

Volume standards for high-risk surgical procedures: Potential benefits of the Leapfrog initiative

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Background. As part of a broader effort aimed at improving hospital safety, a large coalition of employers, the Leapfrog Group, will soon require hospitals caring for their employees to meet volume standards for 5 high-risk surgical procedures. We estimated the potential benefits of full nationwide implementation of these volume standards.

Methods. Using data from Nationwide Inpatient Sample and other sources, we first estimated the total number of each of the 5 procedures—coronary-artery bypass graft, abdominal aortic aneurysm repair, coronary angioplasty, esophagectomy, and carotid endarterectomy—performed each year in hospitals in US metropolitan areas. (Leapfrog exempts hospitals in rural areas to avoid access issues.) We then projected the effectiveness of volume standards (in terms of relative risks of mortality) for each procedure using data from a published structured literature review.

Results. With full implementation nationwide, the Leapfrog volume standards would save 2581 lives. Of the procedures, volume standards would save the most lives with coronary-artery bypass graft (1486), followed by abdominal aortic-aneurysm repair (464), coronary angioplasty (345), esophagectomy (168), and carotid endarterectomy (118). In our estimates of the number of lives saved, we considered assumptions about how many patients would be affected and the effectiveness of volume standards (ie, strength of underlying volume-outcome relationships with each procedure).

Conclusions. If the Leapfrog volume standards are successfully implemented, employers and health-care purchasers could prevent many surgical deaths by requiring hospital volume standards for high-risk procedures. (*Surgery* 2001;130:415-22.)

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LARGE, POPULATION-BASED STUDIES have consistently demonstrated higher surgical mortality rates with cardiovascular operations, major cancer resections, and certain other procedures at hospitals with low volumes of those procedures.¹⁻⁴ Patients undergoing major oncologic procedures at low-volume hospitals (LVHs) may also have poorer long-term survival.⁵⁻⁷ However, despite increased attention to the idea of regionalizing certain procedures in both the med-

ical literature and the lay media,^{4,8-10} very few concerted efforts have been aimed at moving patients to high-volume hospitals (HVHs).

One notable exception is the Leapfrog safety initiative. Motivated in part by a report from the Institute of Medicine (IOM) on medical errors, several large employers and health-care purchasers in the United States have combined to leverage improvements in health-care quality. The Leapfrog coalition includes (among others) General Motors, General Electric, Verizon, the US Office of Personnel Management, and large coalitions of smaller companies, employing collectively over 20 million people in the Midwest and on the Pacific Coast. Additional employers are being actively recruited. To care for Leapfrog employees, hospitals will be required to meet 3 safety standards: (1) computerized order entry by physicians (to reduce medication errors for inpatients),¹¹ (2) ICUs staffed by full-time intensivists (shown to be associated with reduced mortality),¹²⁻¹⁶ and (3) volume standards for 5 selected high-risk procedures and neonatal intensive care.

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Table I. Annual number of patients undergoing 5 selected operations, overall and at low-volume hospitals (LVH) in metropolitan statistical areas (MSAs)

Procedure (volume standard)	Total number performed in US/yr	Total number performed in MSAs (previous column \times .8)	Proportion currently performed at LVHs			Total number at LVHs in MSAs
			California	New York	Baseline estimate for US	
CABG (500/yr)	383,788 ²⁵	307,030	66% ⁴	41% ¹⁸	53.5%	164,261
Coronary angioplasty (400/yr)	531,981 ²⁵	425,585	36% ⁴	21% ³⁷	28.5%	121,292
AAA repair (30/yr)	37,068 ^{*25}	29,654	64% ⁴	61% ^{†38}	62.5%	18,534
CEA (100/yr)	152,859	122,287	64% ⁴	71% ²⁵	67.5%	82,544
Esophagectomy (7/yr)	2,569 ^{‡23}	2,055	82.5% ²³	§	82.5%	1,696

*Estimated by multiplying total number of AAA repairs (44,129) by proportion of AAA repairs performed for nonruptured (and thus elective) AAAs (84%).

