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Statewide Regionalization of Pancreaticoduodenectomy and its Effect on In-Hospital Mortality

Toby A. Gordon, ScD,*†‡ Helen M. Bowman, MS,* James M. Tielsch, PhD,§ Eric B. Bass, MD, MPH,*‡‖
Gregg P. Burleyson, RN, MHS,* and John L. Cameron, MD*†

From the Johns Hopkins Hospital, Baltimore, Maryland; and the Department of Surgery, School of Medicine,† Department of Health Policy and Management, School of Hygiene and Public Health,‡ Department of International Health, School of Hygiene and Public Health,§ and Department of Medicine, School of Medicine,‖ The Johns Hopkins University, Baltimore, Maryland*

Objective
This study examined a statewide trend in Maryland toward regionalization of pancreaticoduodenectomy over a 12-year period and its effect on statewide in-hospital mortality rates for this procedure.

Summary Background Data
Previous studies have demonstrated that the best outcomes are achieved in centers performing large numbers of pancreaticoduodenectomies, which suggests that regionalization could lower the overall in-hospital mortality rate for this procedure.

Methods
Maryland state hospital discharge data were used to select records of patients undergoing a pancreaticoduodenectomy between 1984 and 1995. Hospitals were classified into high-volume and low-volume provider groups. Trends in surgical volume and mortality rates were examined by provider group and for the entire state. Regression analyses were used to examine whether hospital share of pancreaticoduodenectomies was a significant predictor of the in-hospital mortality rate, adjusting for study year and patient characteristics. The portion of the decline in the statewide in-hospital mortality rate for this procedure attributable to the high-volume provider's increasing share was determined.

Results
A total of 795 pancreaticoduodenectomies were performed in Maryland at 43 hospitals from 1984 to 1995 (Maryland residents only). During this period, one institution increased its yearly share of pancreaticoduodenectomies from 20.7% to 58.5%, and the statewide in-hospital mortality rate for the procedure decreased from 17.2% to 4.9%. After adjustment for patient characteristics and study year, hospital share remained a significant predictor of mortality. An estimated 61% of the decline in the statewide in-hospital mortality rate for the procedure was attributable to the increase in share of discharges at the high-volume provider.

Conclusions
A trend toward regionalization of pancreaticoduodenectomy over a 12-year period in Maryland was associated with a significant decrease in the statewide in-hospital mortality rate for this procedure, demonstrating the effectiveness of regionalization for high-risk surgery.

Pancreaticoduodenectomy is a complex, high-risk general surgical procedure usually performed for malignancies of the pancreas, ampulla of Vater, distal bile duct, and duodenum. The procedure, popularized by Whipple and associates in 1935, involves removing the head, neck, and uncinate process of the pancreas, the duodenum and sometimes part of the stomach, and the gallbladder and distal biliary tree. Reconstruction varies but usually involves a pancreaticojejunostomy, a hepaticojejunostomy, and a gastro- or duodenojejunostomy. The Whipple procedure is performed in many, if not most, hospitals in the United States.

Before 1980, the in-hospital mortality rate for this procedure exceeded 20%.[1] Since that time, the in-hospital mortality rate has decreased substantially, with high-volume

Address reprint requests to Toby A. Gordon, ScD, The Johns Hopkins Health System, 600 North Wolfe St./Houck 100, Baltimore, MD 21287-1100.
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tertiary care centers reporting in-hospital mortality rates of 4% or less.[1–3] Moreover, recent studies have demonstrated that high-volume tertiary care centers have significantly lower in-hospital mortality rates for the Whipple procedure than low-volume community hospitals.[1–3] This suggests that regionalization, or the concentration of services at one or a few high-volume centers, could lower the in-hospital mortality rate for pancreaticoduodenectomy for a region's population.

Between 1984 and 1995 in Maryland, one hospital, the Johns Hopkins Hospital, gradually increased the number of pancreaticoduodenectomies it performed, so that by 1995 more than half those performed in the state were performed at that institution. This market trend resulted in substantial regionalization for that one procedure. In this study, experience with pancreaticoduodenectomy in Maryland was examined over the 12-year period to document the extent to which regionalization was responsible for a drop in the statewide in-hospital mortality rate for the procedure.

