

ATTACHMENTS

MedStar - Interested Party Written Comments

Certificate of Need Applications for a Cardiac Surgery Program

Anne Arundel Medical Center - Docket No. 15-02-2360

Baltimore Washington Medical Center - Docket No. 15-02-2361

Filed: July 27, 2015

List of Attachments

1. Katy Reed, MBA, “Rationalizing Cardiology Care in an Era of Hospital Consolidation,” CardioSource WorldNews (May 2015).
2. Mack et.al., “5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomized controlled trial,” The Lancet; Vol. 385 No. 9986, pp. 2477–2484, (June 20, 2015).
3. Sabatine et.al., “Efficacy and Safety of Evolocumab in Reducing Lipids and Cardiovascular Events,” N Engl J Med 2015; 372:1500-1509 (Apr. 16, 2015).
4. Steven Ross Johnson, “Promising Findings Shown for Heart-Related Issues,” Modern Healthcare (Mar. 16, 2015).
5. Chou et al, “Travel Distance and Health Outcomes for Scheduled Surgery,” Medical Care Vol. 52 No. 3 (March 2014).
6. Patient Transfer Agreement by and Between Anne Arundel Medical Center, Inc. and Washington Hospital Center (February 2005).
7. Auerbach et al., Case Volume, Quality of Care, and Care Efficiency in Coronary Artery Bypass surgery (2010).
8. Vassileva et al. “Hospital Volume, Mitral Repair Rates, and Mortality in Mitral Valve Surgery in the Elderly: An Analysis of US Hospitals Treating Medicare Fee-For-Service Patients,” The Journal of Thoracic and Cardiovascular Surgery (Mar. 2015).
9. California CABG Mortality Reporting Program, Hospital Volume and Coronary Artery Bypass Graft Surgery Outcomes (2003).
10. Cheryl Clark, “Welcome Back, Volume – The Original Quality Measure” HealthLeaders Media (May 21, 2015).
11. Peter Pronovost, M.D., “Low Volume Hospitals Create Big Risks for Surgery Patients” U.S. News & World Report: Opinion (June 3, 2015).
12. Steve Sternberg and Geoff Dougherty, “Risks Are High at Low-Volume Hospitals U.S. News & World Report (May 18, 2015).
13. Steve Sternberg, “Hospitals Move to Limit Low-Volume Surgeries” U.S. News & World Report (May 19, 2015).
14. The Joint Commission’s Proposed Requirements for Comprehensive Cardiac Center Certification Program (CCCM) (May 15, 2015).

ATTACHMENT 1



BUSINESS CONSULT

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Rationalizing Cardiology Care in an Era of Hospital Consolidation

The health care landscape has dramatically changed during the past few years—and will continue to do so—as hospitals consolidate into larger entities. For many organizations, mergers and acquisitions present opportunities for greater geographic reach, enhanced clinical capacity, increased care coordination, and economies of scale. When it comes to the cardiovascular (CV) service line, consolidation can enable greater subspecialization for services (e.g., congenital heart disease, TAVR, transplant) that typically have limited volume but are critical to comprehensive patient care. However, consolidation can also create a crowded clinical environment in which newly consolidated hospitals provide overlapping services; and while subspecialty care and patient access are key priorities of the CV service line, redundancies are not.

Enter *rationalization*, the third installment in our series on the five key attributes of a thriving value-based enterprise. To mitigate the potential clutter of consolidation, systems are evaluating the (re)distribution of cardiology services and centralizing or colocating similar service offerings within a particular market. The intent is to contain costs and optimize resource utilization while also providing high-quality care. Yet the decision to rationalize services, although increasingly necessary, can be highly complex. This article highlights the common challenges organizations may face and offers

guidance for determining the appropriate level of rationalization.

YES, RATIONALIZATION IS COMPLICATED

I am currently working with several hospital systems that are managing multiple CV surgery programs within close proximity to each other. While volumes may have justified this service duplication

To mitigate the potential clutter of consolidation, systems are evaluating the (re)distribution of cardiology services and centralizing or colocating similar service offerings within a particular market.

5 or 10 years ago, the practicality and benefits of having two programs are now much more difficult to explain. Most agree that clinical cardiology services (e.g., clinical consults, routine testing) need to be readily available and in close proximity to where people live and work. Conversely, heart transplantation and VAD implants should be centralized on a regional or multiregional basis.

The ideal distribution of subspecialty and surgical services generally lies somewhere in between these two options. Questions regarding the number and location of open-heart programs are obviously important and need to be addressed. From a quality perspective, having a high-volume open-heart program is more advantageous than one with a lower case volume; however, many patients and providers are hesitant to remove on-site surgical backup from their local facilities. Similarly, some systems opt to limit the number of cath labs available for diagnostic interventional procedures and instead, focus on enhancing their processes for transferring STEMI cases from local facilities to a regional cath lab facility. While there are a number of benefits to these rationalization efforts, many health care systems are reluctant to venture down this path for fear of the strategic, financial, operational, and cultural and political considerations that accompany such endeavors.

Even though challenges exist and can be difficult to overcome, systems cannot afford to tip-toe around tough discussions given the steadily growing emphasis on value-based care—particularly for CV services—that continues to be at the forefront of CMS' reimbursement initiatives. Successfully managing the complexities of rationalization strategies requires systems to establish a carefully constructed framework for identifying, evaluating, and prioritizing their options. More importantly, it requires a collaborative process that brings both physicians and administrators to the table to ask the important questions and engage in a logical, unprejudiced assessment of the benefits and risks.

RATIONALIZATION FRAMEWORK

Rationalizing services requires careful analysis, a

TABLE Example Considerations for CV Service Line Rationalization

Strategic	Operational	Financial	Cultural and Political
<ul style="list-style-type: none"> • Patient/provider loyalty and retention when services are relocated • Degree of competitive response and potential local market shifts • Anticipated on-site CV offerings in the long term (that might necessitate a short-term service) 	<ul style="list-style-type: none"> • Potential to improve outcomes through volume consolidation of high-risk procedures • Downstream implications (e.g., impact on cardiac imaging studies, lab tests) • Proximity to related services (e.g., cardiac rehab, SNFs) • Equipment/space under- or over-capacity 	<ul style="list-style-type: none"> • Impact of lost revenue streams and associated contribution margin • Implications of value-based reimbursement and other cost/financial factors • Hospital and CEO performance incentive structures • Capital initiative funding at the local level 	<ul style="list-style-type: none"> • Reactions of medical staff and hospital leadership • Shift in mind-set from silo to system orientation • Previous promises/agreements made to boards, communities, local governments, and donors regarding the types and level of services provided by the facility

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well-defined strategy, and the ability to cultivate influential champions for change. There should ultimately be a compelling case for why service redistribution is necessary, as well as how services will be distributed to best support the strategic and financial success of the system.

Regardless of how services are redistributed, there are several other critical elements that need to be factored into a framework for rationalization.

» **Establish clear ground rules and transparent decision-making criteria.** Providing a clear decision-making path and precise criteria to be followed helps organizations communicate an unbiased, stakeholder-inclusive, and transparent approach to service distribution.

» **Engage stakeholders throughout the decision-making process.** Reactions to rationalization efforts vary and often depend on whether a community perceives it will be losing or gaining services. Engaging stakeholders in the discussion increases the opportunity

to address questions and concerns early on while creating win-win scenarios for those who are directly impacted.

» **Enlist local and/or regional provider input into system initiatives.** If a decision is made to consolidate

a particular service at the system level, ensure that local stakeholders still have venues to provide system-wide guidance and feedback. For example, the implementation of regional, multi-organizational committees for programs like TAVR can provide a strong means to co-

ordinate care pathways across the system and, in the process, secure broad provider support at the local level.

» **Start with services that have the greatest potential for improving quality and cost.** Take manage-

There should ultimately be a compelling case for why service redistribution is necessary, as well as how services are distributed to best support the strategic and financial success of the system.

Pradaxa® (dabigatran etexilate mesylate) capsules for oral use

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Please see package insert for full Prescribing Information.

WARNING: (A) PREMATURE DISCONTINUATION OF PRADAXA INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HEMATOMA

(A) PREMATURE DISCONTINUATION OF PRADAXA INCREASES THE RISK OF THROMBOTIC EVENTS
Premature discontinuation of any oral anticoagulant, including PRADAXA, increases the risk of thrombotic events. If anticoagulation with PRADAXA is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant [see Warnings and Precautions].

(B) SPINAL/EPIDURAL HEMATOMA
Epidural or spinal hematomas may occur in patients treated with PRADAXA who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:

- use of indwelling epidural catheters
- concomitant use of other drugs that affect hemostasis, such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants
- a history of traumatic or repeated epidural or spinal punctures
- a history of spinal deformity or spinal surgery
- optimal timing between the administration of PRADAXA and neuraxial procedures is not known [see Warnings and Precautions].

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary [see Warnings and Precautions].

Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated [see Warnings and Precautions].

INDICATIONS AND USAGE: Reduction of Risk of Stroke and Systemic Embolism in Non-valvular Atrial Fibrillation: PRADAXA is indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. **Treatment of Deep Venous Thrombosis and Pulmonary Embolism:** PRADAXA is indicated for the treatment of deep venous thrombosis and pulmonary embolism in patients who have been treated with a parenteral anticoagulant for 5-10 days. **Reduction in the Risk of Recurrence of Deep Venous Thrombosis and Pulmonary Embolism:** PRADAXA is indicated to reduce the risk of recurrence of deep venous thrombosis and pulmonary embolism in patients who have been previously treated.

CONTRAINDICATIONS: PRADAXA is contraindicated in patients with: Active pathological bleeding [see Warnings and Precautions and Adverse Reactions]. History of a serious hypersensitivity reaction to PRADAXA (e.g., anaphylactic reaction or anaphylactic shock) [see Adverse Reactions]. Mechanical prosthetic heart valve [see Warnings and Precautions].

WARNINGS AND PRECAUTIONS: Increased Risk of Thrombotic Events after Premature Discontinuation: Premature discontinuation of any oral anticoagulant, including PRADAXA, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. If PRADAXA is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant. **Risk of Bleeding:** PRADAXA increases the risk of bleeding and can cause significant and, sometimes, fatal bleeding. Promptly evaluate any signs or symptoms of blood loss (e.g., a drop in hemoglobin and/or hematocrit or hypotension). Discontinue PRADAXA in patients with active pathological bleeding. Risk factors for bleeding include the concomitant use of other drugs that increase the risk of bleeding (e.g., anti-platelet agents, heparin, fibrinolytic therapy, and chronic use of NSAIDs). PRADAXA's anticoagulant activity and half-life are increased in patients with renal impairment. **Reversal of Anticoagulant Effect:** A specific reversal agent for dabigatran is not available. Hemodialysis can remove dabigatran; however the clinical experience supporting the use of hemodialysis as a treatment for bleeding is limited [see Overdosage]. Activated prothrombin complex concentrates (aPCCs, e.g., FEIBA), or recombinant Factor VIIa, or concentrates of coagulation factors II, IX or X may be considered but their use has not been evaluated in clinical trials. Protamine sulfate and vitamin K are not expected to affect the anticoagulant activity of dabigatran. Consider administration of platelet concentrates in cases where thrombocytopenia is present or long-acting antiplatelet drugs have been used.