† Hannan defined LVH as < 26 procedures per year.

‡ Because NIS data were unavailable for esophagectomies, annual number performed in California extrapolated to US estimate based on 1999 census data.

§ No data available.

Although it may ultimately include more direct performance measures (eg, risk-adjusted mortality), the Leapfrog standard is based entirely on annual hospital procedures. The 5 surgical procedures—coronary-artery bypass surgery (CABG), coronary angioplasty, elective abdominal aortic aneurysm (AAA) repair, carotid endarterectomy (CEA), and esophageal cancer surgery—were selected because of strong evidence of their volume-outcome relationships.^{1,3,4,17-22} In this study, we estimated the number of lives that could be saved if the Leapfrog volume standards for the 5 surgical procedures are fully implemented.

METHODS

Calculations of lives saved

Number of patients at low-volume hospitals. To calculate the number of patients who could potentially benefit from volume standards, we first estimated the total number of each of the 5 surgical procedures performed each year in the US (Table I). We used data from the 1997 Nationwide Inpatient Sample (NIS) to estimate the numbers of CABGs, coronary angioplasties, AAA repairs, and CEAs performed. The NIS is a probabilistic sample of hospital discharge data from over 1000 hospitals across the US. The weights provided with the data allowed us to calculate national estimates. Because NIS data were not available for esophagectomies, we estimated the total US counts by using data from California²³ and extrapolating it from 1999 census data.²⁴

In determining the number of patients potentially affected by volume standards, we excluded most patients undergoing emergent operations who would not be appropriate for transfer to HVIs. For example, patients with ruptured AAAs were excluded from our analysis. To estimate the number of elective AAA repairs subject to volume

standards, we multiplied the total number of AAA repairs performed annually (44,129)²⁵ by the proportion performed for nonruptured AAAs (84%), estimated from national Medicare data.²⁶ Because of their relative infrequency, however, we adjusted our calculations for patients undergoing truly "emergent" CABG and coronary angioplasties. Emergent CABG operations, which most often occur because of acute complications of coronary angioplasty, represent a very small proportion of all CABGs (less than 5%). Emergent coronary angioplasties, most commonly performed as alternatives for lytic therapy in patients with acute myocardial infarction, are similarly infrequent. CEA and operations for esophageal cancer are rarely performed emergently.

To avoid access issues and other unintended negative consequences in rural areas, the Leapfrog Group will implement the volume standards only in urban areas. We assumed that 80% of the 5 procedures were performed in hospitals in metropolitan areas, based on our analysis of the 1997 data from the American Hospital Association file of the proportion of hospital beds in metropolitan statistical areas (Sandra M. Sharp, MS, personal communication).

To calculate the proportion of patients likely to be affected, we then estimated the proportion of patients currently undergoing the 5 procedures at LVHs, defined according to the volume standards of the Leapfrog Group (Table I). Leapfrog selected these volume standards after reviewing the analysis by Dudley et al⁴ and by consulting with experts in health services research. Population-based studies necessary for estimating the proportion of patients currently at LVHs come primarily from California and New York. For CABG and coronary angioplasty, California has substantially more LVHs than

Table II. Projected in-hospital mortality rates with 5 procedures at low-volume (LVHs) and high-volume (HVHs) hospitals

Procedure	Overall mortality	Relative risk of mortality (LVH vs HVH)	Projected in-hospital mortality	
			HVH	LVH
CABG	2.9% ²⁵	1.38 ¹⁷	2.4%*	3.3%*
Coronary angioplasty	1.0% ²⁵	1.33 ³⁷	0.9%*	1.2%*
Elective AAA repair	4.9% ²⁸	1.60 ²⁸	4.2%	6.7%
CEA	0.6% ²⁵	1.28 ³⁹	0.5%*	0.7%*
Esophagectomy	14% ²³	3.01 ²³	5.9%	15.8%

*"Back-calculated" from estimates of overall mortality rate (above), relative risks of mortality at LVHs and HVHs, and estimated distribution of patients at LVHs and HVHs (Table I).

