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Potential Benefits of Regionalizing Major Surgery in Medicare Patients

CONTEXT. Given the strong “volume–outcome” relations observed with many surgical procedures, concentrating surgery in high-volume hospitals could substantially reduce the number of surgical deaths. We explored the potential benefits of regionalizing 10 high-risk procedures for the 38 million Americans enrolled in Medicare.

COUNT. Number of lives saved in 1 year.

CALCULATION. Current number of deaths occurring with each procedure multiplied by the average mortality reductions that plausibly could be achieved with regionalization.

DATA SOURCE. The current number of surgical deaths was obtained from the 1995 MEDPAR file of the Medicare claims database. Expected mortality rate reductions with regionalization, estimated from published volume–outcome studies, were tested over a wide range in sensitivity analysis.

RESULTS. Of 381,000 Medicare patients undergoing any 1 of the 10 procedures in 1995, approximately 17,000 surgical deaths occurred. The total number of lives saved by regionalization depends on assumptions about the mortality reductions likely to be achieved, varying from 853 (5% reduction) to 4266 (25% reduction). Regionalizing common, intermediate-risk procedures (e.g., cardiovascular procedures) would save far more lives than regionalizing less-common, higher-risk operations (e.g., major cancer resections).

CONCLUSIONS. Even with conservative assumptions about reduction in surgical mortality likely to be achieved, the benefits of regionalizing major procedures in Medicare patients could be substantial. Policymakers should focus on common procedures before less-common, high-risk operations.

Large population-based studies have consistently demonstrated better outcomes for cardiovascular surgery, major cancer resection, and other high-risk procedures at high-volume centers.^{1–3} This “volume–outcome” effect can be dramatic. For example, in one study of pancreaticoduodenectomy (also known as the Whipple procedure), surgical mortality was fourfold higher at very-low-volume hospitals than at high-volume centers (16% vs. 4%).⁴ Given the strong volume–outcome relations observed with many surgical procedures, concentrating surgery in high-volume hospitals could have substantial benefit.

Regionalization is particularly relevant to the Medicare program. First, Medicare enrollees face considerable risk from surgery. Over half of all patients undergoing surgical procedures that are likely to be considered for regionalization, primarily major cancer resection and cardiovascular procedures, are over 65 years of age.⁵ Because age is strongly related to surgical mortality, Medicare patients represent

The abstract of this paper is available at ecp.acponline.org.

a large majority of those who die after surgery. Second, Medicare has the structures to implement regionalization. Unlike most private payers, Medicare has the size and financial leverage to allow centralized decision making about regionalization. There is at least one precedent to do so: Medicare has previously restricted reimbursement for transplantation to hospitals that meet minimum procedure volume criteria.⁶

In this article, we estimate the numbers of lives that could be saved by regionalizing 10 surgical procedures in the Medicare program.

Methods

We selected 10 procedures that could be considered for regionalization on the basis of two qualitative criteria. First, the procedures needed to be predominantly elective or performed for conditions that can be adequately stabilized so that patients may be safely transferred to referral centers. In addition, the mortality rate associated with each procedure had to be substantial (>1%). For most of the 10 procedures, previous volume–outcome studies suggest the potential for significant mortality reductions with regionalization. As shown in **Table 1**, these procedures are relatively diverse, representing several of the major surgical subspecialties.

We estimated the potential benefits of regionalization in terms of the number of lives saved. This value was calculated by multiplying the current number of

surgical deaths with each procedure by the relative reduction in average surgical mortality that could be expected by moving patients from low-volume hospitals to higher-volume centers (**Figure 1**).

The current number of surgical deaths is in turn the product of the number of patients undergoing each operation and the procedure-specific mortality rate. To estimate these values for the U.S. Medicare program, we used information from the 1995 MEDPAR file of the claims database, which contains hospital discharge abstracts for all Medicare hospitalizations. Medicare patients enrolled in risk-bearing managed care organizations are not included in this file; we also excluded patients under 65 or over 99 years of age. Patients undergoing each of the 10 procedures were identified by the appropriate International Classification of Diseases, Ninth Revision, procedure codes in the hospital discharge abstract. Surgical mortality was assessed in terms of in-hospital mortality as determined by discharge vital status.