METHODS

Sources of Data

Publicly available nonconfidential hospital discharge data collected by the State of Maryland Health Services Cost Review Commission for the years 1984 through 1995 were used for this study. This data base includes records of discharges from all 52 nonfederal acute care hospitals in the state. Before 1993, every discharge record included one primary and up to four secondary discharge diagnosis codes, as well as one primary and as many as two secondary procedure codes. From 1993 onward, up to 14 secondary diagnosis and 14 secondary procedure codes were listed. Using Focus (Information Builders, Inc., New York, NY) and Paradox (Borland International, Scotts Valley, CA) software, discharges with a primary procedure code for pancreaticoduodenectomy (ICD-9 52.7) were selected. STATA 5.0 software (STATA Corporation, College Station, TX) was used for statistical analysis of the selected records.

Classification of Cases by Hospital Attributes

The number of pancreaticoduodenectomies performed by each hospital was examined for each study year. A hospital was included in the analysis if it performed at least one pancreaticoduodenectomy during the study period. Hospitals were classified as high-volume or low-volume providers based on the number of pancreaticoduodenectomies performed, both annually and in total. The criteria to qualify as a high-volume provider were a minimum volume of 20 pancreaticoduodenectomies per year for 6 of the 12 years and an average volume during the 12-year period of $\geq$20 pancreaticoduodenectomies per year. According to these criteria, only one provider, the Johns Hopkins Hospital, qualified as a high-volume hospital. Patients who lived outside Maryland were then excluded from further analysis so that the effects of regionalization on the population of the state could be studied. Inclusion of out-of-state patients could skew the interpretation of volume trends by provider group and the relation of these trends to statewide procedure mortality rates.

Statistical Analysis

Once cases were classified as belonging to the high-volume or low-volume provider groups, trends in volume, percentage of market share, and in-hospital mortality rates were examined for the entire study period by provider group. Three basic questions were then asked in this analysis: To what extent was hospital volume of pancreaticoduodenectomies associated with the mortality rate once we had adjusted for patient characteristics and study year? What proportion of the observed reduction in total statewide mortality was caused by an increasing proportion of cases conducted at the high-volume provider? Was there a difference in the secular trend of declining mortality rate between the high-volume and low-volume providers during this period?

Poisson regression models were used in the first analysis to determine the extent of any association between hospital volume of pancreaticoduodenectomies, defined as a percentage of total statewide volume per year, and in-hospital mortality rate. Poisson regression models were used because we were interested in directly estimating the relative risk (a ratio of mortality rates) of in-hospital death. These models are commonly used in epidemiologic analyses of mortality data in cohort studies, especially when event rates (*i.e.*, death) are low. We also examined trends in relative risk of in-hospital death by provider group using Poisson models.

To identify potential confounders in these analyses, the distributions of patient characteristics among high-volume and low-volume provider groups were compared using standard statistical techniques such as chi square for binary or categorical variables (gender, race, disease complexity, payor status, and nature of admission) and Student's t test for continuous variables such as age. Complexity subclass was measured using the All Patient Refined DRG Grouper (3M Health Information Systems, Provo, Utah), which considers comorbidity, age, and certain sentinel procedures. Based on these factors, a score from 1 to 4 is computed for each patient discharge record, a score of 4 being the most complex.

Exploratory analyses demonstrated that the proportion of total statewide volume of pancreaticoduodenectomies conducted at the high-volume provider increased significantly over the study period (Fig. 1). Additionally, the total in-hospital mortality rate declined over this period, and it declined in both high-volume and low-volume provider