Spinal/Epidural Anesthesia or Puncture: When neuraxial anesthesia (spinal/epidural anesthesia) or spinal puncture is employed, patients treated with anticoagulant agents are at risk of developing an epidural or spinal hematoma which can result in long-term or permanent paralysis [see Boxed Warning]. To reduce the potential risk of bleeding associated with the concurrent use of dabigatran and epidural or spinal anesthesia/analgesia or spinal puncture, consider the pharmacokinetic profile of dabigatran. Placement or removal of an epidural catheter or lumbar puncture is best performed when the anticoagulant effect of dabigatran is low; however, the exact timing to reach a sufficiently low anticoagulant effect in each patient is not known. Should the physician decide to administer anticoagulation in the context of epidural or spinal anesthesia/analgesia or lumbar puncture, monitor frequently to detect any signs or symptoms of neurological impairment, such as midline back pain, sensory and motor deficits (numbness, tingling, or weakness in lower limbs), bowel and/or bladder dysfunction. Instruct patients to immediately report if they experience any of the above signs or symptoms. If signs or symptoms of spinal hematoma are suspected, initiate urgent diagnosis and treatment including consideration for spinal cord decompression even though such treatment may not prevent or reverse neurological sequelae. **Thromboembolic and Bleeding Events in Patients with Prosthetic Heart Valves:** The safety and efficacy of PRADAXA in patients with bileaflet mechanical prosthetic heart valves was evaluated in the RE-ALIGN trial, in which patients with bileaflet mechanical prosthetic heart valves (recently implanted or implanted more than three months prior to enrollment) were randomized to dose adjusted warfarin or 150, 220, or 300 mg of PRADAXA twice a day. RE-ALIGN was terminated early due to the occurrence of significantly more thromboembolic events (valve thrombosis, stroke, transient ischemic attack, and myocardial infarction) and an excess of major bleeding (predominantly post-operative pericardial effusions requiring intervention for hemodynamic compromise) in the PRADAXA treatment arm as compared to the warfarin treatment arm. These bleeding and thromboembolic events were seen both in patients who were initiated on PRADAXA post-operatively within three days of mechanical bileaflet valve implantation, as well as in patients whose valves had been implanted more than three months prior to enrollment. Therefore, the use of PRADAXA is contraindicated in patients with mechanical prosthetic valves [see Contraindications]. The use of PRADAXA for the prophylaxis of thromboembolic events in patients with atrial fibrillation in the setting of other forms of valvular heart disease, including the presence of a bioprosthetic heart valve, has not been studied and is not recommended. **Effect of P-gp Inducers and Inhibitors on Dabigatran Exposure:** The concomitant use of PRADAXA with P-gp inducers (e.g., rifampin) reduces exposure to dabigatran and should generally be avoided. P-gp inhibition and impaired renal function are the major independent factors that result in increased exposure to dabigatran. Concomitant use of P-gp inhibitors in patients with renal impairment is expected to produce increased exposure of dabigatran compared to that seen with either factor alone. **Reduction of Risk of Stroke and Systemic Embolism in Non-valvular Atrial Fibrillation:** Consider reducing the dose of PRADAXA to 75 mg twice daily when dronedarone or systemic ketoconazole is coadministered with PRADAXA in patients with moderate renal impairment (CrCl 30-50 mL/min). Avoid use of PRADAXA and P-gp inhibitors in patients with severe renal impairment (CrCl 15-30 mL/min) [see Drug Interactions and Use in Specific Populations]. **Treatment and Reduction in the Risk of Recurrence of Deep Venous Thrombosis and Pulmonary Embolism:** Avoid use of PRADAXA and concomitant P-gp inhibitors in patients with CrCl <50 mL/min [see Drug Interactions].

ADVERSE REACTIONS: The most serious adverse reactions reported with PRADAXA were related to bleeding [see Warnings and Precautions]. **Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reactions rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. **Reduction of Risk of Stroke and Systemic Embolism in Non-valvular Atrial Fibrillation:** The RE-LY (Randomized Evaluation of Long-Term Anticoagulant Therapy) study provided safety information on the use of two doses of PRADAXA and warfarin. The numbers of patients and their exposures are described in Table 1. Limited information is presented on the 110 mg dosing arm because this dose is not approved.

Drug Discontinuation in RE-LY: The rates of adverse reactions leading to treatment discontinuation were 21% for PRADAXA 150 mg and 16% for warfarin. The most frequent adverse reactions leading to discontinuation of PRADAXA were bleeding and gastrointestinal events (i.e., dyspepsia, nausea, upper abdominal pain, gastrointestinal hemorrhage, and diarrhea). **Bleeding [see Warnings and Precautions]:** Table 2 shows the number of patients experiencing serious bleeding during the treatment period in the RE-LY study, with the bleeding rate per 100 patient-years (%). Major bleeds fulfilled one or more of the following criteria: bleeding associated with a reduction in hemoglobin of at least 2 grams per deciliter or leading to a transfusion of at least 2 units of blood, or symptomatic bleeding in a critical area or organ (intracranial, intracranial, intraspinal or intramuscular with compartment syndrome, retroperitoneal bleeding, intra-articular bleeding, or pericardial bleeding). A life-threatening bleed met one or more of the following criteria: fatal, symptomatic intracranial bleed, reduction in hemoglobin of at least 5 grams per deciliter, transfusion of at least 4 units of blood, associated with hypotension requiring the use of intravenous inotropic agents, or necessitating surgical intervention. Intracranial hemorrhage included intracerebral (hemorrhagic stroke), subarachnoid, and subdural bleeds.

Table 1 Summary of Treatment Exposure in RE-LY

	PRADAXA 110 mg twice daily	PRADAXA 150 mg twice daily	Warfarin
Total number treated	5983	6059	5998
Exposure			
> 12 months	4936	4939	5193
> 24 months	2387	2405	2470
Mean exposure (months)	20.5	20.3	21.3
Total patient-years	10,242	10,261	10,659

Table 2 Bleeding Events* (per 100 Patient-Years)

	PRADAXA 150 mg twice daily N (%)	Warfarin N (%)	Hazard Ratio (95% CI**)
Randomized patients	6076	6022	
Patient-years	12,033	11,794	
Intracranial hemorrhage	39 (0.3)	91 (0.8)	0.42 (0.29, 0.61)
Life-threatening bleed	183 (1.5)	221 (1.9)	0.81 (0.67, 0.99)
Major bleed	409 (3.4)	426 (3.6)	0.94 (0.82, 1.08)
Any bleed	1997 (16.6)	2169 (18.4)	0.91 (0.85, 0.96)

*Patients contributed multiple events and events were counted in multiple categories.

**Confidence interval

The risk of major bleeds was similar with PRADAXA 150 mg and warfarin across major subgroups defined by baseline characteristics, with the exception of age, where there was a trend towards a higher incidence of major bleeding on PRADAXA (hazard ratio 1.2, 95% CI: 1.0 to 1.4) for patients ≥75 years of age. There was a higher rate of major gastrointestinal bleeds in patients receiving PRADAXA 150 mg than in patients receiving warfarin (1.6% vs. 1.1%, respectively, with a hazard ratio vs. warfarin of 1.5, 95% CI, 1.2 to 1.9), and a higher rate of any gastrointestinal bleeds (5.7% vs. 3.9%, respectively). **Gastrointestinal Adverse Reactions:** Patients on PRADAXA 150 mg had an increased incidence of gastrointestinal adverse reactions (35% vs. 24% on warfarin). These were commonly dyspepsia (including abdominal pain upper, abdominal pain, abdominal discomfort, and epigastric discomfort) and gastritis-like symptoms (including GERD, esophagitis, erosive gastritis, gastric hemorrhage, hemorrhagic gastritis, hemorrhagic erosive gastritis, and gastrointestinal ulcer). **Hypersensitivity Reactions:** In the RE-LY study, drug hypersensitivity (including urticaria, rash, and pruritus), allergic edema, anaphylactic reaction, and anaphylactic shock were reported in <0.1% of patients receiving PRADAXA. **Treatment and Reduction in the Risk of Recurrence of Deep Venous Thrombosis and Pulmonary Embolism:** PRADAXA was studied in 4387 patients in 4 pivotal, parallel, randomized, double-blind trials. Three of these trials were active-controlled (warfarin) (RE-COVER, RE-COVER II, and RE-MEDY), and one study (RE-SONATE) was placebo-controlled. The demographic characteristics were similar among the 4 pivotal studies and between the treatment groups within these studies. Approximately 60% of the treated patients were male, with a mean age of 55.1 years. The majority of the patients were white (87.7%), 10.3% were Asian, and 1.9% were black with a mean CrCl of 105.6 mL/min. Bleeding events for the 4 pivotal studies were classified as major bleeding events if at least one of the following criteria applied: fatal bleeding, symptomatic bleeding in a critical area or organ (intracranial, intracranial, intraspinal or intramuscular with compartment syndrome, retroperitoneal bleeding, intra-articular bleeding, or pericardial bleeding), bleeding causing a fall in hemoglobin level of 2.0 g/dL (1.24 mmol/L or more, or leading to transfusion of 2 or more units of whole blood or red cells). RE-COVER and RE-COVER II studies compared PRADAXA 150 mg twice daily and warfarin for the treatment of deep vein thrombosis and pulmonary embolism. Patients received 5-10 days of an approved parenteral anticoagulant therapy followed by 6 months, with mean exposure of 164 days, of oral only treatment; warfarin was overlapped with parenteral therapy. Table 3 shows the number of patients experiencing bleeding events in the pooled analysis of RE-COVER and RE-COVER II studies during the full treatment including parenteral and oral only treatment periods after randomization.

able steps toward rationalization by focusing on initiatives that will improve overall patient care as well as the system's bottom line. For example, begin by transitioning low-volume and/or high-acuity cases to a particular hospital as a way to monitor and garner trust in the

new arrangement before incorporating more sweeping changes.

DIFFICULT BUT OFTEN NECESSARY

Rationalization approaches are often met by internal—and sometimes external (e.g., boards, patient communi-

ty)—resistance, and thus are utilized infrequently. Yet with the continued trend toward consolidation, systems are facing overlapping CV services, diminishing volumes, overcapacity, and increasing costs. Though difficult to work through, a thoughtful strategy for rationalizing services

can represent the means to better manage costs and care delivery in the wake of value-based reform. ■

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Table 3 Bleeding Events in RE-COVER and RE-COVER II Treated Patients

Patients	Bleeding Events-Full Treatment Period Including Parenteral Treatment		Hazard Ratio (95% CI) ^c
	PRADAXA 150 mg twice daily N (%)	Warfarin N (%)	
	N=2553	N=2554	
Major bleeding event ^a	37 (1.4)	51 (2.0)	0.73 (0.48, 1.11)
Fatal bleeding	1 (0.04)	2 (0.1)	
Bleeding in a critical area or organ	7 (0.3)	15 (0.6)	
Fall in hemoglobin ≥2g/dL or transfusion ≥2 units of whole blood or packed red blood cells	32 (1.3)	38 (1.5)	
Bleeding sites for MBE ^b			
Intracranial	2 (0.1)	5 (0.2)	
Retroperitoneal	2 (0.1)	1 (0.04)	
Intraarticular	2 (0.1)	4 (0.2)	
Intramuscular	2 (0.1)	6 (0.2)	
Gastrointestinal	15 (0.6)	14 (0.5)	
Urogenital	7 (0.3)	14 (0.5)	
Other	8 (0.3)	8 (0.3)	
Clinically relevant non-major bleeding	101 (4.0)	170 (6.7)	0.58 (0.46, 0.75)
Any bleeding	411 (16.1)	567 (22.7)	0.70 (0.61, 0.79)

Note: MBE can belong to more than one criterion.
^aPatients with at least one MBE.
^bBleeding site based on investigator assessment. Patients can have more than one site of bleeding.
^cConfidence interval

The rate of any gastrointestinal bleeds in patients receiving PRADAXA 150 mg in the full treatment period was 3.1% (2.4% on warfarin). The RE-MEDY and RE-SONATE studies provided safety information on the use of PRADAXA for the reduction in the risk of recurrence of deep vein thrombosis and pulmonary embolism. RE-MEDY was an active-controlled study (warfarin) in which 1430 patients received PRADAXA 150 mg twice daily following 3 to 12 months of oral anticoagulant regimen. Patients in the treatment studies who rolled over into the RE-MEDY study had a combined treatment duration of up to more than 3 years, with mean exposure of 473 days. Table 4 shows the number of patients experiencing bleeding events in the study.

Table 4 Bleeding Events in RE-MEDY Treated Patients

Patients	Bleeding Events-Full Treatment Period Including Parenteral Treatment		Hazard Ratio (95% CI) ^c
	PRADAXA 150 mg twice daily N (%)	Warfarin N (%)	
	N=1430	N=1426	
Major bleeding event ^a	13 (0.9)	25 (1.8)	0.54 (0.25, 1.16)
Fatal bleeding	0	1 (0.1)	
Bleeding in a critical area or organ	7 (0.5)	11 (0.8)	
Fall in hemoglobin ≥2g/dL or transfusion ≥2 units of whole blood or packed red blood cells	7 (0.5)	16 (1.1)	
Bleeding sites for MBE ^b			
Intracranial	2 (0.1)	4 (0.3)	
Intraocular	4 (0.3)	2 (0.1)	
Retroperitoneal	0	1 (0.1)	
Intraarticular	0	2 (0.1)	
Intramuscular	0	4 (0.3)	
Gastrointestinal	4 (0.3)	8 (0.6)	
Urogenital	1 (0.1)	1 (0.1)	
Other	2 (0.1)	4 (0.3)	
Clinically relevant non-major bleeding	71 (5.0)	125 (8.8)	0.56 (0.42, 0.75)
Any bleeding	278 (19.4)	373 (26.2)	0.71 (0.61, 0.83)

Note: MBE can belong to more than one criterion.
^aPatients with at least one MBE.
^bBleeding site based on investigator assessment. Patients can have more than one site of bleeding.
^cConfidence interval

In the RE-MEDY study, the rate of any gastrointestinal bleeds in patients receiving PRADAXA 150 mg was 3.1% (2.2% on

warfarin). RE-SONATE was a placebo-controlled study in which 684 patients received PRADAXA 150 mg twice daily following 6 to 18 months of oral anticoagulant regimen. Patients in the treatment studies who rolled over into the RE-SONATE study had combined treatment duration up to 9 months, with mean exposure of 165 days. Table 5 shows the number of patients experiencing bleeding events in the study.