The relative reduction in average mortality likely to be achieved by regionalizing each procedure depends on the strength of the volume–outcome relation and the details of the regionalization policy. The decrease in procedure-related mortality would be greater for procedures with strong volume–outcome associations than for those with weaker relations. Because volume–outcome associations vary widely by procedure, so too will the mortality benefits of regionalization. The specific regionalization policy would determine how many

TABLE 1

Number and Surgical Mortality Rates of U.S. Medicare Patients Undergoing 10 Procedures That Could Be Considered for Regionalization

PROCEDURE	MOST COMMON INDICATION	IN-HOSPITAL MORTALITY, %	PATIENTS UNDERGOING PROCEDURE, n	SURGERY-RELATED DEATHS, n
Total gastrectomy or esophagogastrectomy	Gastric or esophageal cancer	12.6%	3344	421
Pancreaticoduodenectomy (Whipple procedure)	Pancreatic cancer	10.9%	1932	211
Heart valve replacement	Aortic stenosis	7.8%	24,211	1888
Major pulmonary resection	Lung cancer	5.6%	28,935	1620
Coronary artery bypass grafting	Coronary artery disease	5.3%	174,354	9241
Abdominal aortic aneurysm repair (nonruptured)	Abdominal aortic aneurysm	5.2%	24,386	1268
Radical nephrectomy	Renal cancer	3.1%	13,466	417
Total cystectomy	Bladder cancer (invasive)	3.1%	4384	136
Abdominoperineal resection	Rectal cancer	2.6%	5881	153
Carotid endarterectomy	Carotid stenosis	1.7%	100,484	1708
Total			381,377	17,064

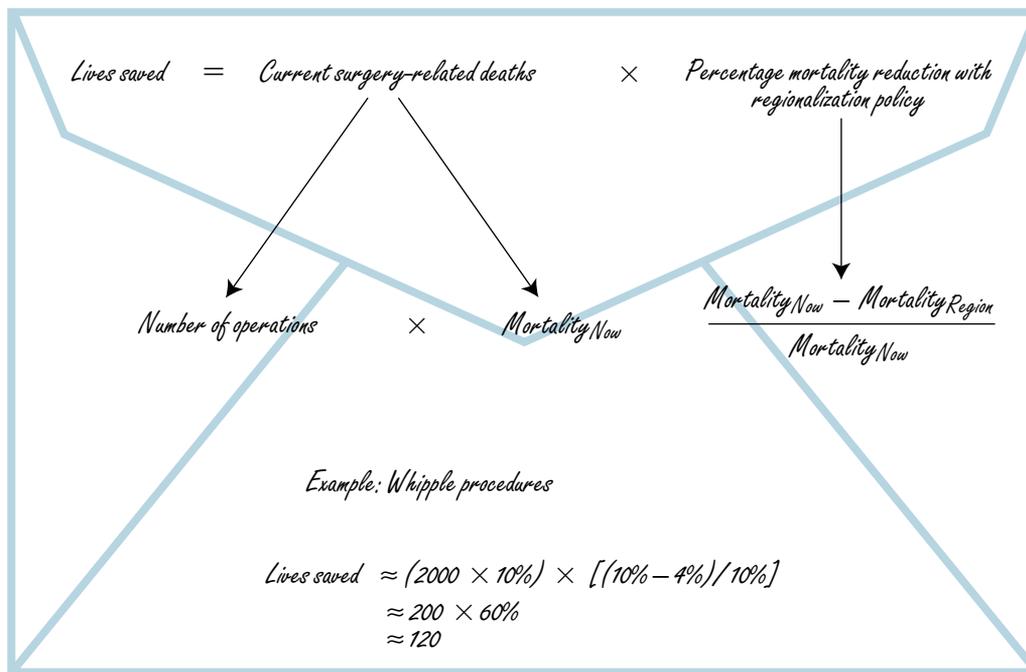


FIGURE 1. Back-of-the-envelope calculation of the number of lives saved each year by regionalizing surgical procedures.

patients would be moved and to which hospitals they would go. Across the spectrum of potential policy approaches, some would move a large proportion of patients undergoing surgery, whereas others would affect a relatively small proportion. Some policies could move all patients into the highest-volume centers, and others would simply close down the lowest-volume centers. As we describe more fully in the **Appendix**, these variables could substantially affect the mortality reductions likely to be achieved with regionalization.