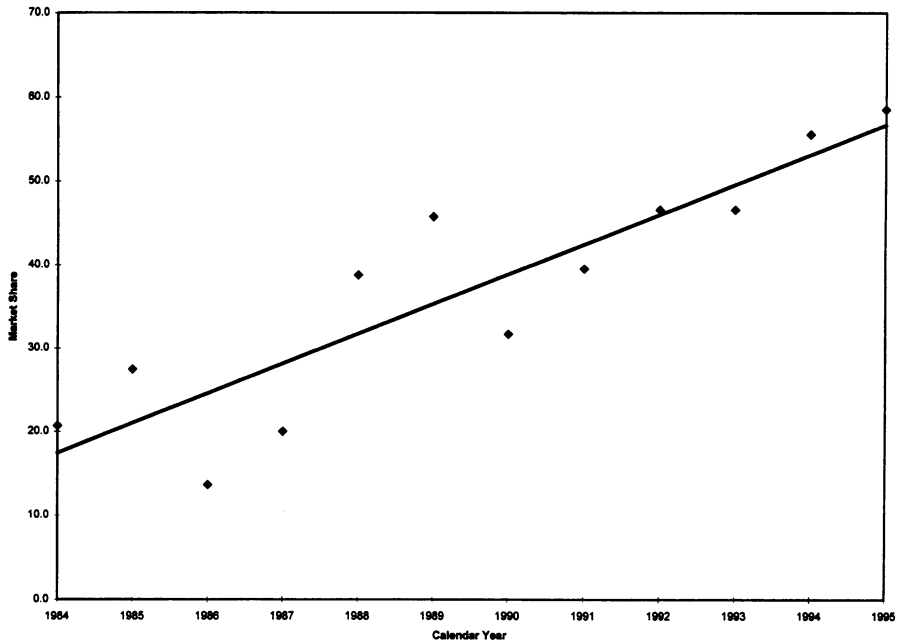

Figure 1. Market share of pancreaticoduodenectomies at the high-volume provider by calendar year (Maryland residents only).

groups (Fig. 2). Given these trends over time, we asked the second question (What proportion of the observed reduction in the total statewide mortality rate was caused by an increasing proportion of cases conducted at the high-volume provider?). To address this question, we used a multistate analytic approach. First, to smooth year-to-year fluctuations in market share and mortality rate, we used linear models to regress the proportion of total volume provided by the regional provider on year. Similarly, we regressed in-hospital mortality rates on year separately for low-volume and high-volume provider groups. The dependent variable in these regressions was the mortality rate in a given year among the high-volume and low-volume providers. From these regressions, predicted values were calculated for each year, and an expected total statewide mortality rate was calculated based on the smoothed market share and mortality rate estimates. Goodness-of-fit was assessed by comparing the observed total statewide mortality rate with these predicted figures.

Second, we calculated the expected total statewide in-hospital mortality rate in each year from 1984 to 1995, assuming that the market share between high-volume and low-volume providers was that observed in 1984. This was done by applying volume-year–specific predicted mortality rates to the 1984 market share—in other words, we calculated the expected total statewide yearly mortality rate that

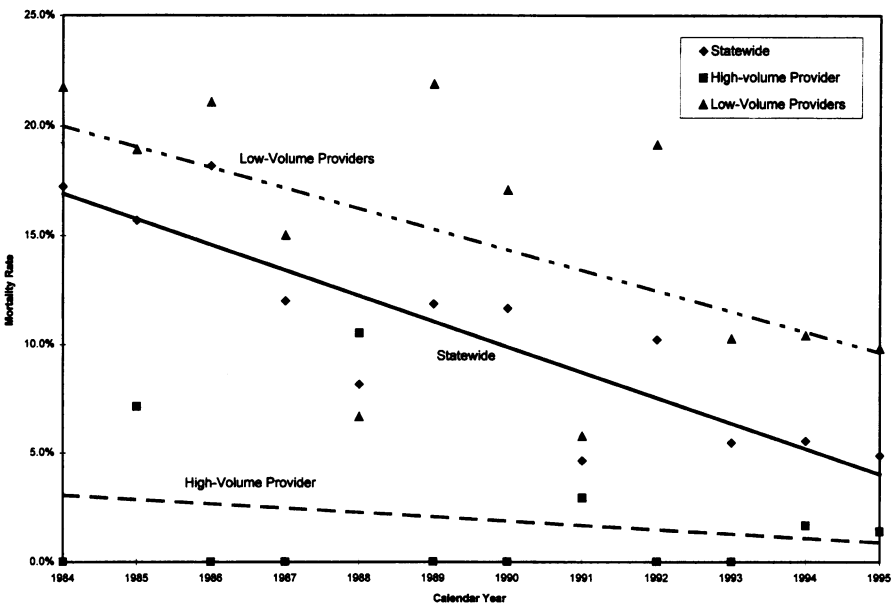

Figure 2. In-hospital mortality rates for pancreaticoduodenectomy by calendar year (statewide, low-volume providers, high-volume provider).

would have occurred if no shifting of cases to the high-volume provider had happened.