Table 5 Bleeding Events in RE-SONATE Treated Patients

Patients	Bleeding Events-Full Treatment Period Including Parenteral Treatment		Hazard Ratio (95% CI) ^c
	PRADAXA 150 mg twice daily N (%)	Placebo N (%)	
	N=684	N=659	
Major bleeding event ^a	2 (0.3)	0	
Bleeding in a critical area or organ	0	0	
Gastrointestinal ^b	2 (0.3)	0	
Clinically relevant non-major bleeding	34 (5.0)	13 (2.0)	2.54 (1.34, 4.82)
Any bleeding	72 (10.5)	40 (6.1)	1.77 (1.20, 2.61)

Note: MBE can belong to more than one criterion.
^aPatients with at least one MBE.
^bBleeding site based on investigator assessment. Patients can have more than one site of bleeding.
^cConfidence interval

In the RE-SONATE study, the rate of any gastrointestinal bleeds in patients receiving PRADAXA 150 mg was 0.7% (0.3% on placebo). **Clinical Myocardial Infarction Events:** In the active-controlled VTE studies, a higher rate of clinical myocardial infarction was reported in patients who received PRADAXA [20 (0.66 per 100 patient-years)] than in those who received warfarin [5 (0.17 per 100 patient-years)]. In the placebo-controlled study, a similar rate of non-fatal and fatal clinical myocardial infarction was reported in patients who received PRADAXA [1 (0.32 per 100 patient-years)] and in those who received placebo [1 (0.34 per 100 patient-years)]. **Gastrointestinal Adverse Reactions:** In the four pivotal studies, patients on PRADAXA 150 mg had a similar incidence of gastrointestinal adverse reactions (24.7% vs. 22.7% on warfarin). Dyspepsia (including abdominal pain, upper abdominal pain, abdominal discomfort, and epigastric discomfort) occurred in patients on PRADAXA in 7.5% vs. 5.5% on warfarin, and gastritis-like symptoms (including gastritis, GERD, esophagitis, erosive gastritis and gastric hemorrhage) occurred at 3.0% vs. 1.7%, respectively. **Hypersensitivity Reactions:** In the 4 pivotal studies, drug hypersensitivity (including urticaria, rash, and pruritus), allergic edema, anaphylactic reaction, and anaphylactic shock were reported in 0.1% of patients receiving PRADAXA. **Postmarketing Experience:** The following adverse reactions have been identified during post approval use of PRADAXA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The following adverse reactions have been identified during post approval use of PRADAXA: angioedema, thrombocytopenia, esophageal ulcer.

In RE-LY, a higher rate of clinical myocardial infarction was reported in patients who received PRADAXA (0.7 per 100 patient-years for 150 mg dose) than in those who received warfarin (0.6).

DRUG INTERACTIONS: Reduction of Risk of Stroke and Systemic Embolism in Non-valvular Atrial Fibrillation: The concomitant use of PRADAXA with P-gp inducers (e.g., rifampin) reduces exposure to dabigatran and should generally be avoided. P-gp inhibition and impaired renal function are the major independent factors that result in increased exposure to dabigatran. Concomitant use of P-gp inhibitors in patients with renal impairment is expected to produce increased exposure of dabigatran compared to that seen with either factor alone. In patients with moderate renal impairment (CrCl 30-50 mL/min), consider reducing the dose of PRADAXA to 75 mg twice daily when administered concomitantly with the P-gp inhibitors dronedarone or systemic ketoconazole. The use of the P-gp inhibitors verapamil, amiodarone, quinidine, clarithromycin, and ticagrelor does not require a dose adjustment of PRADAXA. These results should not be extrapolated to other P-gp inhibitors [see Warnings and Precautions and Use in Specific Populations]. The concomitant use of PRADAXA and P-gp inhibitors in patients with severe renal impairment (CrCl 15-30 mL/min) should be avoided [see Warnings and Precautions and Use in Specific Populations]. **Treatment and Reduction in the Risk of Recurrence of Deep Venous Thrombosis and Pulmonary Embolism:** Avoid use of PRADAXA and P-gp inhibitors in patients with CrCl <50 mL/min [see Warnings and Precautions and Use in Specific Populations].

USE IN SPECIFIC POPULATIONS: Pregnancy: Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Dabigatran has been shown to decrease the number of implantations when male and female rats were treated at a dosage of 70 mg/kg (about 2.6 to 3.0 times the human exposure at maximum recommended human dose [MRHD] of 300 mg/day based on area under the curve [AUC] comparisons) prior to mating and up to implantation

(gestation Day 6). Treatment of pregnant rats after implantation with dabigatran at the same dose increased the number of dead offspring and caused excess vaginal/uterine bleeding close to parturition. Although dabigatran increased the incidence of delayed or irregular ossification of fetal skull bones and vertebrae in the rat, it did not induce major malformations in rats or rabbits. **Labor and Delivery:** Safety and effectiveness of PRADAXA during labor and delivery have not been studied in clinical trials. Consider the risks of bleeding and of stroke in using PRADAXA in this setting [see Warnings and Precautions]. Death of offspring and mother rats during labor in association with uterine bleeding occurred during treatment of pregnant rats from implantation (gestation Day 7) to weaning (lactation Day 21) with dabigatran at a dose of 70 mg/kg (about 2.6 times the human exposure at MRHD of 300 mg/day based on AUC comparisons). **Nursing Mothers:** It is not known whether dabigatran is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from PRADAXA, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. **Pediatric Use:** Safety and effectiveness of PRADAXA in pediatric patients have not been established. **Geriatric Use:** Of the total number of patients in the RE-LY study, 82% were 65 and over, while 40% were 75 and over. The risk of stroke and bleeding increases with age, but the risk-benefit profile is favorable in all age groups [see Warnings and Precautions and Adverse Reactions]. **Renal Impairment: Reduction of Risk of Stroke and Systemic Embolism in Non-valvular Atrial Fibrillation:** No dose adjustment of PRADAXA is recommended in patients with mild or moderate renal impairment. Reduce the dose of PRADAXA in patients with severe renal impairment (CrCl 15-30 mL/min). Dosing recommendations for patients with CrCl <15 mL/min or on dialysis cannot be provided. Adjust dose appropriately in patients with renal impairment receiving concomitant P-gp inhibitors [see Warnings and Precautions and Drug Interactions]. **Treatment and Reduction in the Risk of Recurrence of Deep Venous Thrombosis and Pulmonary Embolism:** Patients with severe renal impairment (CrCl ≤30 mL/min) were excluded from RE-COVER. Dosing recommendations for patients with CrCl ≤30 mL/min or on dialysis cannot be provided. Avoid use of PRADAXA with concomitant P-gp inhibitors in patients with CrCl <50 mL/min [see Warnings and Precautions and Drug Interactions].

OVERDOSSAGE: Accidental overdose may lead to hemorrhagic complications. There is no reversal agent for dabigatran. In the event of hemorrhagic complications, initiate appropriate clinical support, discontinue treatment with PRADAXA, and investigate the source of bleeding. Dabigatran is primarily eliminated by the kidneys with a low plasma protein binding of approximately 35%. Hemodialysis can remove dabigatran; however, data supporting this approach are limited. Using a high-flux dialyzer, blood flow rate of 200 mL/min, and dialysate flow rate of 700 mL/min, approximately 49% of total dabigatran can be cleared from plasma over 4 hours. At the same dialysate flow rate, approximately 57% can be cleared using a dialyzer blood flow rate of 300 mL/min, with no appreciable increase in clearance observed at higher blood flow rates. Upon cessation of hemodialysis, a redistribution effect of approximately 7% to 15% is seen. The effect of dialysis on dabigatran's plasma concentration would be expected to vary based on patient specific characteristics. Measurement of aPTT or ECT may help guide therapy [see Warnings and Precautions].

Rx only

Revised: January 2015

PXD-BS (1-15)

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ATTACHMENT 2



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Articles

5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial

Prof Michael J Mack, MD[✉], Prof Martin B Leon, MD, Prof Craig R Smith, MD, Prof D Craig Miller, MD, Prof Jeffrey W Moses, MD, Prof E Murat Tuzcu, MD, Prof John G Webb, MD, Prof Pamela S Douglas, MD, William N Anderson, PhD, Eugene H Blackstone, MD, Susheel K Kodali, MD, Raj R Makkar, MD, Gregory P Fontana, MD, Prof Samir Kapadia, MD, Prof Joseph Bavaria, MD, Rebecca T Hahn, MD, Prof Vinod H Thourani, MD, Vasilis Babaliaros, MD, Prof Augusto Pichard, MD, Prof Howard C Herrmann, MD, David L Brown, MD, Mathew Williams, MD, Michael J Davidson, MD[†], Prof Lars G Svensson, MD for the PARTNER 1 trial investigators

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Summary Full Text Tables and Figures References Supplementary Material

Summary

Background

The Placement of Aortic Transcatheter Valves (PARTNER) trial showed that mortality at 1 year, 2 years, and 3 years is much the same with transcatheter aortic valve replacement (TAVR) or surgical aortic valve replacement (SAVR) for high-risk patients with aortic stenosis. We report here the 5-year outcomes.

Methods

We did this randomised controlled trial at 25 hospitals, in Canada (two), Germany (one), and the USA (23). We used a computer-generated randomisation sequence to randomly assign high-risk patients with severe aortic stenosis to either SAVR or TAVR with a balloon-expandable bovine pericardial tissue valve by either a transfemoral or transapical approach. Patients and their treating physicians were not masked to treatment allocation. The primary outcome of the trial was all-cause mortality in the intention-to-treat population at 1 year, we present here predefined outcomes at 5 years. The study is registered with ClinicalTrials.gov, number [NCT00530894](#).

Findings

We screened 3105 patients, of whom 699 were enrolled (348 assigned to TAVR, 351 assigned to SAVR). Overall mean Society of Thoracic Surgeons Predicted Risk of Mortality score was 11.7%. At 5 years, risk of death was 67.8% in the TAVR group compared with 62.4% in the SAVR group (hazard ratio 1.04, 95% CI 0.86–1.24; p=0.76). We recorded no structural valve deterioration requiring surgical valve replacement in either group. Moderate or severe aortic regurgitation occurred in 40 (14%) of 280 patients in the TAVR group and two (1%) of 228 in the SAVR group (p<0.0001), and was associated with increased 5-year risk of mortality in the TAVR group (72.4% for moderate or severe aortic regurgitation vs 56.6% for those with mild aortic regurgitation or less; p=0.003).

Interpretation

Our findings show that TAVR as an alternative to surgery for patients with high surgical risk results in similar clinical outcomes.

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ATTACHMENT 3

ORIGINAL ARTICLE

Efficacy and Safety of Evolocumab in Reducing Lipids and Cardiovascular Events

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ABSTRACT

BACKGROUND

Evolocumab, a monoclonal antibody that inhibits proprotein convertase subtilisin-kexin type 9 (PCSK9), significantly reduced low-density lipoprotein (LDL) cholesterol levels in short-term studies. We conducted two extension studies to obtain longer-term data.

METHODS

In two open-label, randomized trials, we enrolled 4465 patients who had completed 1 of 12 phase 2 or 3 studies (“parent trials”) of evolocumab. Regardless of study-group assignments in the parent trials, eligible patients were randomly assigned in a 2:1 ratio to receive either evolocumab (140 mg every 2 weeks or 420 mg monthly) plus standard therapy or standard therapy alone. Patients were followed for a median of 11.1 months with assessment of lipid levels, safety, and (as a prespecified exploratory analysis) adjudicated cardiovascular events including death, myocardial infarction, unstable angina, coronary revascularization, stroke, transient ischemic attack, and heart failure. Data from the two trials were combined.

RESULTS

As compared with standard therapy alone, evolocumab reduced the level of LDL cholesterol by 61%, from a median of 120 mg per deciliter to 48 mg per deciliter ($P < 0.001$). Most adverse events occurred with similar frequency in the two groups, although neurocognitive events were reported more frequently in the evolocumab group. The risk of adverse events, including neurocognitive events, did not vary significantly according to the achieved level of LDL cholesterol. The rate of cardiovascular events at 1 year was reduced from 2.18% in the standard-therapy group to 0.95% in the evolocumab group (hazard ratio in the evolocumab group, 0.47; 95% confidence interval, 0.28 to 0.78; $P = 0.003$).

CONCLUSIONS

During approximately 1 year of therapy, the use of evolocumab plus standard therapy, as compared with standard therapy alone, significantly reduced LDL cholesterol levels and reduced the incidence of cardiovascular events in a prespecified but exploratory analysis. (Funded by Amgen; OSLE-1 and OSLE-2 ClinicalTrials.gov numbers, NCT01439880 and NCT01854918.)