In our analysis, we calculated the number of lives saved, assuming that regionalizing each of the 10 procedures would reduce average surgical mortality by 5% (the most conservative assumption) to 25% (the most optimistic assumption). Data suggesting that this range is plausible appear in the **Appendix**.

Results

As shown in **Table 1**, average surgical mortality varied markedly among the 10 procedures, from 12.6% for total gastrectomy or esophagogastrectomy to 1.7% for carotid endarterectomy. The procedures also varied in how often they were performed in 1995, from 1932 for pancreaticoduodenectomy to 174,354 for coronary artery bypass grafting (CABG). Of the 381,000 Medicare patients undergoing these 10 procedures, approx-

imately 17,000 surgical deaths occurred. **Table 1** also shows that the procedure frequency was a stronger determinant than the average surgical mortality rate of the number of surgical deaths occurring with each procedure. Thus, four times as many deaths occurred with carotid endarterectomy (1.7% mortality) as with total gastrectomy or esophagogastrectomy (12.6% mortality).

The total number of lives saved by regionalization depends on assumptions about expected mortality reductions. With a conservative assumption about its effectiveness (5% mortality reduction), moving surgery from low-volume hospitals to higher-volume centers would save approximately 853 lives each year (**Table 2**). With a more optimistic assumption (25% reduction), regionalization could save 4266 lives.

The benefits likely to be achieved by regionalizing different procedures vary widely. The major cancer resection procedures are higher risk than the other procedures (with the exception of pulmonary resection) but are performed infrequently. Even with 25% reductions in mortality, regionalizing any of the cancer resection procedures would save no more than 100 lives each year in Medicare patients, which is substantially less of a benefit than could be achieved by regionalizing cardiovascular procedures (**Table 2**). Greater benefit could be realized from regionalizing heart valve replacement,

TABLE 2

Number of Lives Saved Each Year by Regionalizing Different Procedures in the U.S. Medicare Program according to Different Assumptions about Relative Reductions in Average Surgical Mortality

PROCEDURE	LIVES SAVED ANNUALLY, <i>n</i>		
	5% MORTALITY REDUCTION	10% MORTALITY REDUCTION*	25% MORTALITY REDUCTION*
Total gastrectomy or esophagogastrectomy	21	42	105
Pancreaticoduodenectomy (Whipple procedure)	11	21	53
Heart valve replacement	94	189	472
Major pulmonary resection	81	162	405
Coronary artery bypass grafting	462	924	2310
Abdominal aortic aneurysm repair (nonruptured)	63	127	317
Radical nephrectomy	21	42	104
Total cystectomy	7	14	34
Abdominoperineal resection	8	15	38
Carotid endarterectomy	85	171	427
Total	853	1706	4266

*Numbers may not add up precisely because of rounding.

abdominal aneurysm repair, and pulmonary resection (high-risk, intermediate-frequency procedures) and carotid endarterectomy (a low-risk, high-frequency procedure). Regionalizing CABG, which is both high risk and common, would save the most lives.

Discussion

Our analysis shows that regionalizing selected procedures in a large, high-risk population, such as Medicare patients, could have substantial benefits. Even with conservative assumptions about efficacy, thousands of lives could be saved by regionalization. Our analysis also points out that regionalizing common procedures associated with intermediate risk (e.g., CABG and other cardiovascular procedures) would save far more lives than regionalizing high-risk procedures that are performed infrequently, even those for which dramatic volume–outcome associations have been documented (e.g., pancreaticoduodenectomy or esophagogastrectomy).

