\geq 1$  input field. It is constructed by identifying the most relevant attributes on which to partition a feature space, resulting in structural descriptions of the data in the form of *if-then* rules.

The decision tree also can function to identify the strongest or most relevant attributes with respect to predicting the outcome variable. Features that are toward the top of the tree are deemed most relevant. The model can then be used to predict the outcome for new or unseen observations that do not contain a class label for the outcome variable.<sup>20</sup> The predictive model was built using RStudio (R x64 3.1.3, Boston, MA), rpart add-on package. The minimum number of observations per node selected was 210, and the cost complexity factor was 0.001.

## RESULTS

### Baseline characteristics of the study population.

The study population included 1,663 patients that resided in the state of Florida and underwent pancreatic resection for pancreatic cancer in their home state. Patient socioeconomic and demographic factors are summarized in Table 1. Baseline characteristics of the overall cohort included a mean age of 66.3 years (standard deviation [SD] = 11.3), female sex for 47.4% of patients, and a mean Charlson Comorbidity Index of 5.2 (SD = 3.1). The cohort was comprised of 78.2% Caucasian, 9.9% Hispanic, and 7.5% African-American patients. Most patients were covered by either Medicare (56.6%) or private (33.0%) insurance. Overall, the mean distance traveled by the patient to the institution where the operation was performed was 40.0 miles (SD = 48.4), while the mean distance to the closest HVH was 46.4 miles (SD = 45.8).

### Volume and socioeconomic factors association.

Five out of 30 institutions performing  $\geq 1$  pancreatic resection per year were classified as HVH. Those 5 centers treated 1,056 (63.5%) patients, while 607 (36.5%) patients received care at LVH. Crude inpatient mortality and duration of hospital stay in HVH were 2.5% and 13.0 days, respectively. These numbers rose to 6.1% ( $P = .001$ ) and 16.5 days ( $P < .001$ ) in LVH.

Factors that were significantly different between patients being treated at HVH versus LVH were distance traveled to current hospital (54.3 miles vs 15.1 miles,  $P < .001$ ), and distance from patient’s zip code to the closest HVH (43.2 miles vs 52.0 miles,  $P < .001$ ; Fig 1). Furthermore, to reach the closest HVH, 518 (85.3%) of the 607 patients that underwent an operation at LVH would be required to travel longer distances if volume restrictions were enforced. The mean travel distance for these patients currently traveling 12.4 miles would be 57.3 miles, requiring an extra mean

**Table I.** Baseline characteristics of the study population and utilization of high-volume hospitals (HVH) and low-volume hospitals (LVH)

	Total N = 1,663	LVH N = 607	HVH N = 1,056	P value
Demographic				
Mean age (y, SD)	66.3 (11.3)	66.6 (10.8)	66.2 (11.5)	.449
Sex (% female)	47.4	47.0	47.7	.761
Comorbidities				
Weighted Charlson Comorbidity Index	5.2 (3.1)	5.1 (3.1)	5.3 (3.1)	.107
Socioeconomic				
Race				<.001
Caucasian (%)	1,301 (78.2)	437 (72.0)	864 (81.8)	
African-American (%)	124 (7.5)	63 (10.4)	61 (5.8)	
Hispanic (%)	164 (9.9)	73 (12.0)	91 (8.6)	
Other (%)	74 (4.5)	34 (5.6)	40 (3.8)	
Income				.206
\$0–\$39,999 (%)	403 (24.2)	127 (20.9)	276 (26.1)	
\$40,000–\$49,999 (%)	514 (30.9)	198 (32.6)	316 (29.9)	
\$50,000–\$65,999 (%)	457 (27.5)	174 (28.7)	283 (26.8)	
≥\$66,000 (%)	259 (15.6)	96 (15.8)	163 (15.4)	
Unknown (%)	30 (1.8)	12 (2.0)	18 (1.7)	
Insurance				.578
Medicare (%)	942 (56.6)	339 (55.9)	603 (57.1)	
Medicaid (%)	99 (6.0)	36 (5.9)	63 (6.0)	
Private insurance (%)	549 (33.0)	199 (32.8)	350 (33.1)	
Self-pay (%)	27 (1.6)	11 (1.8)	16 (1.5)	
No charge: other (%)	46 (2.8)	22 (3.6)	24 (2.3)	
Education level: high school graduation				.177
≤77% (%)	396 (23.8)	127 (20.9)	269 (25.5)	
77–84% (%)	427 (25.7)	168 (27.7)	259 (24.5)	
84–89% (%)	436 (26.2)	161 (26.5)	275 (26.0)	
≥89% (%)	379 (22.8)	139 (22.9)	240 (22.7)	
Unknown	25 (1.5)	12 (2.0)	13 (1.2)	
Geographic				
Population density				<.001
<50 residents/sqmi (%)	407 (24.5)	112 (18.5)	295 (27.9)	
750–2,250 residents/sqmi (%)	412 (24.8)	132 (21.8)	280 (26.5)	
2,250–3,900 residents/sqmi (%)	411 (24.7)	170 (28.0)	241 (22.8)	
>3,900 residents/sqmi (%)	409 (24.6)	181 (29.8)	228 (21.6)	
Unknown	24 (1.4)	12 (2.0)	12 (1.1)	
Traveled distance in miles (mean, SD)	40.0 (48.4)	15.1 (23.3)	54.3 (53.1)	<.001
Distance to closest HVH in miles (mean, SD)	46.4 (45.8)	52.0 (56.8)	43.2 (37.8)	<.001