New York, which has stricter restrictions on the delivery of cardiovascular health care (enforced in part through its Certificate of Need process).¹⁸ Because relevant information from other parts of the US was not available, we averaged estimates from those states for our baseline analysis. For CEA and AAA repair, the proportion of patients undergoing operations at LVHs is very similar in California and New York. Because no data were available from New York for esophagectomies, we relied exclusively on the data from California.²³

Projected effectiveness of volume standards. In projecting mortality reductions likely to be achieved with volume standards for the 5 surgical procedures, we relied on point estimates from Dudley et al⁴ for our baseline analysis. In their systematic review of the volume-outcome literature, they selected the "single best study" for each procedure based on several explicit criteria, including case-mix adjustment, sample size, location of study, and currency of the data. They then used data from the chosen articles to determine the odds ratio for mortality between LVHs and HVHs. We converted these odds to relative risks using the formula described by Zhang and Yu²⁷ (Table II).

Mortality rates at low-volume hospitals. We then applied assumptions about the efficacy-of-volume standards to the estimates of current mortality rates at LVHs. For many high-risk procedures, there is evidence that surgical mortality rates have declined over the last decade. For this reason, we relied on recent overall mortality estimates from the NIS²⁵—instead of older data from the volume-outcome studies on which the efficacy-of-volume standards were derived—for CABG, coronary angioplasty, and CEA. We then derived estimates of current mortality rates at LVHs by "back-calculation," using 3 variables: the current overall mortality for each procedure, the proportion of patients at LVHs and HVHs, and the relative risk of mortality at LVHs versus HVHs. Since the NIS database does not contain information about current overall mortality

rates for elective AAA repair and esophagectomy, we used rates reported in the original volume-outcome studies.^{23,28}

Lives saved. For each procedure, we calculated the number of lives potentially saved as the difference between expected deaths with and without volume standards (Table III). Because our calculations were based on multiple assumptions, we performed sensitivity analyses on 2 variables: (1) the number of patients affected (ie, moved) by the volume-standards policy and (2) the effectiveness of the volume standards in reduced mortality. Varying the number of affected patients accounts for uncertainty in the proportion of patients currently at LVHs in metropolitan areas and in how "successful" the Leapfrog standards will be in redistributing patients. In testing a range of assumptions about the true effectiveness of the volume standards, we varied the relative risk of mortality, LVH versus HVH, with each procedure. If the volume standards were only half as effective for a certain procedure, a baseline relative risk of 1.4 (hypothetically) would be reduced to 1.2. If twice as effective, the baseline relative risk would be increased to 1.8.

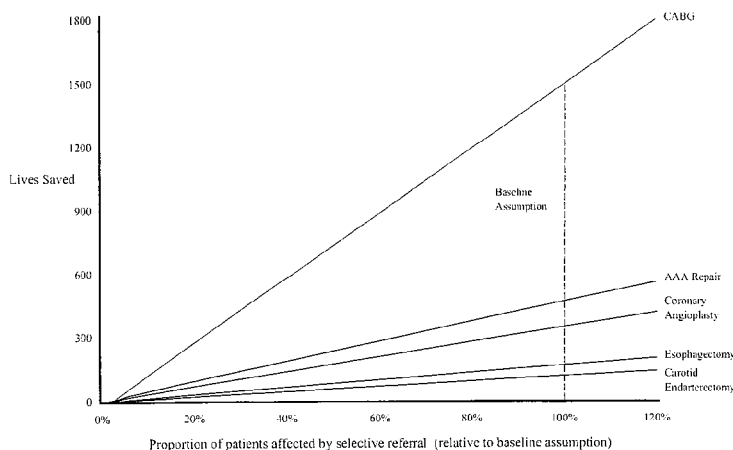
RESULTS

In our baseline analysis, we estimated that full implementation of the volume standards would save 2581 lives each year in the US (Table III). The greatest number of deaths would be prevented with CABG (1486 deaths annually), followed by elective AAA repair (464 deaths annually), and coronary angioplasty (345 deaths annually). Lives potentially saved with esophagectomy and CEA were 168 and 118, respectively.