It is important to acknowledge several limitations in our approach to estimating the potential benefits of regionalizing procedures in Medicare patients. Calculations were made partially on the basis of the number of surgical deaths that currently occur with each procedure. This approach assumes that these deaths all occurred in patients who would be eligible for regionalization. Although the 10 procedures selected for this analysis are usually elective, some are occasionally performed on an emergency basis in patients with urgent problems who cannot be safely transferred to a referral center (e.g., gas-

trectomy for bleeding). With claims data, it would have been difficult to identify and exclude these patients from our analysis. To this extent, we may have overestimated the benefits likely to be achieved by regionalization.

Our estimates of reductions in average surgical mortality that are likely to be achieved with regionalization are also imprecise. As described further in the **Appendix**, mortality reductions depend heavily on procedure-specific volume–outcome relations. First, although the volume–outcome literature is substantial, much of it is outdated, reflecting observations from more than a decade ago. The mortality rates associated with many procedures have declined greatly.^{7,8} Whether this trend has affected relations between procedural volume and outcomes has yet to be determined. Second, much of the volume–outcome literature is not generalizable; a large proportion of published studies is based on results from highly selected national referral centers. More population-based studies are needed to inform policymakers.

As described in the **Appendix**, the mortality reductions likely to be achieved also depend on the specific policy used to implement regionalization, which would determine how many patients would be affected and at which hospital they would undergo surgery. Policymakers could choose from an array of conservative to aggressive approaches to regionalization. The range of possible approaches is exemplified in Grumbach and colleagues' examination⁹ of CABG procedures in three regions in 1989. In California, a state that imposes no volume-related restrictions on provision of cardiac surgery, 65% of CABG procedures were done at low-volume hos-

pitals (<200 procedures/yr), including 31% at very-low-volume hospitals (<100). In New York State, which has strict Certificate of Need regulations based in part on volume criteria, only 20% of CABG procedures were performed at low-volume hospitals. Finally, in Canada, where cardiac surgery is restricted to designated regional centers within each province, only 7% of CABG procedures were performed at low-volume hospitals and none were performed at very-low-volume centers.

Although mortality benefits are no doubt important in decisions about regionalization, policymakers must consider other factors. First, careful accounting is needed to determine the net effect of regionalization on health care costs. Many assume that concentrating big-ticket procedures in high-volume hospitals would save money—for example, from improved economies of scale with delivering resource-intensive procedures (e.g., cardiac surgery) and from fewer surgical complications and thus shorter hospital stays.¹⁰ However, transferring patients between hospitals on a large scale would increase both administrative and travel-related costs. In addition, high-volume centers, which are predominantly teaching hospitals, may deliver inpatient services at higher costs than smaller, nonteaching hospitals.¹¹ The second important variable to consider is patient preference. Although it is widely assumed that well-informed patients would rather travel for lower surgical mortality risks, many patients may prefer the intangible benefit of care close to home by familiar providers.¹²

Finally, policymakers must consider the potential effects of regionalization on low-volume hospitals, particularly those in rural areas. Loss of surgical volume could threaten the financial viability of local hospitals or their ability to recruit and retain surgeons. Even if regionalization had no effect on the availability of local providers, it could reduce their proficiency in delivering emergency care that must be handled locally. For example, the local general surgeon who is no longer allowed to perform elective repair of abdominal aortic aneurysm may be less prepared to do emergency surgery on ruptured aneurysms.

Each year, many patients die after elective surgery. In 1995, 17,000 Medicare patients died undergoing 1 of these 10 procedures. Efforts to improve surgical mortality will need to take several approaches, including quality improvement initiatives at the local and regional levels. These efforts would be important in reducing mortality at all hospitals (i.e., a rising tide lifts all ships). But for many procedures, strong volume–outcome relations suggest that regionalizing surgery may be equally important. Our analysis suggests that Medicare decision makers should consider regionalization as part of broader efforts to improve surgical quality.

Take-Home Points

- Given the strong volume–outcome relations observed with many surgical procedures, concentrating surgery in high-volume hospitals could substantially reduce surgical mortality.
- We estimated how many lives would be saved by regionalizing 10 surgical procedures for Medicare patients.
- Depending on assumptions about the mortality reductions likely to be achieved, regionalization would save 853 (5% reduction) to 4266 (25% reduction) lives each year.
- Regionalizing common, intermediate-risk procedures (e.g., many cardiovascular procedures) would save far more lives than regionalizing less common, higher-risk operations (e.g., major cancer resection).
- Medicare decision makers should consider regionalization as part of broader efforts to improve surgical quality.