SD, Standard deviation; sqmi, square miles.

travel distance of 45.0 extra miles. The ratio between the distance they would have to travel and the distance currently traveled would be 15:1 on average.

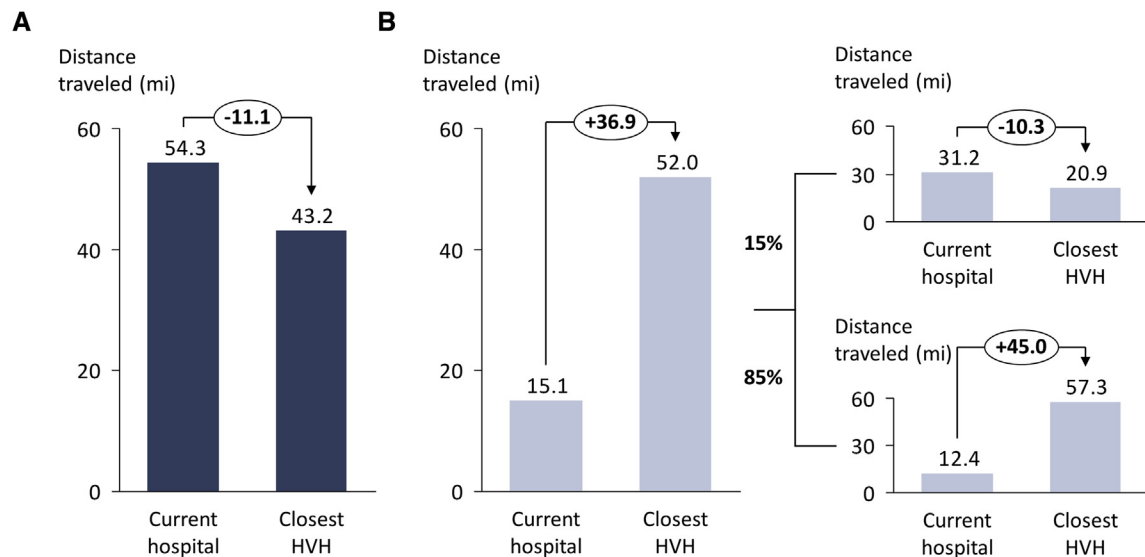
The population density of patients' residence between patients at HVH versus LVH also was notable, in that 27.9% vs 18.5% lived in the lowest density areas (<750 residents/square mile), while 21.6% vs 29.8% lived in the highest density areas (>3,900 residents/square mile;  $P < .001$ ).

With regard to race, while 66.4% of Caucasian patients attended HVH, only 55.5% of Hispanic

patients and 49.2% of African-American patients received care at HVH ( $P < .001$ ).

Non-Caucasian patients, patients with an income >\$40,000, those residing far from HVH, and patients living in areas with the highest population densities had decreased odds of obtaining care at HVH. Results of the multivariable analysis are summarized in [Table II](#).

**Predicting patients at risk of losing access to care.** A CART-based predictive tool was developed to identify patient socioeconomic and demographic factors that predicted whether a patient



**Fig 1.** (A) Mean distance traveled by patients currently being cared for at high-volume hospitals (HVH;  $N = 1,056$ ) compared with distance to the closest HVH. (B) Mean distance traveled by patients currently being cared for at low-volume hospitals (LVH;  $N = 607$ ) compared with distance to the closest HVH, including detail of patients who could travel less and patients who would be required to travel farther. *mi*, Miles.

underwent an operation at a high- or low-volume center. Non-Caucasian patients >58 years and residing in areas with high population density, as well as Caucasian patients >58 years living in high population-density areas and far from HVH, were identified by the model as those patients most likely to undergo operation at LVHs. In addition, patients from areas with lower population density and living between 16.2 and 32.4 miles from a HVH also were identified as patients likely to undergo pancreatic resection at LVHs (Fig 2).