Third, we regressed expected total statewide in-hospital mortality rates on year for both this "1984 market share" situation and for the market share distribution that actually existed. The regression coefficients were interpreted as the average annual decline in the statewide mortality rate under two different models of market share distribution. The difference between these two regression coefficients was calculated and divided by the coefficient for the observed market share to arrive at an estimate of the proportion of the average annual decline in the statewide in-hospital mortality rate for pancreaticoduodenectomy attributable to a shift in patients from low-volume to high-volume providers over this period.

Finally, the third question was addressed (Was there a difference in the secular trend of declining mortality rates between the high-volume and low-volume providers during this period?). Poisson regression models were used to model the total statewide mortality rate as a function of year, provider group, and the interaction of provider and year. Again, Poisson regression techniques were used because we wished to model the relative risk directly.

Table 1. CHARACTERISTICS OF PROVIDER GROUPS

Characteristic	Provider Group	
	Low-Volume	High-Volume
All discharges (n = 1093)		
No. of hospitals	42	1
Discharges	480	613
Avg. per year		
Group	40.0	51.1
Individual hospital*	0.95	51.1
Range		
Group	(25–55)	(8–147)
Individual hospital	(0–9)	(8–147)
In-Hospital mortality rate	14.2%	1.8%
Maryland residents only (n = 795)		
No. of hospitals	42	1
Discharges	458	337
Avg. per year		
Group	38.2	28.1
Individual hospital*	0.91	28.1
Range		
Group	(20–52)	(5–72)
Individual hospital	(0–9)	(5–72)
In-Hospital mortality rate	14.2%	1.8%

* Average per year per individual hospital in low-volume provider group.

RESULTS

From January 1984 through December 1995, 43 Maryland hospitals recorded 1093 discharges with a primary procedure code of pancreaticoduodenectomy. Only 1 of the 43 hospitals, the Johns Hopkins Hospital, fulfilled the criteria for a high-volume provider, with an average of 51.1 pancreaticoduodenectomies per year over the study period (range 8 to 147). The remaining 42 hospitals together performed an average of 40 pancreaticoduodenectomies per year (range 25 to 55), or slightly less than 1 per year per hospital (range 0 to 9 actual procedures performed; Table 1). The 298 out-of-state patients excluded from further analysis contributed primarily to the volume experience of the high-volume provider (276 patients for the high-volume provider and 22 patients for the other 42 hospitals). Excluding the out-of-state patients had no impact on the in-hospital mortality rates for the procedure at either the high-volume or low-volume providers.

During the 12-year period, 795 pancreaticoduodenectomies were performed on Maryland residents in 43 Maryland hospitals. Across the study period, there was a fourfold increase in annual state volume, from 29 pancreaticoduodenectomies in 1984 to 123 in 1995. The number of pancreaticoduodenectomies at the high-volume provider increased from 6 in 1984 (20.7% of in-state discharges) to 72 in 1995 (58.5% of in-state discharges). The annual number of pancreaticoduodenectomies at the low-volume providers increased from 23 (79.3% of discharges) to 51 (41.5% of discharges) over the same time period. In the last 2 years studied, the high-volume provider's volume exceeded the total volume of the 42 other hospitals combined. During this same 12-year period, the annual statewide in-hospital mortality rate for this procedure decreased from 17.2% to 4.9%. The unadjusted mortality rate at the high-volume provider decreased from 3.2% in 1984 to 1987 to 1% in 1992 to 1995, and the unadjusted mortality rate at the low-volume providers decreased from 19.5% to 12.4% for the same points in time.

Poisson regression techniques were used to model the effect of hospital volume on mortality rate, adjusting for other potentially confounding variables. Variables considered in these analyses were hospital share, year, age, gender, race, payor status, nature of admission (urgent/emergent *vs.* elective), and complexity. Table 2 details the aggregate distribution of these variables among provider groups. We also looked at patient characteristics for each of the study years. Overall, the distributions were similar to those in Table 2, and so are not fully reported here. The largest differences were seen in mean age and the nature of admission. Whereas mean age at the low-volume providers remained relatively constant over the study period, mean age at the high-volume provider increased substantially from 56 in 1984 to 66.4 in 1995. The proportion of urgent/emergent *versus* elective cases at the low-volume providers shifted from >66% urgent cases in the early study years to about 40% urgent in the 1992 to 1995 period; at the high-volume provider, the proportion shifted from 80% to 90% in the early period to 30% to 40% in the later period. The higher proportion of elective cases at the high-volume provider may reflect referral patterns.