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Appendix

The extent to which regionalization of a given surgical procedure reduces average mortality depends on the strength of the volume–outcome relation and the specific policy used to implement regionalization. The first factor is intuitive: Relative mortality reductions will be greatest if regionalization focuses on procedures with the steepest volume–outcome curves (i.e., those for which mortality rates decrease most with increasing hospital volume). The second factor—determining how many patients would be moved and to which hospitals they would go—is more subtle. Policies that move the most patients from low-volume to high-volume hospitals will reduce average mortality to the greatest extent. Policy implementation would also determine where patients are moved on the volume–outcome curve: Policies that move patients from low-volume to high-volume centers will reduce mortality more than those that move patients from low- to medium-volume hospitals.

Using pancreaticoduodenectomy and carotid endarterectomy as examples, we illustrate below the importance of both volume–outcome relations and the implementation policy in estimating the mortality reductions that are likely to be achieved by regionalization.

Volume–Outcome Relations

The strength of the association between procedural volume and patient outcomes is procedure specific.¹ The most complex procedures tend to have the strongest volume–outcome associations. However, even among complex procedures, the nature of volume–outcome relations can vary markedly.

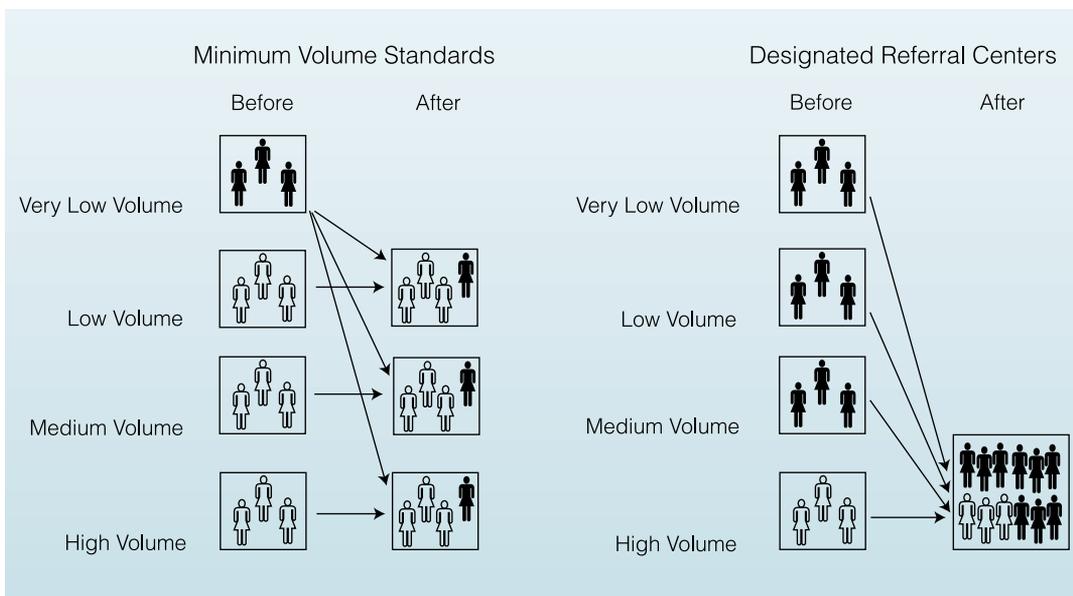
In our studies of Medicare patients undergoing pancreaticoduodenectomy and carotid endarterectomy,^{4, 13} we divided the study samples into four evenly sized patient groups (quartiles), according to hospital-specific procedural volume. For carotid endarterectomy, mortality decreased modestly with increasing hos-

pital volume, from 2.1% (in very-low-volume hospitals) to 1.6% (in high-volume hospitals). For pancreaticoduodenectomy, however, mortality decreased dramatically with increasing volume, from 16% (in very-low-volume hospitals) to 4% (in high-volume hospitals).