From the Thrombolysis in Myocardial Infarction (TIMI) Study Group, Division of Cardiovascular Medicine, Brigham and Women’s Hospital, and the Department of Medicine, Harvard Medical School, Boston (M.S.S., R.P.G., S.D.W.); the Carbohydrate and Lipid Metabolism Research Unit, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg (F.J.R.), and the Division of Lipidology, Department of Medicine, University of Cape Town, Cape Town (D.J.B.) — both in South Africa; the Departments of Epidemiology and Medicine, College of Public Health, University of Iowa, Iowa City (J.R.); the Sections of Cardiovascular Research and Cardiology, Department of Medicine, Baylor College of Medicine, and the Center for Cardiovascular Disease Prevention, Houston Methodist DeBakey Heart and Vascular Center, Houston (C.M.B.); Amgen, Thousand Oaks, CA (R. Somaratne, J.L., S.M.W., R. Scott); Jacksonville Center for Clinical Research, Jacksonville, FL (M.J.K.); and the Metabolic and Atherosclerosis Research Center, Cincinnati (E.A.S.). Address reprint requests to Dr. Sabatine at the TIMI Study Group, Cardiovascular Division, Brigham and Women’s Hospital, 75 Francis St., Boston, MA 02115, or at msabatine@partners.org; or to Dr. Stein at the Metabolic and Atherosclerosis Research Center, 5355 Medpace Way, Cincinnati, OH 45225, or at esteinmrl@aol.com.

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REDUCTION IN LOW-DENSITY LIPOPROTEIN (LDL) cholesterol levels has proved to be highly effective in reducing rates of major cardiovascular events in numerous large outcome trials.¹⁻³ For this reason, LDL cholesterol reduction has been incorporated into practice guidelines as a fundamental means of reducing cardiovascular morbidity and mortality.⁴⁻⁷

During the past 3 years, monoclonal antibodies that inhibit proprotein convertase subtilisin-kexin type 9 (PCSK9) have emerged as a new class of drugs that very effectively lower LDL cholesterol levels.⁸ One of the members of this class is evolocumab, a fully human monoclonal antibody that typically achieves approximately a 60% reduction in LDL cholesterol levels when administered at the doses that were studied in phase 3 trials.⁹⁻¹³

On completing a trial of evolocumab (parent trial), patients could enroll into one of two longer-term extension trials, designated Open-Label Study of Long-Term Evaluation against LDL Cholesterol 1 (OSLER-1), for patients completing phase 2 trials, and OSLER-2, for those completing phase 3 trials. The OSLER-1 and OSLER-2 trials had as their primary goal the gathering of longer-term data on safety, side-effect profile, and LDL cholesterol reduction and also included a prespecified exploratory analysis on adjudicated cardiovascular outcomes. Here, we report on the combined results of the OSLER-1 and OSLER-2 trials.

METHODS

STUDY DESIGN AND OVERSIGHT

The OSLER-1 trial was an open-label, randomized, controlled study conducted at 190 centers that participated in at least one of five phase 2 studies of evolocumab.¹⁴⁻¹⁹ Analogously, the OSLER-2 trial was an open-label, randomized, controlled study conducted at 305 centers that participated in at least one of seven phase 3 studies of evolocumab (Table 1).^{9-13,20,21}

The protocols for the OSLER-1 and OSLER-2 trials were approved by the relevant ethics committee at each participating site and are available with the full text of this article at NEJM.org. Amgen sponsored and designed the two trials and was responsible for data collection and analysis. The first draft of the manuscript was written by the first and last authors. All the coauthors

participated in subsequent revisions of the manuscript. The academic authors had full access to the data and vouch for their accuracy and completeness and for the analyses as presented and for the fidelity of this report to the trial protocols. The first and last authors made the decision to submit the manuscript for publication.

PATIENTS

There was variation in the clinical characteristics of the patients enrolled in the 12 parent studies (Table 1). Patients who had completed one of the parent studies could enroll in one of the OSLER extension studies, provided that they did not have an adverse event that led to the discontinuation of a study drug during the parent trial, did not have an unstable medical condition (in the judgment of the investigator), and were not expected to need unblinded lipid measurements or adjustment of background lipid-regulating therapy during the first 12 weeks of participation in the OSLER trials. All patients provided written informed consent before enrollment in the extension study.

RANDOMIZATION, STUDY TREATMENT, AND FOLLOW-UP

Regardless of the study-group assignment in the parent study, eligible patients were randomly assigned at the last visit in the parent study, or as soon as possible thereafter, to receive either evolocumab plus standard therapy (evolocumab group) or standard therapy alone (standard-therapy group) in a 2:1 ratio. Randomization was performed centrally with the use of an interactive voice-response or Web-response system, with stratification in OSLER-1 according to the study-group assignment in the parent trial and in OSLER-2 according to the parent trial and study-drug dose frequency in the parent trial.

Evolocumab was administered subcutaneously at a dose of 420 mg once a month in OSLER-1 and, on the basis of patient choice, at a dose of either 140 mg every 2 weeks or 420 mg once a month in OSLER-2. Both regimens have been shown to reduce LDL cholesterol levels by approximately 60% in this patient population.⁹⁻¹³ All patients, investigators, and care providers were aware of the randomized treatment assignments; no placebo was used for the standard-therapy group. Standard-of-care background therapy in the two groups was based on local guidelines for the treatment of LDL cholesterol.

Table 1. Features of the Parent Trials.*

Trial	No. of Patients Enrolled in Parent Trial†	No. of Patients Enrolled in OSLER Trials	Patient Population
Phase 2‡			
MENDEL-1 ¹⁵	406	300	LDL cholesterol level, ≥ 100 and < 190 mg/dl; no background antilipid therapy
LAPLACE-TIMI 57 ¹⁴	629	530	LDL cholesterol level, ≥ 85 mg/dl while receiving statin with or without ezetimibe
GAUSS-1 ¹⁷	157	128	Statin-intolerant; LDL cholesterol level, ≥ 100 mg/dl
RUTHERFORD-1 ¹⁶	167	147	Heterozygous familial hypercholesterolemia; LDL cholesterol level, ≥ 100 mg/dl while receiving statin with or without ezetimibe
YUKAWA-1 ¹⁹	307	219	High-risk patients in Japan; LDL cholesterol level, ≥ 116 mg/dl while receiving statin
Phase 3§			
MENDEL-2 ¹¹	614	378	LDL cholesterol level, ≥ 100 and < 190 mg/dl; no background antilipid therapy
LAPLACE-2 ¹⁰	1896	1382	LDL cholesterol level, ≥ 80 mg/dl (intensive statin at screening), ≥ 100 mg/dl (nonintensive statin at screening), or ≥ 150 mg/dl (no statin at screening); moderate- or high-intensity statin with or without ezetimibe
GAUSS-2 ¹²	307	254	Statin-intolerant patients; LDL cholesterol level, ≥ 100 and < 190 mg/dl
RUTHERFORD-2 ¹³	329	293	Heterozygous familial hypercholesterolemia; LDL cholesterol level, ≥ 100 mg/dl while receiving statin with or without ezetimibe
DESCARTES ⁹	901	612	LDL cholesterol level, ≥ 75 mg/dl while receiving statin with or without ezetimibe
THOMAS-1 ²⁰	149	112	LDL cholesterol level, > 85 mg/dl while receiving statin
THOMAS-2 ²¹	164	110	LDL cholesterol level, > 85 mg/dl while receiving statin

* To convert the values for low-density lipoprotein (LDL) cholesterol to millimoles per liter, multiply by 0.02586.

† Included in this category is the number of patients who underwent randomization and received at least one dose of a study drug.

‡ Patients who were enrolled in phase 2 parent trials and who agreed to participate in the extension study were enrolled in OSLER-1.

§ Patients who were enrolled in phase 3 parent trials and who agreed to participate in the extension study were enrolled in OSLER-2.

To avoid inadvertent unblinding of the parent study, lipid results from the central laboratory were unblinded only after the week 12 visit in the OSLER trials. Adjustments to background lipid-lowering therapies were discouraged. The study-visit schedules were similar in OSLER-1 and OSLER-2. Common to the two trials, patients were to have in-person clinic visits on day 1 and then quarterly at weeks 12, 24, 36, and 48. At other time points, patients in the evolocumab group had in-person visits, whereas patients in the standard-therapy group had telephone contact only.

The trial protocols specified that randomized treatment was to conclude at week 56 in OSLER-1 and at week 48 in OSLER-2. After the end of randomized treatment, all patients were to receive open-label evolocumab for longer-term, nonrandomized assessment of efficacy and safety.

END POINTS

The primary end point in the two trials was the incidence of adverse events. Additional safety end points included serious adverse events, adverse events leading to the discontinuation of the study drug (for patients in the evolocumab group), abnormalities in creatine kinase levels and liver-function testing, and the development of binding and neutralizing antibodies against evolocumab, which were assayed as reported previously.²²

The secondary end point was the percent change in the LDL cholesterol level. Other efficacy lipid measurements included non-high-density lipoprotein (HDL) cholesterol, total cholesterol, triglycerides, HDL cholesterol, apolipoproteins A1 and B, and lipoprotein(a). Lipids were measured at a central laboratory (Medpace Reference Laboratories, Cincinnati, and Leuven, Belgium) after

a fast of at least 9 hours. The LDL cholesterol level was calculated with the use of the Friedewald formula.²³

A prespecified exploratory outcome was the incidence of adjudicated cardiovascular events, which was ascertained over the course of the study. (Definitions are provided in the Methods section in the Supplementary Appendix, available at NEJM.org.) Cardiovascular events included death, coronary events (myocardial infarction, unstable angina requiring hospitalization, or coronary revascularization), cerebrovascular events (stroke or transient ischemic attack), and heart failure requiring hospitalization. Potential cardiovascular events were adjudicated by the central clinical-events committee at the Thrombolysis in Myocardial Infarction (TIMI) Study Group in Boston, whose members were unaware of treatment assignments. All cardiovascular events were combined in an exploratory composite analysis that was based on the events that were prespecified in the trial protocols. In addition, all cardiovascular end points except for heart failure were combined into a post hoc composite of major adverse cardiovascular events.

STATISTICAL ANALYSIS

The timing of the analysis in this report was triggered by a planned submission of a biologics license application to the Food and Drug Administration. The authors decided to present these data to the scientific community at the next major scientific meeting. In anticipation of that meeting, the data were updated with cardiovascular outcomes that were based on adjudicated data through January 21, 2015, along with demographic, lipid, and safety data that were based on cleaned data through October 31, 2014.

The data from the OSLER-1 and OSLER-2 trials were combined into a single analysis set. Data for patients were censored at the start of the uncontrolled period in each study. Lipid measurements were summarized with the use of means or medians, and treatment differences were tested with the use of the Wilcoxon rank-sum test without adjustment for multiplicity. We used the Kaplan–Meier method to estimate time-to-event cumulative incidence on an intention-to-treat basis. Safety was described according to the incidence of adverse events. The minimum LDL cholesterol category for a patient was determined by the minimum value observed in the randomized, con-

trolled period of the studies. We used the log-rank test to analyze the difference in cumulative incidence curves for cardiovascular events. Hazard ratios were estimated with the use of Cox proportional-hazard models without stratification. Statistical analyses were performed with the use of SAS software, version 9.3, and R software, version 3.0.3.

RESULTS

PATIENTS

From October 2011 through June 2014, we enrolled a total of 4465 patients in the OSLER program (1324 patients in OSLER-1 and 3141 patients in OSLER-2), which represented 74.1% of eligible patients in the parent studies (Table 1). Of the 4465 patients, 2976 were randomly assigned to receive evolocumab plus standard therapy and 1489 to receive standard therapy alone (Fig. S1 in the Supplementary Appendix). The median duration of follow-up was 11.1 months (interquartile range, 11.0 to 12.8), for a total of 4219.4 patient-years of follow-up.

The mean age of the patients was 58 years, and 80.4% had at least one cardiovascular risk factor (Table 2). A total of 3128 patients (70.1%) were receiving statin therapy at the start of the OSLER trials. Premature permanent discontinuation of evolocumab occurred in 7.2% of patients. Changes in open-label statin therapy were infrequent (for details, see the Results section in the Supplementary Appendix).

LIPID CHANGES

The median baseline LDL cholesterol, before randomization into a parent study, was 120 mg per deciliter. At the week 12 visit in the OSLER trials, evolocumab, as compared with standard therapy, reduced the LDL cholesterol level by 61% (95% confidence interval [CI], 59 to 63; $P < 0.001$), for a mean absolute reduction of 73 mg per deciliter to a median of 48 mg per deciliter. Data were similar in the OSLER-1 and OSLER-2 trials (Table S1 in the Supplementary Appendix). The reduction in LDL cholesterol levels with evolocumab was consistent over time (Fig. 1). At 12 weeks, the LDL cholesterol level was reduced to 100 mg per deciliter or less in 90.2% of patients and to 70 mg per deciliter or less in 73.6% of patients in the evolocumab group, as compared with 26.0% and 3.8%, respectively, in the standard-therapy group.