Table 2. DISTRIBUTION OF PATIENT CHARACTERISTICS BY PROVIDER GROUP

Patient Characteristics	Provider Group		p value†
	Low-Volume n = 458 n (%)*	High-Volume n = 337 n (%)*	
Age (Mean, SD)	63.0 (±11.7)	62.4 (±13.5)	0.50
Gender			
Men	246 (53.7)	168 (49.9)	0.28
Women	212 (46.3)	169 (50.2)	
Total	458 (100.0)	337 (100.0)	
Race			
White	331 (72.3)	283 (84.0)	<0.01
African-American	119 (26.0)	44 (13.1)	
Other	8 (1.8)	10 (3.0)	
Total	458 (100.0)	337 (100.0)	
Nature of admission			
Urgent/Emergent	265 (57.9)	179 (53.1)	0.05
Elective	188 (41.1)	158 (46.9)	
Unknown	5 (1.1)	0 (0.0)	
Total	458 (100.0)	337 (100.0)	
Complexity (only available 1990–1995, 538 cases)			
1	14 (5.0)	24 (9.2)	<0.01
2	53 (19.1)	92 (35.4)	
3	99 (35.6)	78 (30.0)	
4	112 (40.3)	66 (25.4)	
Total	278 (100.0)	260 (100.0)	
Payor status			
Medicare	216 (47.2)	171 (50.7)	0.23
Medicaid	36 (7.9)	15 (4.5)	
Commercial	148 (32.3)	113 (33.5)	
HMO	34 (7.4)	18 (5.3)	
Other	24 (5.2)	20 (5.9)	
Total	458 (100.0)	337 (100.0)	

* Percents are rounded, so they do not always add up to 100.
† Chi-square statistic for gender, race, nature of admission, complexity, and payor status. t-test statistic for age.

In exploratory regression models, we included all patient variables except complexity. Because payor status and nature of admission were not significant predictors of death, we did not include them in the more parsimonious final model reported here. The final model, using data from all years of the study, was adjusted for provider share, study year, age, gender, and race, although only provider share, year, and age were significant predictors of death (Table 3). The results of the model indicate that for every 1% increase in a hospital's market share, the relative risk of in-hospital death decreased by 5%..

Because patient complexity data were available only for discharges for 1990 to 1995 (538 observations, or 68% of the total sample), a second set of Poisson regressions was

Table 3. RESULTS FROM POISSON REGRESSION MODEL WITH MORTALITY AS THE DEPENDENT VARIABLE

Variable	Relative Risk	(95% Confidence Interval)	p value
Provider share	0.95	(.93, 0.98)	<0.01
Study year	0.92	(0.86, 0.99)	0.02
Age (continuous)	1.05	(1.02, 1.07)	<0.01
Gender*			
Women *vs.* men	0.80	(0.50, 1.29)	0.37
Race†			
African-American *vs.* white/other	1.37	(0.80, 2.34)	0.25

* Men = 1, women = 2; men are the reference group.
† White/Other = 1, African-American = 2; White is the reference group.

Table 4. ADJUSTED RELATIVE RISK* OF MORTALITY FOR THE LOW-VOLUME PROVIDER GROUP

4-Year Increments	Adjusted Relative Risk	(95% Confidence Interval)	p value
1984–1987	4.44	(0.59, 33.35)	0.15
1988–1991	3.77	(1.11, 12.77)	0.03
1992–1995	12.63	(2.93 54.43)	<0.01
Total 1984–1995	7.62	(3.29, 17.66)	<0.01

* Poisson regression models compare low-volume providers to high-volume provider, adjusted for age, gender, and race.

conducted on this subset to determine whether adjusting for complexity altered the results. This analysis yielded results regarding the role of hospital share on mortality rate similar to those models without complexity. Although increasing complexity was significantly associated with a higher mortality rate, it did not confound the relation between hospital share and mortality rate, and the results of that analysis are therefore not reported here.

The relative risk of in-hospital death comparing the low-volume providers to the high-volume provider, adjusted for age, gender, and race, was 7.6 (95% confidence interval 3.3 to 17.7, $p < 0.01$) for the entire study period (Table 4). The adjusted relative risk of death was 4.4 (95% confidence interval 0.6 to 33.4, $p = 0.15$) for the period 1984 to 1987 and 12.6 (95% confidence interval 2.9 to 54.4, $p < 0.01$) for 1992 to 1995. Although the in-hospital mortality rates decreased in both provider groups over time, the relative risks actually increased, as a function of the differential reductions in mortality rates.