In the sensitivity analysis, the number of lives saved with each procedure varied according to assumptions about the number of affected patients by the volume standards and assumptions about effectiveness. As expected, the benefits fall proportionally as fewer patients are affected (Fig 1). For example, if only 50% of the patients estimated to

Table III. Number of lives potentially saved by implementation of Leapfrog volume standards

Procedure	Total patients at LVHs in MSAs	Expected deaths without volume standards	Expected deaths with volume standards	Lives saved by volume standards
CABG	164,261	5428	3942	1486
Coronary angioplasty	121,292	1405	1059	345
AAA repair	18,534	1242	778	464
CEA	82,544	543	425	118
Esophagectomy	1,696	267	99	168
Total	388,327	8884	6304	2581

**Fig 1.** Number of lives saved by Leapfrog volume standards for 5 procedures according to proportion of patients affected by volume standards (relative to baseline assumption).

be at metropolitan LVHs were moved to HVHs, 1290 total lives would be saved. Similarly, the number of lives saved with each procedure is directly proportional to the relative risk of mortality, LVH versus HVH (Fig 2). Thus, if the volume standards were only half as effective as our baseline assumptions, 1290 lives would be saved.

DISCUSSION

The universal adoption of the Leapfrog volume standards for the 5 high-risk procedures could have substantial benefits, saving approximately 2500 lives each year in the US. As demonstrated in the sensitivity analysis, the precise projections of the benefits likely to be achieved depend on many underlying assumptions. However, despite varying estimates of the effectiveness of, and the number of patients affected by, the volume standards, the number of lives potentially saved remains substantial. Our findings are also generally in line with 2 previous analyses. Dudley et al estimated that 500 lives would be saved each year in California by adopting "selective referral" for 10 procedures (including the 5 selected by Leapfrog).⁴ Birkmeyer

et al estimated that 800 to 4000 lives could be saved by regionalizing a similar group of 10 procedures in the US Medicare population.²⁹

There should be little controversy that HVHs have lower mortality rates with the 5 procedures selected by the Leapfrog Group (Table IV). In addition to the structured literature review on which our analysis was based, the IOM recently released its synthesis of the evidence.²² A total of 88 volume-outcome studies (of several hundred reviewed) met its criteria for currency and scientific rigor. Of these, 77% were found to be statistically significant in inverse relationships between hospital volume and mortality. The remaining 23% did not have significant volume-outcome associations, but no study demonstrated a statistically significant association in the opposite direction. The IOM report acknowledged, as have others,³⁰ that the majority of volume-outcome studies have relied on administrative data, raising concerns about adequacy of risk adjustment. However, the IOM panel found no evidence that studies based on clinical data reported weaker volume-outcome relationships than those based on administrative data. In

Table IV. Summary of volume-outcome studies of procedures selected for inclusion by Leapfrog Group, as summarized by Dudley et al

Procedure	Total	Number of studies			
		High volume SS* better	NS† trend toward high volume better	NS† trend toward high volume worse	High volume SS* worse
CABG 17-19,31,40-46	11	9	2	0	0
Coronary angioplasty 37,47-51	6	6	0	0	0
Elective AAA repair 19,28,31,38,52-56	9	9	0	0	0
CEA 20,21,39,57-62	9	6	3	0	0
Esophagectomy ^{3,23}	2	2	0	0	0

*Statistically significant.

†Not significant.