Table 2. Clinical Characteristics of the Patients at Baseline.*

Characteristic	Evolocumab Group (N=2976)	Standard-Therapy Group (N=1489)
Mean age ±SD — yr	57.8±11.0	58.2±10.9
Male sex — no. (%)	1490 (50.1)	765 (51.4)
White race — no. (%)†	2559 (86.0)	1267 (85.1)
Region		
North America	1402 (47.1)	705 (47.3)
Europe	1205 (40.5)	597 (40.1)
Asia Pacific or South Africa	369 (12.4)	187 (12.6)
Cardiovascular risk factor — no. (%)	2379 (79.9)	1211 (81.3)
Hypertension	1545 (51.9)	777 (52.2)
Diabetes mellitus	382 (12.8)	217 (14.6)
Metabolic syndrome	1035 (34.8)	475 (31.9)
Current cigarette use	465 (15.6)	222 (14.9)
Family history of premature coronary artery disease‡	724 (24.3)	362 (24.3)
Known familial hypercholesterolemia	289 (9.7)	151 (10.1)
Moderately high risk or high risk on NCEP§	1332 (44.8)	693 (46.5)
Coronary artery disease — no. (%)		
Any	589 (19.8)	307 (20.6)
Myocardial infarction	276 (9.3)	141 (9.5)
Percutaneous coronary intervention	325 (10.9)	170 (11.4)
Coronary-artery bypass grafting	185 (6.2)	110 (7.4)
Cerebrovascular or peripheral-artery disease — no. (%)		
Any	266 (8.9)	141 (9.5)
Carotid- or vertebral-artery disease	94 (3.2)	62 (4.2)
Stroke	81 (2.7)	37 (2.5)
Peripheral-artery disease	85 (2.9)	50 (3.4)
Medication use — no. (%)		
Statin¶		
Any	2073 (69.7)	1055 (70.9)
High-intensity	795 (26.7)	415 (27.9)
Moderate-intensity	1034 (34.7)	522 (35.1)
Low-intensity	240 (8.1)	118 (7.9)
Unknown	4 (0.1)	0
Ezetimibe	376 (12.6)	229 (15.4)
Median lipid measure at baseline in parent study (IQR) — mg/dl		
LDL cholesterol	120 (97–148)	121 (97–151)
Total cholesterol	202 (175–234)	205 (174–235)
HDL cholesterol	51 (42–62)	51 (42–62)
Triglycerides	120 (89–165)	119 (89–167)

* Baseline characteristics are based on data that were obtained at the start of the parent study; values for statin use and intensity are based on data from the start of the OSLER program. There were no significant differences between the two groups at baseline. To convert the values for triglycerides to millimoles per liter, multiply by 0.01129. HDL denotes high-density lipoprotein, and IQR interquartile range.

† Race was self-reported.

‡ A family history of premature coronary artery disease was defined as the presence of coronary artery disease in a first-degree male relative 55 years of age or younger or in a first-degree female relative 65 years of age or younger.

§ According to the criteria of the National Cholesterol Education Program (NCEP), moderately high or high risk is defined as coronary heart disease, coronary heart disease equivalent, or two or more cardiovascular risk factors with an estimated 10-year risk of cardiovascular events of 10% or more.

¶ The intensity of statin therapy was defined according to recent guidelines.⁴

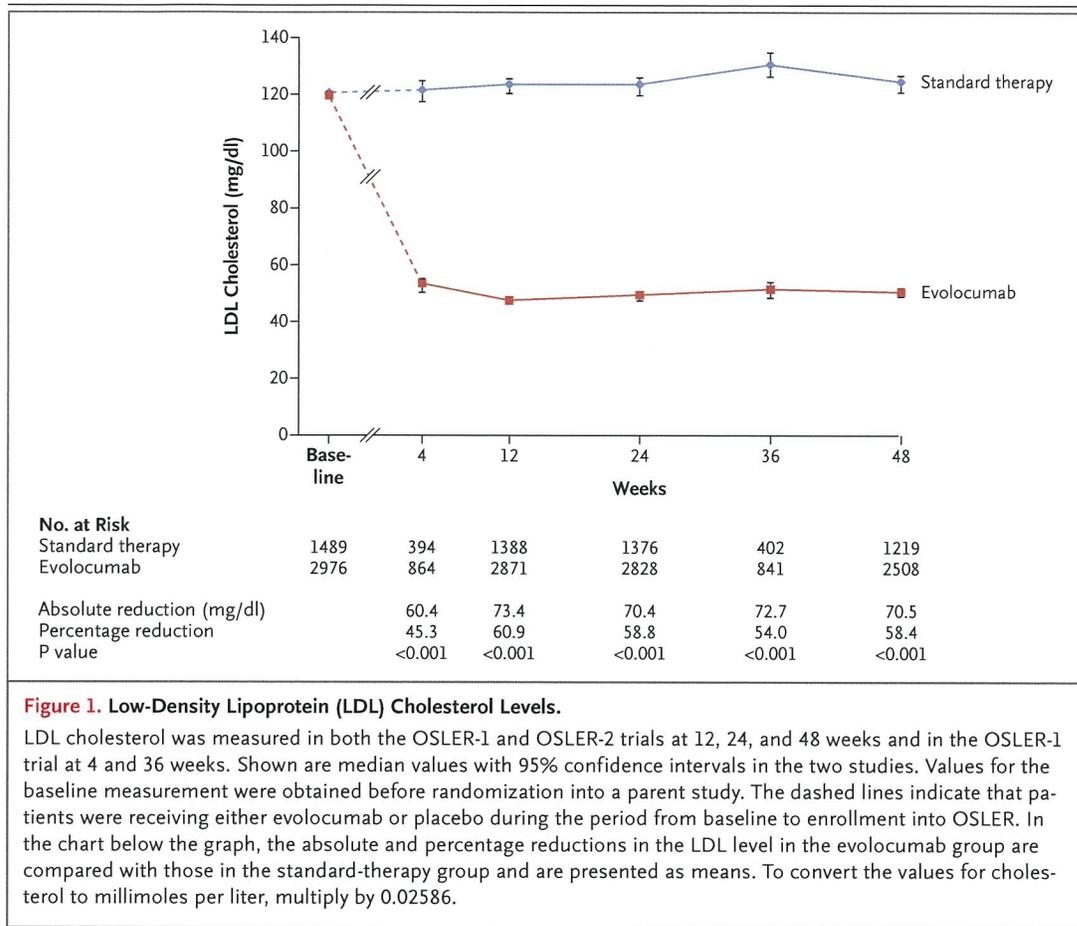


Figure 1. Low-Density Lipoprotein (LDL) Cholesterol Levels.

LDL cholesterol was measured in both the OSLER-1 and OSLER-2 trials at 12, 24, and 48 weeks and in the OSLER-1 trial at 4 and 36 weeks. Shown are median values with 95% confidence intervals in the two studies. Values for the baseline measurement were obtained before randomization into a parent study. The dashed lines indicate that patients were receiving either evolocumab or placebo during the period from baseline to enrollment into OSLER. In the chart below the graph, the absolute and percentage reductions in the LDL level in the evolocumab group are compared with those in the standard-therapy group and are presented as means. To convert the values for cholesterol to millimoles per liter, multiply by 0.02586.

In the evolocumab group, as compared with the standard-therapy group, changes in related atherogenic lipid measures were similar to those observed for LDL cholesterol, with reductions of 52.0% in non-HDL cholesterol, 47.3% in apolipoprotein B, 36.1% in total cholesterol, 12.6% in triglycerides, and 25.5% in lipoprotein(a) ($P < 0.001$ for all comparisons) (Fig. S2 in the Supplementary Appendix). Evolocumab raised levels of HDL cholesterol and apolipoprotein A1 by 7.0% and 4.2%, respectively ($P < 0.001$ for both comparisons).

SAFETY AND SIDE-EFFECT PROFILE

Adverse events occurred in 2060 of 2976 patients (69.2%) in the evolocumab group and in 965 of 1489 patients (64.8%) in the standard-therapy group (Table 3). Serious adverse events occurred in 222 patients (7.5%) in the evolocumab group and in 111 patients (7.5%) in the standard-therapy group. Elevations in aminotransferase or creatine kinase levels occurred at a similar rate in the two groups: 1.0% in the evolocumab group and 1.2% in

the standard-therapy group for elevated amino transferase levels and 0.6% and 1.1%, respectively, for elevated creatine kinase levels. Although the rate of neurocognitive adverse events was low ($< 1\%$), such events were reported more frequently in the evolocumab group. Of note, the incidence of neurocognitive adverse events did not appear to be related to the LDL cholesterol level during treatment (Table S2 in the Supplementary Appendix). Other adverse events are listed in Table S3 in the Supplementary Appendix.

Injection-site reactions were reported in 129 patients (4.3%) in the evolocumab group (the only group in which such events were analyzed) and led to discontinuation of evolocumab in 6 patients (0.2%). New evolocumab-binding antibodies were detected in 9 patients (0.3%) in the evolocumab group and in 4 patients (0.3%) in the standard-therapy group, and binding-antibody titers were transient in patients who had repeat testing. No neutralizing antibodies against evolocumab were detected.

Table 3. Adverse Events and Laboratory Results.*

Variable	Evolocumab Group (N = 2976)	Standard-Therapy Group (N = 1489)
Adverse events		
Any	2060 (69.2)	965 (64.8)
Serious	222 (7.5)	111 (7.5)
Leading to discontinuation of evolocumab	71 (2.4)	NA
Muscle-related	190 (6.4)	90 (6.0)
Injection-site reaction	129 (4.3)	NA
Neurocognitive event†	27 (0.9)	4 (0.3)
Other‡		
Arthralgia	137 (4.6)	48 (3.2)
Headache	106 (3.6)	32 (2.1)
Limb pain	99 (3.3)	32 (2.1)
Fatigue	83 (2.8)	15 (1.0)
Laboratory results		
Alanine or aspartate aminotransferase >3 × ULN at any visit after baseline	31 (1.0)	18 (1.2)
Creatine kinase >5 × ULN at any visit after baseline	17 (0.6)	17 (1.1)

* NA denotes not applicable, and ULN upper limit of the normal range.

† Neurocognitive events were delirium (including confusion), cognitive and attention disorders and disturbances, dementia and amnesic conditions, disturbances in thinking and perception, and mental impairment disorders.

‡ Included in this category are adverse events that were reported in at least 1% of patients in the evolocumab group and in more patients in the evolocumab group than in the standard-therapy group by at least 1 percentage point.

Rates of overall adverse events, serious adverse events, and elevations in aminotransferase or creatine kinase levels were similar among patients in the evolocumab group who had LDL cholesterol levels of less than 40 mg per deciliter or less than 25 mg per deciliter as in those with higher levels during OSLER (Table S2 in the Supplementary Appendix).

CARDIOVASCULAR EVENTS

Cardiovascular events were prospectively adjudicated in an exploratory analysis (Table S4 in the Supplementary Appendix). When these events were combined in a composite of all cardiovascular events, patients in the evolocumab group had a significantly lower rate of all cardiovascular events than did patients in the standard-therapy group (Kaplan–Meier estimates at 1 year, 0.95% and 2.18%, respectively; hazard ratio, 0.47; 95% CI, 0.28 to 0.78; P=0.003). The cumulative incidence curves diverged progressively over time (Fig. 2). Similar results were obtained for the post hoc composite

of major adverse cardiovascular events (Table S4 in the Supplementary Appendix).

DISCUSSION

In the OSLER-1 and OSLER-2 trials, open-label treatment with evolocumab reduced LDL cholesterol levels by 61%, from a pretreatment median level of 120 mg per deciliter to a 12-week on-treatment median level of 48 mg per deciliter. This result was consistent with reports from previous short-term trials of evolocumab.^{9-17,19} In the OSLER trials, the reduction in LDL cholesterol levels was sustained through 48 weeks, a finding consistent with the results of a much smaller study of evolocumab.⁹ Effects on other lipid fractions were also similar to those seen in previous studies.