To estimate the effect of regionalization of pancreaticoduodenectomies on in-hospital death in the face of strong temporal trends in market share and mortality rates, a multistage analysis was used as described above. Yearly predicted values for hospital share and mortality rate based on the linear regression models are presented in Table 5. Predicted total yearly statewide mortality rates based on the regressions fit the data well, as can be seen by comparing these predicted rates with the observed rates (see Table 5). These results estimate that the transfer of cases from low-volume hospitals to the high-volume hospital was responsible for 60.8% of the observed reduction in statewide deaths among patients un-

Table 5. PREDICTED YEARLY HOSPITAL SHARE AND IN-HOSPITAL MORTALITY RATES

Year	Predicted Proportion of Surgeries Conducted at High-Volume Provider*	Predicted Mortality Per 100 Cases for Low-Volume Providers†	Predicted Mortality Per 100 Cases for High-Volume Providers‡	Predicted Total Statewide Mortality Per 100 Cases§	Predicted Weighted Total Statewide Mortality Per 100 Cases‖	Predicted Weighted Total Statewide Mortality Per 100 Cases if Market Share as in 1984
1984	0.174	20.0	3.0	16.9	17.0	17.0
1985	0.211	19.1	2.8	15.8	15.7	16.3
1986	0.247	18.1	2.7	14.6	14.3	15.4
1987	0.283	17.2	2.5	13.4	13.0	14.6
1988	0.319	16.2	2.3	12.2	11.8	13.7
1989	0.355	15.3	2.1	11.1	10.6	13.0
1990	0.391	14.3	1.9	9.9	9.5	12.1
1991	0.428	13.4	1.7	8.7	8.4	11.4
1992	0.464	12.5	1.5	7.6	7.4	10.6
1993	0.500	11.5	1.3	6.4	6.4	9.7
1994	0.536	10.6	1.1	5.2	5.5	8.9
1995	0.572	9.6	0.9	4.0	4.6	8.1

Predicted Values Based On:

* Linear regression results: $\alpha = -2.86$, $\beta = 0.036$, $r^2 = 0.79$.
† Linear regression results: $\alpha = 0.993$, $\beta = -0.94$, $r^2 = 0.33$.
‡ Linear regression results: $\alpha = 0.195$, $\beta = -0.196$, $r^2 = 0.04$.
§ Linear regression results: $\alpha = 1.152$, $\beta = -1.17$, $r^2 = 0.76$.
‖ Calculated by applying yearly predicted share to yearly predicted volume-specific mortality rates.

dergoing this procedure over this 12-year period. Although there was some indication that the relative decline in mortality rate over time was larger at the high-volume provider compared with low-volume hospitals (15.7% average annual decline *vs.* 6%), the statistical evidence to support this difference was weak ($p = 0.47$).

DISCUSSION

Regionalization has been shown to be an effective approach to improving population-based outcomes for trauma and neonatal services,[5,6] but heretofore the effectiveness of regionalization for elective general surgery has not been demonstrated. In the past 2 years, three major studies have shown that the in-hospital mortality rate for the complex, high-risk operation of pancreaticoduodenectomy is lower when performed in a high-volume tertiary care setting than when performed in low-volume settings.[1–3] This suggests that regionalization of pancreaticoduodenectomy to one or more high-volume tertiary care centers in a state could result in a substantial decrease in the statewide in-hospital mortality rate for the procedure.

The current study found that over a 12-year period in Maryland, the in-hospital mortality rate for pancreaticoduodenectomy dropped. During this same period, pancreaticoduodenectomy became concentrated at one high-volume tertiary care center, the Johns Hopkins Hospital. The in-hospital mortality rate at the high-volume tertiary care center was substantially and significantly lower than at the low-volume providers. Although the in-hospital mortality rate for pancreaticoduodenectomy decreased for both provider groups during the study period, the adjusted relative risk of death at the low-volume providers compared with the high-volume provider more than doubled during the time period. We estimate that concentration of this procedure at the high-volume provider accounted for nearly 61% of the observed reduction in statewide deaths for pancreaticoduodenectomy. The remaining decrease was caused by the overall improvement in the mortality rate for pancreaticoduodenectomies during the study period in both provider groups.