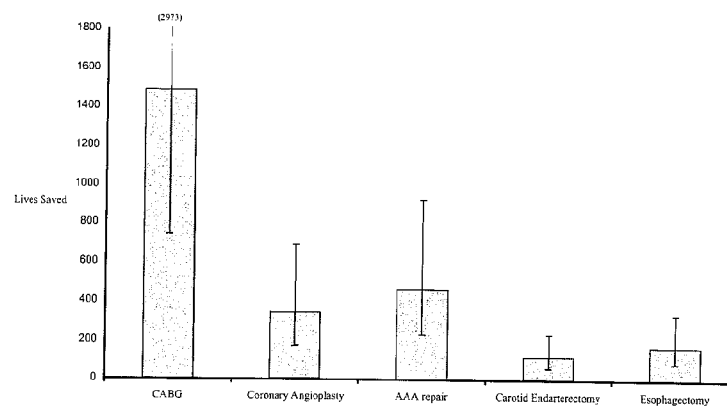


Fig 2. Number of lives saved by Leapfrog volume standards for 5 procedures according to excess mortality at low-volume hospitals. *Shaded columns* indicate projected lives saved from baseline estimates. *Error bars* indicate projected lives saved in sensitivity analysis when excess mortality estimate is varied from 50% to 200% of our baseline estimate.

fact, all 16 studies with the highest-quality scores in the IOM report (all based on clinical data) reported statistically significant relationships between volume and mortality.

Although the general direction of the effect is clear, there remains considerable uncertainty about point estimates of volume-outcome relationships with specific procedures. The volume-outcome literature is too heterogeneous for formal meta-analysis. To avoid potential biases associated with “hand-picked” estimates, we used point estimates from the structured literature review by Dudley et al, who identified the “single best” study for each procedure based on several explicit criteria for study quality (including sample size, adequacy of risk adjustment, and currency). However, relying on data from individual studies makes point estimates of the volume-outcome relationships considerably less precise. It also discounts substantial variation in results across studies. A few studies, including a well-known one from Veterans Affairs hospitals,³⁰ have

shown essentially no volume-outcome effect; others have demonstrated relationships considerably stronger than we used in our analysis.

Do the benefits of procedure volume standards depend on the underlying mechanisms of volume-outcome relationships? Many assume a causal relationship—that higher volume leads directly to better outcomes (“practice makes perfect”). However, the reverse relationship—that better outcomes lead to more referrals and thus higher volumes—may be equally plausible in many settings.³¹ The distinction between these 2 causal models may be important for policies that create new HVHs. For policy initiatives (such as Leapfrog) that simply increase patient flow to established HVHs, however, better outcomes would be achieved either way, to the degree suggested by strength of the observed volume-outcome relationships.

It is important to consider other potential, indirect benefits of the Leapfrog initiative in surgical procedures. Although its initial focus is exclusively

on procedural volume standards, the Leapfrog initiative leaves open the possibility of replacing volume standards with more direct quality measures (at least for procedures performed commonly enough to allow for adequately precise measures of hospital-specific mortality). Surgical quality could be improved considerably if hospitals responded to these incentives, collected data on their own performance, and participated in collaborative quality improvement initiatives.^{32,33}

Unintended harms. Many of the potential downsides of regionalization policies are most relevant to patients living in isolated rural areas. These include unreasonable travel burdens, problems with continuity of care after operation, and underutilization of some procedures.³⁴ Losing surgical volume could threaten the financial viability of local hospitals or their ability to recruit and retain surgeons, with attendant effects on patient access to routine surgical care. By restricting its initial efforts to metropolitan areas, however, the Leapfrog Group is trying to avoid many of these problems.

There may be other potential harms, however. First, procedure-volume standards would create incentives for hospitals near the volume thresholds to increase the number of procedures they perform. This pressure would create the potential for unnecessary operations for patients with "discretionary" conditions, such as lifestyle-limiting coronary artery disease, small AAAs, and asymptomatic carotid stenosis.