Some nonspecific adverse events (arthralgia, headache, limb pain, and fatigue) and neurocognitive adverse events were reported more frequently in the evolocumab group than in the

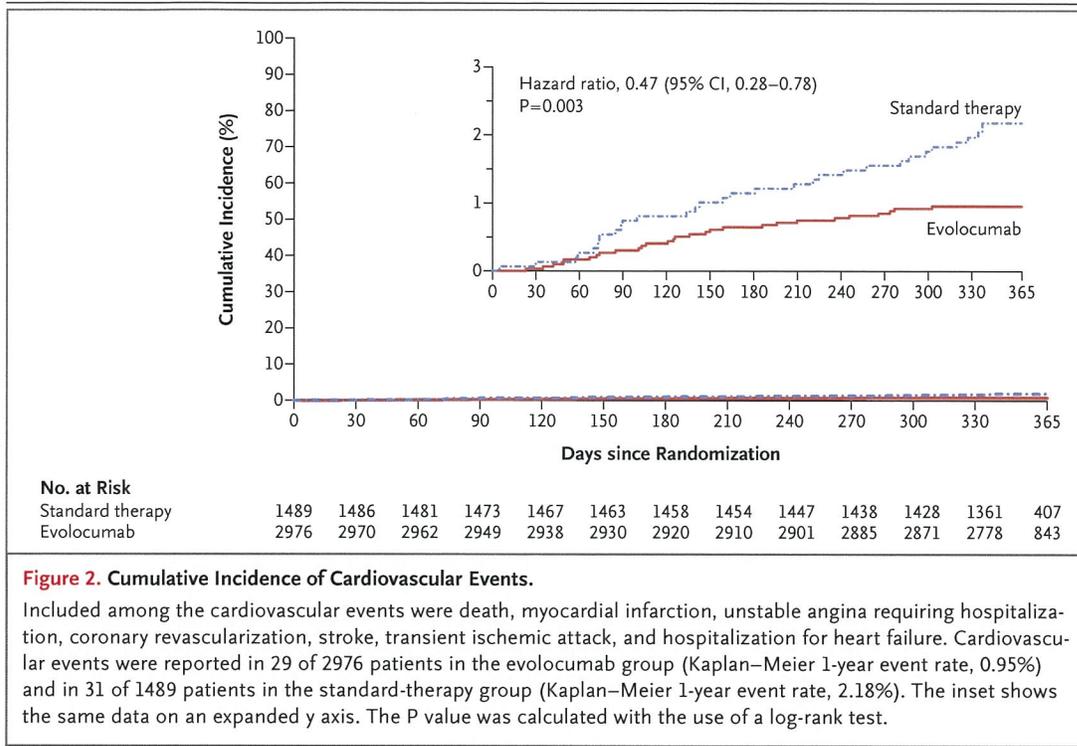


Figure 2. Cumulative Incidence of Cardiovascular Events.

Included among the cardiovascular events were death, myocardial infarction, unstable angina requiring hospitalization, coronary revascularization, stroke, transient ischemic attack, and hospitalization for heart failure. Cardiovascular events were reported in 29 of 2976 patients in the evolocumab group (Kaplan–Meier 1-year event rate, 0.95%) and in 31 of 1489 patients in the standard-therapy group (Kaplan–Meier 1-year event rate, 2.18%). The inset shows the same data on an expanded y axis. The P value was calculated with the use of a log-rank test.

standard-therapy group. These observations should be viewed in the context of the greater number of protocol-stipulated in-person visits for patients in the evolocumab group as well as the open-label nature of the trial, which could predispose patients who are receiving the study intervention to be more likely to note adverse events, particularly those associated with other therapies that reduce LDL cholesterol.²⁴ Moreover, there did not appear to be any excess of these events in patients who had very low versus higher on-treatment levels of LDL cholesterol. Furthermore, PCSK9 loss-of-function variants have not been associated with impaired cognitive performance.²⁵ Nonetheless, much larger trials, including a dedicated neurocognitive substudy (ClinicalTrials.gov number, NCT02207634),²⁶ are ongoing to provide more definitive assessments of safety over longer-term follow-up.

An unanswered question is whether a reduction in the LDL cholesterol level with a PCSK9 inhibitor will lead to a reduction in cardiovascular events. Reduction in such events with statins has been well established during the past two decades in numerous large, randomized, controlled trials.^{1,2} In contrast, it has been difficult

to show that adding other lipid-modifying drugs to statins results in a further decrease in cardiovascular events, which is probably due to the modest effects on LDL cholesterol or off-target adverse effects.^{27–30} This issue was a factor contributing to the most recent set of practice guidelines from the American College of Cardiology–American Heart Association, in which the role of nonstatin lipid-modifying drugs was diminished, as compared with previous guidelines.⁴ Recently, however, in the Improved Reduction of Outcomes: Vytorin Efficacy International Trial (IMPROVE-IT), an additional reduction in LDL cholesterol levels with the addition of ezetimibe, a cholesterol-absorption inhibitor, to a statin significantly reduced cardiovascular events, as compared with statin monotherapy.³ These data have refocused attention on the potential cardiovascular benefit of greater LDL cholesterol reduction through nonstatin mechanisms.

Evolocumab, unlike other nonstatin lipid-modifying drugs, reduces LDL cholesterol levels as much as, if not more than, high doses of statins. Also, PCSK9 inhibitors have the same ultimate mechanism for LDL reduction as statins — namely, by increasing LDL receptor activity on

the hepatocyte surface,⁸ suggesting that PCSK9 inhibitors should similarly have a beneficial effect on cardiovascular outcomes. Additional support for the potential of PCSK9 inhibition in reducing cardiovascular events comes from the observation that loss-of-function genetic variants leading to reductions in PCSK9 activity have been associated with significantly lower lifetime rates of cardiovascular events.³¹ Thus, the reduction in cardiovascular events seen in the OSLER trials within the first year of evolocumab therapy, even though the analysis was both exploratory and based on a relatively small number of events, is consistent with the large reduction in LDL cholesterol levels, the mechanism of action, and the PCSK9 genetic data.

The Further Cardiovascular Outcomes Research with PCSK9 Inhibition in Subjects with Elevated Risk (FOURIER) study (NCT01764633) is an ongoing trial that is intended to provide a definitive assessment of the cardiovascular benefit of evolocumab. The FOURIER study is a randomized, placebo-controlled trial involving 27,500 high-risk patients with cardiovascular disease who are receiving background statin therapy; the primary end point is a composite of cardiovascular death, myocardial infarction, hospitalization for unstable angina, stroke, or coronary revascularization.³² Similar trials of alirocumab and bococizumab to evaluate cardiovascular outcomes are in progress (NCT01663402, NCT01975376, and NCT01975389).³³⁻³⁵

Several study limitations are noteworthy. First, the open-label design of the trials could have had an influence on the reporting of events, both cardiovascular and safety. This issue would es-

pecially be a concern for coronary revascularization, the single most frequently reported cardiovascular event, since the decision to perform this procedure could have been influenced by knowledge of treatment assignment. Second, the numbers of cardiovascular and select adverse events were relatively small. Third, although rates of adverse events and study-drug discontinuation were low in the parent trials,^{9-17,19} patients were eligible to transition to the OSLER trials if they had not had an adverse event that led to the discontinuation of a study drug. Thus, data on safety and side-effect profiles in our study come from a cohort of patients who had all successfully received injections and many of whom had received evolocumab for at least 12 weeks. Fourth, the OSLER program included a mix of patients with varying degrees of cardiovascular risk and use and intensity of statin therapy. Thus, not all the study patients would necessarily have been the optimal target population for this novel treatment.

In conclusion, patients who had previously participated in 12 shorter-term parent trials of the PCSK9 inhibitor evolocumab underwent repeat randomization to receive either evolocumab or standard therapy in the OSLER program. Evolocumab reduced levels of LDL cholesterol by 61% by 12 weeks, with sustained reduction through the median 11-month follow-up. In a prespecified exploratory analysis, there was evidence of a reduction in the rate of cardiovascular events among patients receiving evolocumab.

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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ATTACHMENT 4

Promising findings shown for heart-related issues

By [Steven Ross Johnson](#) | March 16, 2015

Positive results supporting the use of non-invasive heart valve replacement as a potential alternative to surgery, plus evidence a new class of cholesterol-lowering drugs may also reduce the risk of cardiac events were just two of the highlights from the second day of the American College of Cardiology meeting this past weekend.

One of the most highly anticipated studies presented at the 64th annual ACC Scientific Sessions in San Diego Sunday were results from the PARTNER 1 trial that looked at outcomes of patients who underwent transcatheter aortic valve replacement who were deemed to be at high risk to have open heart surgery.

Five-year outcomes among TAVR patients were similar to those of surgical patients, according to the subsequent study published Sunday in the [Lancet](#).

Data for the findings were based on 699 patients, of whom 348 received TAVR and 351 underwent surgery. At five years, risk of death was 67.8% in the TAVR group compared with 62.4% in the surgical aortic valve replacement group.

“Our findings show that TAVR as an alternative to surgery for patients with high surgical risk results in similar clinical outcomes,” researchers wrote.

TAVR was first approved in the U.S. in 2011 by the Food and Drug Administration for use in patients not eligible for surgery. The technique involves inserting a prosthetic valve with a catheter threaded through an artery in the groin or rib cage. The method typically requires a shorter recovery time than open-heart surgery. Approval was granted in 2012 to expand TAVR for use in patients at high risk for surgery.

Valve replacement is the recommended treatment for severe cases of aortic stenosis, a condition in which the heart's aortic valve narrows; it affects more than 1 million Americans, most of them elderly.

Despite the results, cost concerns over a TAVR device, which can run more than \$30,000 compared with the \$4,000 to \$7,000 price of surgical valves, could act as a barrier to increased use.

Also presented at the session on Sunday were results of a study that found patients who took PCSK9 inhibitors along with standard therapy saw a 61% drop in low-density lipoprotein cholesterol in 12 weeks, which was sustained over a period of 11 months. Findings were published in the [New England Journal of Medicine](#) and were based on a clinical random trial of more than 4,500 patients who took Amgen's new drug evolocumab.

“The reduction in LDL was profound and that may be why we saw a marked reduction in cardiovascular events so quickly,” study lead author Dr. Marc Sabatine said in a statement. “It suggests that if we can drive a patient's LDL cholesterol down a large amount to a very low level, we may start to see a benefit sooner than would be expected with a more modest intervention.”

PCSK9 inhibitors are being heralded by many as a potential breakthrough in lowering cholesterol. For years statins have been the primary drugs used for the conditions. But studies have shown they are not effective in some patients. PCSK9 inhibitors appear to work effectively to lower cholesterol in those patients where statins have not worked, making it a potential blockbuster drug.

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ATTACHMENT 5

Travel Distance and Health Outcomes for Scheduled Surgery

ShinYi Chou, PhD,* † Mary E. Deily, PhD,* and Suhui Li, PhD‡

Background: Changes in the location and availability of surgical services change the distances that patients must travel for surgery. Identifying health effects related to travel distance is therefore crucial to evaluating policies that affect the geographic distribution of these services. We examine the health outcomes of coronary artery bypass graft (CABG) patients in Pennsylvania for evidence that traveling further to a hospital for a one-time, scheduled surgical procedure causes harm.

Methods: We perform instrumental-variable regressions to test for the effect of distance to the admitting hospital on the in-hospital mortality and readmission rates of 102,858 CABG patients in Pennsylvania during 1995–2005, where the instrumental variables are constructed based on the quality of and distance to nearby CABG hospitals.

Results: We found that patients living near a CABG hospital with acceptable quality traveled significantly less and if they were high-risk, had lower in-hospital mortality rates. Readmission rates in general are not affected by patients' travel distance.

Discussion: The positive correlation between travel distance and health outcomes observed by previous studies may reflect the confounding effects of behavioral factors and patient health risks. We found instead that living further from the admitting hospital increases in-hospital mortality for high-risk CABG patients. More research on the possible causes of these effects is necessary to identify optimal policy responses.

Key Words: travel distance, scheduled surgery, hospital quality, outcomes, CABG, regionalization, United States

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The authors declare no conflict of interest.

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Changes in the location and availability of surgical services change the distances that patients must travel for surgery. For example, regionalizing surgical programs or adopting volume-based referral practices so that patients go to higher-volume centers for surgery would increase the distances many travel.^{1–3} Conversely, removing regulatory barriers limiting entry of new surgical programs would decrease travel distances if more providers enter the market.⁴ Identifying health effects related to travel distance is therefore crucial to evaluating policies that affect the geographic distribution of surgical services, but the causal relationship is difficult to identify because confounding factors such as patients' behavioral patterns and the quality of admitting hospitals are likely correlated with both travel distance and surgical outcomes. In this paper, we use a novel set of instrumental variables to determine whether travel distance affects health outcomes of patients having scheduled coronary artery bypass graft (CABG) surgery in Pennsylvania during the period 1995–2005.

Travel distance may most obviously affect health outcomes if it reduces utilization of preventive care or delays care in emergency conditions.^{5,6} However, for one-time, nonemergent surgical patients, greater distances may result in worse health outcomes if they delay preoperative procedures, impair preoperative education of patients and families, reduce the amount of informal care provided by families, or reduce the continuity of postoperative care. Prior literature reveals that preoperative education and family support decrease patients' emotional stress, reduce deterioration of patients' functional and psychological status during the perioperative waiting period, and decrease postoperative complications.^{7,8} The benefits of preoperative preparation may be particularly important for high-risk patients: preoperative intensive inspiratory muscle training, for example, can prevent postoperative pulmonary complications in high-risk patients undergoing CABG surgery.⁹

However, identifying the causal relationship between travel distance and health outcomes is difficult because unobserved preferences and characteristics of patients may be correlated with both travel distance and health outcomes. For example, patients may travel further because they have a stronger will to live that helps them achieve better outcomes, or they do so to be treated at “centers of excellence” and thus experience better outcomes.^{10–13} In contrast, patients traveling further to seek better hospitals may be sicker and, thus, experience worse outcomes.¹⁴ If, as we hypothesize, the true effect of greater travel distance is to cause harm, then

regressing outcomes on travel distance results in coefficients that underestimate the true effect in the former case, biasing estimates toward zero, and overestimate the true effect in the latter case, biasing estimates away from zero. Identification is further complicated because travel distance is often measured with error, which will bias estimates toward zero.