Those populations predicted to go to LVHs were interpreted as being at risk of losing access to operative care for pancreatic cancer if a volume threshold of  $\geq 20$  pancreatectomies per year was implemented in the state of Florida. The performance of the model was estimated using k-fold cross-validation. Our sample was randomly partitioned into 10 sets, and a model was fit using all but one subset. This first subset then was returned to the training set and the procedure was repeated with each of the remaining 9 subsets held out. The 10 estimates of performance obtained then were summarized and the mean was calculated. The cross-validated error of this CART model was 35.7%, the c-statistic was 0.66, and the accuracy was 66.5%.

## DISCUSSION

The “Take the Volume Pledge” campaign aims to improve operative outcomes by restricting the

number of centers allowed to perform prespecified operative procedures based on volume thresholds. We demonstrate that if this policy were implemented across all centers in a single state, some patient populations would be at risk of losing access to care. Using predictive modeling, we identify elderly non-Caucasian patients who reside in areas with high population density and elderly Caucasian patients living far from HVH as those with greatest likelihood of developing a disparity in access.

Similar to existing literature, our data showed increased inpatient mortality and duration of stay in LVH, but it remains unclear if limiting operative care to HVH will result in improved or absence of care in at-risk populations. Notably, referral to HVH could lead to delays in operations or loss of postoperative care, both of which are harder to quantify than mortality or duration of stay but might ultimately affect patients significantly. Additionally, factors other than volume could be associated with improved outcomes in high-volume institutions (there are, for example, low-volume institutions with good outcomes), and imposing restrictive thresholds without exploring alternatives to identifying high-performing institutions might not be in the best interest of the patients.

Finally, social support often is overlooked, but studies have found that many patients, even if informed of greater risks, prefer to receive care



**Table II.** Unadjusted and adjusted analysis comparing patient characteristics and utilization of low-volume hospitals versus high-volume hospitals (HVH)