Importance of Policy Implementation

Although details about policy implementation and other specifics may vary widely, policymakers could take two basic regulatory approaches to concentrating surgery in high-volume centers: minimum volume standards and designated referral centers (Appendix Figure). With minimum volume standards, policymakers would establish the minimum number of each procedure that each hospital must perform annually to remain accredited or to receive reimbursement. This approach focuses on low-volume centers and on hospitals that cannot do selected procedures. For example, Medicare limits reimbursement for cardiac transplantation to centers that perform at least 12 procedures annually.⁶ With the designated referral center approach, policymakers would select a single or limited number of hospitals allowed to perform specific procedures within each referral area. This approach focuses on high-volume centers and on which hospitals can do selected procedures. For example, cardiac surgery in Canada is restricted to a small number of referral centers in each province.⁹

By setting minimum volume standards for pancreaticoduodenectomy, for example, policymakers could prohibit (or withhold reimbursement for) this procedure at very-low-volume hospitals (those that perform less than one procedure per year in Medicare patients). With this approach, 25% of patients would have to undergo surgery at a low-, medium-, or high-volume hospital (Appendix Figure). Mortality would fall from 10.8% (average rate before regionalization) to 9.0% (average rate after exclusion of very-low-volume hospitals), a 16.7% relative reduction (Appendix Table). In contrast, policymakers could designate regional referral



APPENDIX FIGURE. Two general approaches to regionalization. With minimum volume standards, patients currently at hospitals below a specified procedure volume threshold (very-low-volume hospitals) are “redistributed” to hospitals above the threshold. With designated referral centers, all patients are directed to selected (high-volume) hospitals.

APPENDIX TABLE

Estimating the Relative Reduction in Average Surgical Mortality Likely To Be Achieved with Two Regionalization Policies

PROCEDURE AND MORTALITY RATE	HOSPITAL VOLUME (PROCEDURES/YR)	SURGICAL MORTALITY (DEATHS PER 100 PATIENTS)		
		NO REGIONALIZATION	MINIMUM VOLUME STANDARDS POLICY*	DESIGNATED REFERRAL CENTER POLICY†
Pancreaticoduodenectomy	Very low (<1)	16.1		
	Low (1–2)	12.7	12.7	Eliminated
	Medium (2–5)	10.1	10.1	
	High (≥6)	4.1	4.1	4.1
Average mortality		10.8	9	4.1
Relative reduction in average mortality, %			16.7%	62.0%
Carotid endarterectomy	Very low (<21)	2.06		
	Low (21–40)	1.68	1.68	Eliminated
	Medium (41–67)	1.72	1.72	
	High (≥68)	1.56	1.56	1.56
Average mortality		1.76	1.65	1.56
Relative reduction in average mortality, %			6.2%	11.4%

*Under this policy, patients who would usually receive care at very-low-volume hospitals would be transferred to hospitals with higher procedure volumes.

†Under this policy, all patients would be transferred to high-volume hospitals.

centers for pancreaticoduodenectomy. With this approach, patients currently at very-low-, low-, and medium-volume centers (75% of all patients) would have to travel to high-volume hospitals for surgery. Average mortality would fall from 10.8% to 4.1% (the rate at high-volume centers), a 62% relative reduction in surgical mortality.

Similarly, with carotid endarterectomy, relative mortality reductions associated with minimum volume standards for carotid endarterectomy are somewhat smaller than those expected from policies designating referral centers (6.2% vs. 11.4%, respectively). With either policy approach, relative mortality reductions are considerably smaller for carotid endarterectomy than for pancreaticoduodenectomy, reflecting the much stronger volume–outcome relation of the latter procedure.

In terms of the average mortality reductions likely to be achieved by regionalization, these two procedures probably represent both ends of the spectrum. CABG, which is associated with the most surgical deaths, is restricted to relatively few hospitals and thus for practical purposes is already somewhat regionalized.

For this reason, average mortality reductions with this procedure would probably be closer to those seen with carotid endarterectomy (6% to 11% reductions) than to those seen with pancreaticoduodenectomy (16% to 62% reductions). To be conservative in estimating the benefits that could be expected from regionalization, we used a range of 5% to 25% in calculating the number of lives saved for each of the 10 procedures.

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