We address these identification problems using a novel instrumental-variable approach that controls for potentially confounding factors and for measurement errors.¹⁵ Our instrumental variables are based on the availability and quality of hospitals near a patient’s home because of evidence showing that hospital patients strongly prefer to minimize their travel distance but also care about quality.^{16–18} As patients value both hospital quality and less travel, the distance that patients actually travel will be correlated with the quality of nearby hospitals, but the quality of nearby hospitals will have no direct effect on patients’ outcomes at their admitting hospitals.

We measure the quality of hospitals using report card grades for CABG surgery providers that have been published by Pennsylvania since the early 1990s. Although measures based on the distance to the closest hospital have been used as exogenous variables in a variety of studies,^{19–23} this is, to the best of our knowledge, the first use of both the availability and the report card grades of nearby hospitals to create instrumental variables.

METHODS

Data and Sample

Patient data are from the PHC4 inpatient database, which includes patient sex, age, race, insurance type, diagnostic codes, and residential zip code, whether the procedure was scheduled, whether the patient died in the hospital, and an identification number and zip code for the admitting hospital. Each record also contains a patient identifier that allows us to link patient records from quarter to quarter. Our sample is drawn from the set of patients undergoing isolated CABG surgery (CABG surgery with no other major heart surgery during the same admission) in Pennsylvania hospitals during the period 1995–2005. (Our sample ends in 2005 because we only had data through 2006 and needed the last 12 mo to measure one of our outcomes variables.) Distance from a patient’s home to a hospital is the straight-line distance from the centroid of a patient’s residential zip code to the hospital’s location as computed by the Geographic Information System. Hospital longitudes and latitudes are from the American Hospital Association *Annual Survey of Hospitals*.

We eliminated rural patients because almost all the CABG hospitals are located in more densely populated areas; therefore, the distance/quality trade-offs faced by rural patients may be quite different. We further eliminated patients admitted from the emergency room, so as to focus on the health impacts of travel in nonemergency situations. After eliminating observations missing data for any variable, our sample comprised 102,858 patients.

Outcome Equation

Our main specification is:

$$P(\text{Outcome}_{ijkt}) = a + b_1 * \text{Travel Distance}_{ijkt} + b_2 * P_{ijkt} + b_3 * AH_{kt} + H_k + Y_t + \epsilon_{ijkt} \quad (1)$$

where i is an individual patient residing in zip code j and undergoing s at admitting hospital k in year t , P_{ijkt} and AH_{kt} are vectors of patient and admitting-hospital characteristics, H_k and Y_t are fixed effects for admitting hospital (67 dummies) and year (10 dummies), and ϵ_{ijkt} is the error term.

We estimate the effect of travel distance on 2 different health outcomes, in-hospital mortality and readmission. For mortality, Outcome_{ijkt} is a dummy variable that equals one if the patient died in the hospital, and 0 if not. For readmission, Outcome_{ijkt} is a dummy variable that equals 1 if the patient was readmitted to any hospital during the 12 months following the quarter of their CABG surgery with a diagnosis of ischemic heart disease, congestive heart failure, or post-surgery infection. These conditions capture the most common causes of readmission following CABG surgeries.²⁴

Instrumental Variables Estimation

$\text{Travel Distance}_{ijkt}$, the distance between the patient’s zip code and the admitting hospital, is our proxy for the actual cost of travel in driving distance and time.²⁵ We instrument for this variable to control for confounding effects using information about the quality and location of a patient’s nearby, as opposed to admitting, hospital. The first stage of the IV estimation is specified as:

$$\text{Travel Distance}_{ijkt} = \alpha + \beta_1 * IV_{jt} + \beta_2 * P_{ijkt} + \beta_3 * AH_{kt} + H_k + Y_t + \epsilon_{ijkt}, \quad (2)$$

where IV_{jt} represents the instrumental variables, and the other variables are as defined in Eq. (1). The instrumental variables are based on the quality of CABG hospitals available near a patient’s home, where CABG hospital quality is measured using the grades from *Pennsylvania’s Guide to Coronary Artery Bypass Graft Surgery*, published by the Pennsylvania Health Care Cost Containment Council (PHC4).²⁶ Although these reports are available to patients, we do not assume that patients select hospitals based on the reported grades. Rather, we use these grades as proxies for patients’ perceptions of hospital quality, which may be formed by their own experience, recommendations of their referring cardiologist, or word-of-mouth.²⁷

In a report, a hospital receives a grade of “Same as expected” if its actual in-hospital mortality rate falls within a 95% confidence interval (CI) around its predicted mortality rate (a grade referred to in this paper as “as expected”). Hospitals with mortality rates that fall outside of a 95% CI around their predicted rate receive a “Lower than expected” grade, if their mortality rate falls below their 95% CI (a grade referred to here as “superior”), or a “Higher than expected” grade if it falls above (a grade referred to here as “poor”). Mortality rates are risk-adjusted, and hospitals must perform at least 30 isolated CABG procedures on adults in a year to receive a grade.

The report cards have been published at irregular intervals since the first was issued in 1992. The second column

of Table 1 identifies the date of the most recent report card for each year in our sample (by quarter when there was >1 grade for the year), with the year in which the data for the report card were collected in parentheses. The next 3 columns of Table 1 show the number of hospitals with each type of grade each year, where the grade is the one most recently reported.

Some CABG operations occurred at hospitals that were not graded because <30 surgeries were performed at a hospital when the report card information was being collected or because the hospital started a CABG program after data for the report card were collected. The number of such facilities increased after December 1996, when Pennsylvania ended the Certificate of Need program that had restricted entry of CABG programs. As the new programs grew to the “gradable” threshold, the number of ungraded CABG providers fell, most sharply in 2002, the first year that report cards based on data collected after the CON regulations ended were issued (see columns 6 and 7 of Table 1).

We assign each hospital its most recent CABG report card grade in each period to measure its quality and add information about hospital locations to create 4 instruments. The first 2 IVs are categorical, measuring location by indicating whether or not at least one hospital of acceptable quality is located within a 10-mile radius of the patient, 10 miles being the median travel distance of our sample. IV1 equals one if there is a graded CABG hospital nearby. IV2 includes IV1 plus its interaction with a dummy variable that equals one if the nearby hospital’s grade was average or superior. We expect the estimated coefficients to be negative because a patient likely travels less if a CABG hospital of acceptable quality is nearby.

These IVs identify patients who have a nearby hospital of acceptable quality with which they are likely to be familiar and more comfortable. However, our 10-mile radius is essentially arbitrary, so we also use a second set of IVs that measure location as the distance from the patient to the closest CABG hospital of acceptable quality. IV3 is the distance to the closest graded hospital. IV4 includes both the distance to the closest graded hospital and the distance to the closest hospital with an as-expected or superior grade. We expect the estimated coefficients to be positive because research suggests that patients strongly prefer their closest hospital but are willing to travel further for better quality.^{16–18}

The equations were estimated using probit or IV probit (Stata, Version 12; StataCorp. College Station, TX). We assess the endogeneity of travel distance using a Durbin-Wu-Hausman test, under the null hypothesis that travel distance is exogenous.

Control Variables

P_{ijkt} in Eqs. (1) and (2) represents a set of patient characteristics that may affect the patient’s health outcome, including dummy variables for patient gender (equals one if male), race (equals one if white), and age category, and whether the patient is covered by Medicare. (Virtually, all other patients are privately insured, with a few uninsured or covered by Medicaid.) We control for differences in patients’ illness severity using their Elixhauser comorbidities,²⁸

TABLE 1. Pennsylvania CABG Report Cards and Hospitals, 1995–2005

Year	Most Recent Report Card	No. Hospitals With Grades That Were			No. Hospitals That Were		No. CABG Patients [†]
	Most Recent Report (Years of Data Collection)*	Poor	Average	Superior	Graded	Not Graded	
1995	1st Qtr: 1994 (1992); 2nd–4th Qtr: 1995 (1993)	5	29	3	37	5	11,007
1996	1995 (1993)	5	29	3	37	5	11,611
1997	1995 (1993)	5	29	3	37	8	11,466
1998	1st Qtr: 1995 (1993); 2nd–4th Qtr: 1998 (1994–1995)	4	33	3	40	11	10,888
1999	1998 (1994–1995)	4	33	3	40	13	10,468
2000	1998 (1994–1995)	3	32	3	38	15	9875
2001	1998 (1994–1995)	3	32	3	38	19	9185
2002	1st Qtr: 1998 (1994–1995); 2nd–4th Qtr: 2002 (2000)	4	45	3	52	8	8422
2003	2002 (2000)	4	45	3	52	9	7533
2004	2004 (2002)	7	49	2	58	2	6708
2005	2005 (2003)	3	55	1	59	1	5975

*The report card released in the second quarter of 1998 reflects data from 1994 to 1995. Other report cards are based on data from a single year.

[†]Patients live in nonrural areas and underwent scheduled CABG procedures.

identified from patients' ICD-9 diagnosis codes at the time they were admitted for surgery. We include separate dummy variables for the top 10 comorbidities and summarize all other comorbidities into a single dummy variable that equals one if the patient had at least one of these conditions. We also include dummies to indicate whether 1, 2, 3, or 4 or more vessels were revascularized, and whether the surgery involved a cardiopulmonary bypass. Although we exclude patients admitted from the emergency room from our sample so as to focus on scheduled surgeries, we include 2 dummies to indicate whether those scheduled surgeries were emergent or urgent. Finally, we control for the season of the patient's surgery (3 dummies) and for the region of their residence (8 dummies).

AH_{kt} in equations (1) and (2) represents a set of admitting-hospital characteristics that may affect the patient's health outcome. These variables are: dummies indicating whether, in the most recent report card, the hospital is

graded, the grade is as-expected or the grade is superior, the number of CABG surgeries performed at the hospital in the preceding year, the number of CABG surgeries performed by the operating surgeon in the preceding year, and the hospital size category.

RESULTS

Descriptive statistics are shown in Table 2 for the whole sample and by whether a patient lived near a graded hospital. Travel distance was shorter for patients living near a graded hospital, but the mean patient characteristics show no systematic differences, lending support to our assumption that the grade of the nearby hospital is randomly assigned among patients of different age and severity of illness.

The first-stage estimation results are reported in Table 3, with SEs clustered by admitting hospital. Means and SDs for each IV are reported in column (1). Travel distance has been rescaled from miles to hundreds of miles to make

TABLE 2. Descriptive Statistics by Hospital Quality and Location, and for Sample*

	(1) Whole Sample	(2) No Graded Hospital Nearby	(3) Graded Hospital Nearby
Death	0.020	0.022	0.019
One-year readmission [†]	0.263	0.263	0.262
Distance to admitting hospital (in hundreds of miles)	0.149 (0.160)	0.233 (0.159)	0.088 (0.131)
Patient characteristics [‡]			
Male	0.709	0.708	0.710
White	0.874	0.873	0.874
Medicare	0.531	0.515	0.542
Age, 50–59 y	0.192	0.200	0.187
Age, 60–69 y	0.317	0.321	0.314
Age, 70–79 y	0.342	0.328	0.353
Age, ≥ 80 y	0.079	0.074	0.082
Hypertension, uncomplicated	0.516	0.511	0.519
Chronic pulmonary disease	0.134	0.136	0.132
Peripheral vascular disorders	0.096	0.090	0.100
Obesity	0.076	0.076	0.076
Fluid and electrolyte disorders	0.073	0.072	0.073
Hypothyroidism	0.056	0.053	0.057
Diabetes, complicated	0.038	0.038	0.038
Diabetes, uncomplicated	0.224	0.228	0.222
Coagulopathy	0.034	0.035	0.034
Deficiency anemia	0.055	0.053	0.056
Other comorbidities [§]	0.025	0.023	0.026
1 vessel revascularized	0.140	0.142	0.138
2 vessel revascularized	0.329	0.339	0.322
3 vessels revascularized	0.314	0.310	0.317
4+ vessels revascularized	0.163	0.152	0.171
Cardiopulmonary bypass	0.774	0.784	0.767
Emergency	0.221	0.234	0.212
Urgent	0.280	0.316	0.254
Admitting-hospital characteristics			
Graded	0.925	0.896	0.947
Grades are average	0.776	0.726	0.813
Grades are superior	0.102	0.127	0.083
Lagged surgeon volume	138.806 (57.895)	137.983 (57.705)	139.409 (58.028)
Lagged hospital volume	528.382 (276.14)	538.904 (276.284)	520.669 (275.782)
Bed size between 200 and 400	0.303	0.275	0.323
Bed size above 400	0.638	0.659	0.623

*SDs for continuous variables are reported in parentheses.