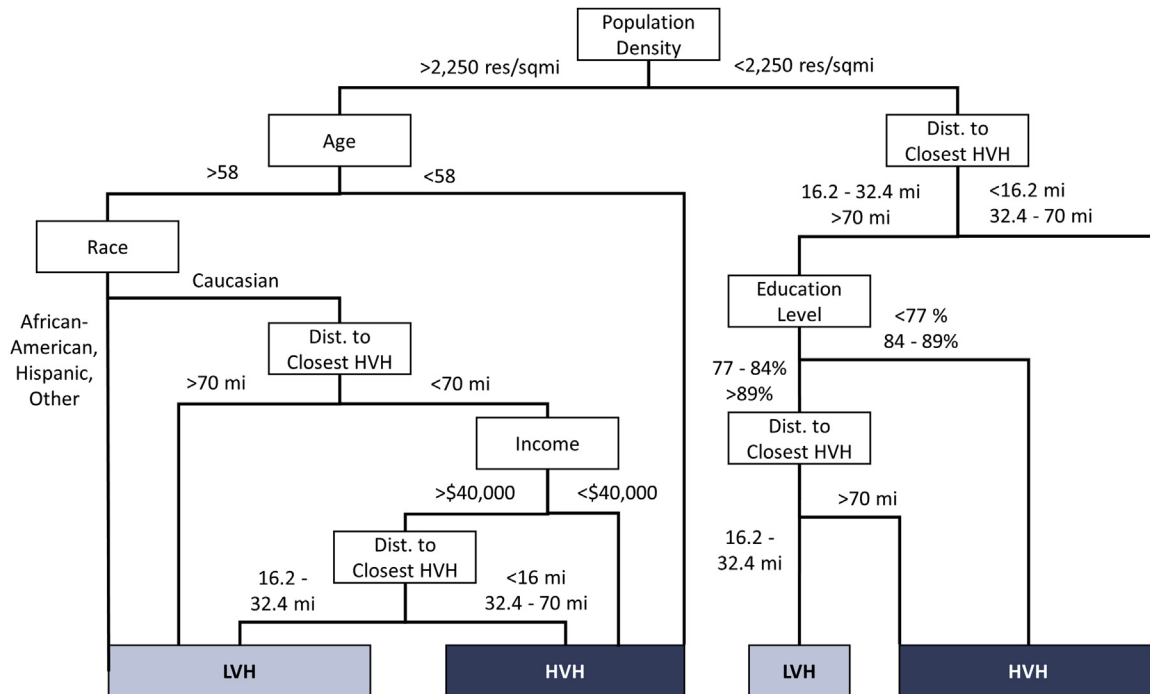
	OR	95% CI	P value	aOR	95% CI	P value
Demographic						
Age	1.00	0.99–1.01	.449	0.99	0.98–1.00	.119
Sex (female)	1.03	0.84–1.26	.761	0.99	0.80–1.22	.934
Comorbidities						
Weighted Charlson Comorbidity Index	1.03	0.99–1.06	.107	1.03	0.99–1.07	.075
Socioeconomic						
Race						
Caucasian	Reference			Reference		
African-American	0.49	0.34–0.71	<.001	0.39	0.26–0.59	<.001
Hispanic	0.63	0.45–0.88	.006	0.59	0.41–0.86	.006
Other	0.60	0.37–0.95	.031	0.60	0.36–0.99	.043
Income						
\$0–\$39,999	Reference			Reference		
\$40,000–\$49,999	0.73	0.56–0.97	.028	0.66	0.49–0.89	.006
\$50,000–\$65,999	0.75	0.56–0.99	.044	0.67	0.49–0.92	.012
>\$66,000	0.78	0.56–1.08	.141	0.62	0.42–0.90	.013
Insurance						
Medicare	Reference			Reference		
Medicaid	0.98	0.64–1.51	.941	1.10	0.66–1.84	.720
Private insurance	0.99	0.79–1.23	.920	0.98	0.72–1.32	.873
Self-pay	0.82	0.38–1.78	.613	0.83	0.36–1.92	.663
Other	0.61	0.34–1.11	.106	0.62	0.32–1.20	.156
Education level: high school graduation						
≤77%	Reference			Reference		
77–84%	0.73	0.55–0.97	.030	0.88	0.65–1.20	.432
84–89%	0.81	0.61–1.07	.142	1.00	0.73–1.38	.987
≥89%	0.82	0.61–1.10	.177	0.96	0.68–1.34	.794
Geographic						
Population density						
<750 residents/sqmi	Reference			Reference		
750–2,250 residents/sqmi	0.81	0.60–1.09	.158	0.91	0.66–1.25	.562
2,250–3,900 residents/sqmi	0.54	0.40–0.72	<.001	0.52	0.38–0.72	<.001
>3,900 residents/sqmi	0.48	0.36–0.64	<.001	0.40	0.28–0.57	<.001
Distance to closest HVH						
<16.2 miles	Reference			Reference		
16.2–32.4 miles	0.81	0.61–1.07	.137	0.55	0.40–0.75	<.001
32.4–70 miles	1.50	1.11–2.02	.007	0.83	0.58–1.19	.313
>70 miles	0.69	0.52–0.91	.009	0.39	0.28–0.55	<.001

aOR, Adjusted odds ratio; OR, odds ratio; sqmi, square miles.

locally when given the choice.<sup>21</sup> Enforcing volume restrictions without addressing their potential limitations might be as questionable as not referring patients to HVH. If performance data were available to physicians, they could educate patients and suggest high-performing centers to them. In addition, patients could be offered resources, such as transportation, to lessen the social and economic burden of travel.

Our findings are supported by several previous studies measuring access and other proposed volume limits. One prior study assessed the nationwide effect of enforcing volume restrictions on

travel time if a threshold of 17 pancreatectomies per year was set. The result was that 80% of the Medicare patient population studied would have to change hospitals, with 47% having to travel >1 hour to reach the closest HVH.<sup>22</sup> Similar to that study, assuming a threshold of 20 pancreatectomies advocated by “Take the Volume Pledge,” we found that 36.5% of patients would have to change hospitals, 85% of whom would have to increase the distance traveled by an average of 45 miles. Considering that the Euclidean distance metric was used, the actual distance required to travel could be considerably longer.



**Fig 2.** Classification and regression tree model for predicting care at low-volume hospitals (LVH) and high-volume hospitals (HVH). *Dist*, Distance; *mi*, miles; *sqmi*, square miles.

In our study, all patients regardless of age and primary payer were included, as HCUP-SID data are not limited to Medicare patients. Additionally, Liu et al<sup>23</sup> reported potential harm to non-Caucasian patients arising from volume restrictions in California. Likewise, Riall et al<sup>5</sup> showed that Hispanic patients would be the most affected by regionalization based on a threshold of 10 pancreatic resections per year per hospital in Texas.