The shift toward regionalization during this study period occurred without intervention from providers, payors, or the government. The institution that became the regional provider, the Johns Hopkins Hospital, developed an interest in the pancreaticoduodenectomy procedure and developed a team of health care providers dedicated to caring for these patients. This included formulation of treatment protocols and critical pathways for the procedure, as well as standardization of diagnostic workups, technical operative details, and the management of the postoperative course. The institution disseminated information regarding provider capabilities and surgical results locally, regionally, and nationally. This included presentations at local hospitals, to managed care organizations, and at national surgical meetings. The institution also established a home page on the Internet documenting the success of the care program for patients requiring pancreaticoduodenectomy. An increased number of patients were consequently referred to the institution, and regionalization resulted.

Although the increase in referrals to the regional provider benefited the state's population through decreased statewide in-hospital deaths for this procedure, this study also found growth in the volume of pancreaticoduodenectomies performed in community hospital settings during this period. We attribute this increased volume in community hospitals primarily to the proliferation of knowledge in the community regarding the effectiveness of this surgical procedure, and an increased interest among surgeons at community hospitals in performing this procedure. Disease incidence for the various periampullary cancers for which this operation is most commonly performed has been level in recent years, so this does not explain the volume growth for this procedure.[4] Growth in volume is better explained by an increased acceptance of surgical treatment for these diseases. Despite the increase in the number of procedures performed at the low-volume institutions, volume increased even more rapidly at the high-volume institution, resulting in a trend toward regionalization.

The significant drop in the statewide mortality rate demonstrates that regionalization can benefit the population of a state through the reduction of in-hospital deaths. Although this study was not able to examine readmission rates, functional status, quality of life, or length of survival, in-hospital mortality rate is an important objective measurement and one of great interest and concern to consumers. The findings of this study support the use of regional centers for complex, high-risk surgical procedures.

Although numerous studies[1–3,5–11] have shown that physicians and hospitals that perform a large volume of surgical procedures have lower mortality rates, the evolution toward regionalization in the United States has been limited. The few procedures targeted for regionalization generally have been of financial concern to insurance companies and governmental health-planning agencies. Patients requiring procedures that have a high cost to a payor, either because they are performed often or are very expensive, are often referred to a "center of excellence" chosen by the insurance plans.[12,13] In this approach, insurance plans define desired provider attributes and seek providers on a regional or national basis to provide services to enrollees. Many surgical procedures are complex and carry a high risk of death but have not yet been targeted for regionalization. Reasons for this include the lack of outcome data and performance standards; the lack of standardized diagnostic, treatment, and referral guidelines; barriers posed by administrative logistics required to establish regional centers; lack of access to regional centers in some geographic areas; and

requirements for emergency care, which may preclude transfer to a regional center.

To improve survivorship for patients undergoing complex, high-risk procedures, actions will be required of payors, consumers, providers, and regulators to identify additional procedures appropriate for regionalization, to establish criteria for regional centers, and to triage patients to these centers. Specific clinical indications for referring patients to such centers could be developed by providers and their representative professional specialty societies. Payors could commit to using these indications to ensure that their enrollees will receive care in the most appropriate settings.

Regionalization could also be accomplished through the Medicare and Medicaid programs. Currently, state health planners have limited jurisdiction through the Certificate of Need process to direct care to certain settings, but the process is focused on regulating capital expenditures, which are generally not required for complex high-risk surgical care. Nevertheless, federal and state guidelines could be developed to ensure that consumers receive their care at the optimal site.

Consumers and special-interest groups are expected to emerge as major forces in the health care market. These groups will need access to health care outcomes data to influence how and where care is delivered. Accepted, objective analytic methodologies will ultimately be necessary for this purpose. Issues regarding access to care in underserved areas will also have to be weighed against the benefits of regionalization. The physician community and specialty societies can exert influence in this arena through credentialing and certification of physicians and facilities, including establishment of minimum facility and provider volume standards for selected procedures.

Regionalization of health care services should result in the optimization of outcomes for complex, high-risk elective surgery. Additional research is needed, however, to identify procedures for which regionalization is most likely to have a beneficial effect, and to determine how best to achieve the regionalization.

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