Second, concentrating certain procedures in a few HVHs could reduce the proficiency of the remaining hospitals and their surgeons in delivering emergency care that must be handled locally. For example, the local general surgeon no longer performing elective repair of AAAs could be less prepared for emergency operation on a ruptured aneurysm. For nonemergent procedures, the volume standards might turn some LVHs into very LVHs, increasing mortality risks for their remaining patients.

Third, the Leapfrog initiative could affect the delivery and quality of care for procedures other than the 5 directly targeted. For example, the restrictions on where CABG can be performed have obvious implications for where heart-valve replacement can be offered. Policies aimed at improving the quality of AAA repair and CEA could diminish the quality of other related procedures. For example, could hospital- or surgeon-specific performance with lower extremity bypass suffer as a result of lower total volumes of major vascular procedures? Although the data necessary to answer these questions are currently unavailable, policy makers may need to consider individual pro-

cedures in the context of all high-risk procedures in subspecialties.

How should surgeons respond? The Leapfrog initiative may redirect many patients undergoing certain procedures to HVHs, but its direct effects may be modest. Although their numbers are growing, Leapfrog companies represent only 20 million employees and retirees, less than 10% of the total US population. Thus, many regions will be largely unaffected by the Leapfrog initiative, although these companies have a powerful presence particularly in the Midwest and on the Pacific Coast. However, its indirect effects could be substantial. Efforts in the private sector may pressure other regulatory bodies and the government to follow suit. For example, the Health Care Financing Agency, a Leapfrog liaison, is exploring volume standards for the Medicare population. Even without regulatory intervention, the Leapfrog initiative, which has received considerable attention in the lay media,³⁵ may also increase the flow of patients to HVHs simply by making them more aware of the importance of volume for certain procedures.

For these reasons, surgeons and their professional societies will need to respond to initiatives emphasizing surgical volume. Because many surgeons resent any infringement on their professional autonomy, resistance will be a natural response. In resisting, surgeons could simply deny that procedure volume is important or assert that the benefits of volume standards are outweighed by some of the harms outlined above. If they choose this tack, however, surgeons may threaten their credibility with patients, payers, and policy makers. For example, some may ask, "Would a surgeon undergo a pancreatic resection at a hospital performing, on average, only 2 procedures a year?" In addition, many may question surgeons' motives in resisting volume standards. Finally, surgeons will also risk giving up their influence in policy implementation.

Instead, surgeons could implement alternative approaches to improving surgical quality. For example, if hospitals and surgeons wish to defuse the current focus on proxy measures of quality (such as volume), they could initiate systematic efforts to monitor more direct measures of their performance. There are several successful templates for this approach in cardiac surgical procedures and in the VA.^{32,36} Unfortunately, tracking risk-adjusted mortality and morbidity requires substantial commitment and investment of resources. In addition, sample size issues limit the usefulness of this approach for procedures performed relatively infrequently (eg, esophagectomy), or those associated with low event

rates (eg, CEA), particularly at LVHs. Patients and payers may also insist on public disclosure of quality measures, another potential obstacle.

Finally, surgeons could decide to work with policy makers to find a middle ground. For example, for cardiac operations and other common vascular procedures, the surgeons and their societies could work toward universal adoption of programs for measuring performance directly. If volume standards are the only practical approach for less common procedures (eg, major cancer resections), at least surgeons can help to ensure that sensible volume standards are selected.

Surgeons also must get involved in the clinical science underlying these policy initiatives. As a start, surgeons could help fill in the gaps in the volume-outcome literature. Although the volume-outcome literature is extensive, much more research is needed about processes of care responsible for better outcomes at HVHs and about the relative importance of surgeon-versus-hospital factors with various procedures. Surgeons should also participate in studying the real consequences of policy initiatives, such as the Leapfrog effort. In addition to assessing the benefits, researchers need to monitor potentially negative effects of volume-based initiatives on access, patient satisfaction, and training programs, to name just a few areas needing future study. By taking the lead in these areas, surgeons can help to ensure that volume standards are implemented in the ways that optimize patient benefits while minimizing unintended harms.

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