The current literature focuses on continuity of care in rural patients as one of the biggest challenges for regionalization.<sup>10,11,22</sup> Among patients included in this study, as population density decreased, utilization of HVH increased despite having to travel greater distances. It is worth noting that some high population-density areas in Florida (particularly those located toward the north of the state) have only low-volume providers. Most of these patients currently are being cared for locally and undergo pancreatic resection at LVH. Other studies found that rural patients tend to seek care in urban centers when they require highly complex procedures.<sup>24</sup> In these cases, patients often follow their physicians' advice, which we hypothesize led most rural patients to high-volume/well-known surgical centers in Florida.<sup>25</sup>

Based on our results, volume standards would have a small impact on this already disadvantaged

population. However, there also was a group of rural patients that did not seek care at HVH and needed to travel an additional 45 minutes to obtain care if access to a nearer LVH was removed. Restricting implementation of volume thresholds to metropolitan areas, as proposed by the Leapfrog group, would not be enough to prevent disparities in access.<sup>10</sup> In addition, patients residing in high population-density areas were another group predicted to be at risk for losing access. For these patients, the burden of traveling to another center to obtain greater quality care would be less significant than those living in rural areas. In this case, implementation of thresholds could have the desired effect of improving care.

Despite the considerable advancements achieved in operative outcomes, there remains room for new measures to continue to improve patient outcomes after pancreatectomy. The existing evidence strongly supports that volume standards would lead to better outcomes, but it is important to ensure that no delays in procedures or loss of postoperative care arise from efforts to improve quality. The limits set by the "Take the Volume Pledge" are greater than those identified in previous studies, and if the policy was implemented statewide, it would lead to only 5 hospitals being allowed to perform pancreatic resections in the whole state of Florida.

Strategies designed to prevent access disparities could focus on identifying a volume threshold that leads to less centralized care while still significantly improving outcomes. Alternatively, access could be maintained by designating referral center regions in which HVH are not currently available. Also, transportation to HVH could be provided during the perioperative time period, both for patients and their families.

The CART model developed is a simple and interpretable tool that allows for an easy analysis of interactions between patient characteristics and fully characterizes those at risk. For this reason, our model could serve as a resource for policy-makers to identify the most vulnerable populations and develop targeted strategies.

It also is important to point out that while volume may be the best readily available proxy indicator of quality today, this association might be the result of other underlying factors that positively influence outcomes. Studies by Urbach et al<sup>9,26</sup> and Lieberman et al<sup>6</sup> found better outcomes at HVH not to be procedure-specific and to be associated with hospital rather than surgeon volumes. For this reason, efforts should be made to accompany volume information with more accurate quality indicators.

Big data and predictive analytics could aid the identification of hospital resources and organizational characteristics that account for improved outcomes. As a result, health care could be improved further without the potentially negative consequences from reducing accessible medical centers. From a hospital perspective, LVH could lose the ability to recruit qualified surgeons, and HVH could face an overwhelming increase in the number of cases. From a patient perspective, preference, loss of time from work, and inadequate transportation usually are overlooked.<sup>5,16,21,23</sup> Our study found that the implementation of volume standards would lead to an increase in pancreatic resection volume between 23–106% in the remaining 5 hospitals. It is uncertain whether this increase would not overwhelm these institutions as the available literature suggests.<sup>5</sup>

This study has several limitations. First, it was conducted using an administrative database, which gave us the opportunity to study most of the existing institutions across several years but may lack information and contain inaccuracies due to coding or reporting errors.<sup>27</sup> Also, income and education level were estimated based on zip codes because patients are deidentified. The availability of roads, the differences in time traveled due to types of roads available, and the associated costs

were not evaluated. Rather, Euclidean distances were calculated. For this reason, they are most likely underestimated.

Another limitation is that a primary focus was to identify patients at risk for losing access but not to explore the impact of outcomes in detail. Although we did measure crude mortality and duration of stay, these were not risk adjusted and should be interpreted with caution. Finally, this study focuses on a single procedure and a single state. Although the performance of the model on a subpopulation of patients was tested, the ability of this tool to correctly classify different patient populations remains unknown and requires further validation.

In conclusion, while the “Take the Volume Pledge” initiative may be an effective way to improve operative outcomes for pancreatectomy by limiting operations to high-volume centers, unintended health disparities, including restricting access to pancreatic cancer care, also may result. Policy-makers must consider carefully the institution of volume thresholds in pancreatic cancer, balancing outcomes, access to care, and patient preference.

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