[†]Sample sizes for readmission are smaller. They are 10,000 whole sample, 42,606 no graded hospital nearby, and 58,305 graded hospital nearby.

[‡]Patient characteristics also include 3 seasonal dummies and 8 regional dummies that are not shown in this table.

[§]This dummy variable equals 1 if the patient has ≥ 1 of the remaining Elixhauser comorbidities.

the coefficients easier to read. As expected, the coefficients for IV1 and IV2 are negative, for IV3 and IV4 are positive, and all are significant. The *F* statistics on the joint significance of all 4 IVs are >10, evidence against the possibility that the IVs are only weakly correlated with travel distance to the admitting hospital.²⁹

Table 4 shows our main results. Estimates of the marginal effect of travel distance on in-hospital mortality and readmission using Probit are reported in columns 1 and 6; the other columns show the estimated relationships using IV Probit. The estimates in columns 1–5 suggest that patients traveling further for surgery were more likely to die in the hospital. The effect of travel distance on mortality is considerably larger when IV estimation is used (columns 2–5), suggesting that Probit estimates are downward biased because of measurement error or because of the confounding effects from patients with stronger wills to live traveling further or traveling further to a center of excellence. The estimates in columns 6–10 suggest that the correlation between travel distance and the readmission rate is not statistically significant.

Validity of Instrumental Variables

Our results for in-hospital mortality in particular hinge on the quality of our instrumental variables. For example, for the instrumental-variable “Lives near graded hospital” to be valid, it must be correlated with travel distance (as is demonstrated in Table 3) but not correlated with health outcomes. Although we cannot directly test this latter assumption, there is evidence to support its validity. First, health indicators such as age and the prevalence of comorbidities are similar between those patients who live near a graded CABG hospital and those who do not (Table 2), suggesting that there is no obvious selection based on health conditions that would explain the different mortality rates.

Second, if the assumption is true, we can calculate a simple Wald estimate of the effect of travel distance on health outcomes by dividing the decrease in the mortality rate due to being near a graded hospital (the difference be-

tween columns 2 and 3 in Table 2, or 0.3 percentage points) and by the decrease in travel distance due to being near a graded hospital (the difference between columns 2 and 3, translated to hundreds of miles, or 0.145).³⁰ The Wald estimate (–0.3/–0.145) indicates that every additional 100 miles of travel is associated with a 0.021 increase in the mortality rate, which is very close to the estimates reported for IV1 and IV2 on Table 4 and suggests that living near a graded hospital is not correlated with observable differences in mortality rates.

Third, if our IVs do capture crucial elements concerning a patient’s hospital choice, so that living near a graded hospital leads to shorter travel distances to the admitting hospital, then we would expect to see a larger effect if the hospital has an average or superior grade. Columns 3 and 5 of Table 3 show results consistent with this expectation.

Fourth, including the IVs in the main specification does not change our results, and the IV coefficients are insignificant. Finally, we reestimated the specification as a linear probability model so we could test the relevance of the IVs after the first-stage estimations using a Kleibergen-Paap rank LM test, under the null hypothesis that the instruments are jointly uncorrelated with travel distance,^{31,32} and the validity of the IVs using the Hansen’s *J* test, under the null hypothesis that the instruments are jointly exogenous.^{31,33} Test results indicated that the IVs are strong and that there is no overidentification problem when using IV2 or IV4.

Patient Severity

We investigate whether traveling further was more harmful for sicker patients by reestimating our equations on subsamples of low-severity (Elixhauser index <2) and high-severity (Elixhauser index ≥ 2) patients. (First-stage results were similar to those on Table 3.) The results in columns 2–5 of Table 5 indicate that travel distance did not affect the mortality of relatively healthy patients, once the effects of endogeneity are controlled. However, for high-severity patients, mortality rates were 2 to 5 times higher among those

TABLE 3. First-stage Results on the Effects of Hospital Grades on Patient Travel Distance[†]

	(1) Mean (SD)	(2) IV1	(3) IV2	(4) IV3	(5) IV4
Live near graded hospital	0.577 (0.494)	–0.127*** (0.008)	–0.043* (0.023)		
Live near hospital with average or superior grade	0.550 (0.498)		–0.088*** (0.022)		
Distance to the closest graded hospital [‡]	0.109 (0.093)			0.936*** (0.059)	0.329** (0.162)
Distance to the closest hospital with average or superior grade [‡]	0.115 (0.096)				0.613*** (0.137)
<i>F</i> statistics on joint significance of instrumental variables		259.5	147.6	253.4	182.2
Sample size	102,858	102,858	102,858	102,858	102,858

[†]The first-stage estimates an OLS model of patient’s actual travel distance. The equation includes patient and admitting-hospital characteristics and admitting hospital and year fixed effects. Values of the dependent variable “Travel distance” are divided by 100. Robust SEs, clustered by admitting hospital, are reported in brackets.

[‡]Values of distance to the closest graded hospital and to the closest hospital with average or superior grade are divided by 100.

*Significant at the 10% level.

**Significant at the 5% level.

***Significant at the 1% level.

TABLE 4. Travel Distance to Admitting Hospital and Health Outcomes[†]

	Mortality				Readmission					
	(1) Probit	(2) IV1	(3) IV2	(4) IV3	(5) IV4	(6) Probit	(7) IV1	(8) IV2	(9) IV3	(10) IV4
Travel distance	0.008*** (0.002)	0.022*** (0.008)	0.022*** (0.008)	0.014*** (0.004)	0.013*** (0.004)	0.008 (0.012)	0.024 (0.033)	0.021 (0.032)	0.007 (0.025)	0.006 (0.024)
Durbin-Wu-Hausman Test		2.067	2.395	0.489	0.258		0.396	0.291	0.002	0.005
<i>P</i>		0.150	0.122	0.484	0.611		0.529	0.589	0.966	0.943
Sample size	102,858	102,858	102,858	102,858	102,858	100,911	100,911	100,911	100,911	100,911

[†]Marginal effects of travel distance are reported. Equation includes patient and admitting-hospital characteristics and admitting hospital and year fixed effects. Values of the dependent variable "Travel distance" are divided by 100. Robust SEs, clustered by admitting hospital, are reported in brackets.

*Significant at the 10% level.

**Significant at the 5% level.

***Significant at the 1% level.

TABLE 5. Health Outcomes and Travel Distance to Admitting Hospital, By Patient Severity[†]

	Mortality				Readmission					
	(1) Probit	(2) IV1	(3) IV2	(4) IV3	(5) IV4	(6) Probit	(7) IV1	(8) IV2	(9) IV3	(10) IV4
Low-severity patients										
Travel distance	0.005** (0.003)	0.001 (0.009)	0.003 (0.009)	0.006 (0.006)	0.006 (0.006)	0.020 (0.018)	0.059* (0.036)	0.055 (0.035)	0.021 (0.032)	0.023 (0.031)
Durbin-Wu-Hausman Test		0.614	0.303	0.0387	0.0435		2.173	1.814	0.003	0.028
<i>P</i>		0.433	0.582	0.844	0.835		0.140	0.178	0.958	0.868
Sample size	57,386	57,386	57,386	57,386	57,386	56,515	56,515	56,515	56,515	56,515
High-severity patients										
Travel distance	0.009*** (0.002)	0.050*** (0.015)	0.048*** (0.014)	0.024*** (0.008)	0.022*** (0.008)	-0.007 (0.016)	-0.016 (0.045)	-0.018 (0.044)	-0.003 (0.037)	-0.007 (0.036)
Durbin-Wu-Hausman Test		9.311	8.963	2.573	1.849		0.0553	0.0843	0.0205	0.000
<i>P</i>		0.002	0.003	0.109	0.174		0.814	0.772	0.886	0.999
Sample size	44,530	44,530	44,530	44,530	44,530	44,396	44,396	44,396	44,396	44,396

[†]Marginal effects of travel distance are reported. Equation includes patient and admitting-hospital characteristics and admitting hospital and year fixed effects. Values of the dependent variable "Travel distance" are divided by 100. Robust SEs, clustered by admitting hospital, are reported in brackets.

*Significant at the 10% level.

**Significant at the 5% level.

***Significant at the 1% level.

who traveled further. Moreover, the Durbin-Wu-Hausman test rejects the hypothesis that travel distance is exogenous for these patients, suggesting that Probit estimation underestimates the true effect of travel distance on severely ill patients because of better outcomes among those who travel further to centers of excellence or who have stronger wills to live.

Columns 6–10 of Table 5 again show that travel distance has little effect on readmission. Although results from IV1 indicate that low-severity patients might be experiencing higher readmission rates, the estimated effect is marginally significant, and travel distance is not significant in the other specifications.

DISCUSSION

We use IVs based on the quality of nearby hospitals to investigate whether traveling further to a hospital for a one-time, scheduled, surgical procedure harms patients. The results of the first-stage estimations imply that the local availability of better quality hospitals was associated with less travel for patients. Estimation of our main specification suggests that in-hospital mortality rates are higher for more severely ill patients who travel further to their admitting hospital. Readmission rates did not appear to be strongly related to travel distance.

The number of CABG surgery centers increased during our sample period because in December 1996, Pennsylvania repealed its Certificate of Need law, which, until then, had restricted the entry of new CABG programs. Consequently, the average distance traveled by severely ill patients in our sample fell by 2.66 miles during our sample period. Multiplying this reduction by the estimated coefficients in Table 5 (0.00022 and 0.0005 when rescaled to represent deaths per additional mile traveled), we concluded that mortality rates fell by 0.0005852 to 0.00133 because of shorter travel distances, a reduction of 4.5%–10.23% (based on a mean mortality of 0.013 for severely ill patients over the sample period).

Our results are in line with those of a very different study that compared predicted to actual outcomes for patients undergoing a number of different types of elective surgeries at the Mayo Clinic, which relied on risk-adjusting to control for confounding effects and which came to the unexpected conclusion that patients who lived closer to the hospital did better than predicted.¹⁴ Such findings contribute to the debate as to the desirability of steering patients to high-volume providers for specialized surgery.^{1,3} The mortality effects we found are small but provide evidence that travel distance may negatively affect health outcomes even for the type of complex surgery most likely to benefit from greater regionalization. However, given the potential gains from increased surgical volume and the cost of new programs,^{4,34–36} the appropriate policy goal may be to try to improve the quality of care at existing locations rather than increasing the number of providers.³⁷

Our analysis has limitations. Although our results about the effects of travel may generalize to other types of scheduled surgery, the specific findings apply to CABG patients in

Pennsylvania. Further, our readmission data are confined to readmission in the quarter following surgery and may be missing important readmissions occurring sooner after a patient's operation occurs. This may partly explain why we did not find a precise effect on readmission. We also lack data on whether a patient dies once they have left the hospital, so we are unable to discern the effects of travel on other important patient outcomes such as 7-day or 30-day mortality.

Finally, although our analysis suggests that longer travel distance harms patients, we do not identify the specific causes of harm. Various mechanisms such as psychological stress, lack of family support, and difficulties in coordinating care may explain why outcomes are worse for patients who travel further, but each mechanism calls for a different response, such as providing preoperative care and education at more locations, or supplementing the informal care provided by families by encouraging the use of hospitalists, intensivists, and/or information technology. More research on why travel distance affects health outcomes is necessary before the appropriate policy responses can be determined.

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ATTACHMENT 6



**Washington
Hospital Center**

MedStar Health

Janis M. Orlowski, MD
*Senior Vice President and
Chief Medical Officer*

Office of Medical Affairs

March 6, 2008

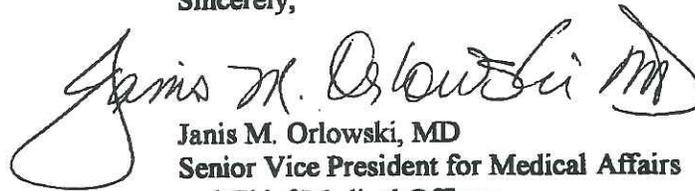
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Baltimore, MD 21215

Dear Dr. Neumann:

Washington Hospital Center maintains an active Patient Transfer Agreement ("Agreement") with Anne Arundel Medical Center ("AAMC"). An addendum to the Agreement was made on February 21, 2006, which further describes the transfer of patients enrolled in the Percutaneous Coronary Intervention Program and includes Washington Hospital Center's agreement to accept unconditionally the transfer of patients enrolled in the PCI program for any required additional care, including emergent or elective cardiac surgery or PCI and to provide timely transmission of required follow up data on transferred patients.

Washington Hospital Center will continue to receive patients from AAMC as part of its Research Waiver to Perform Non-Primary PCI's in hospitals without on-site surgery, including those patients who are randomized as part of the research study. Thank you.

Sincerely,



Janis M. Orlowski, MD
Senior Vice President for Medical Affairs
and Chief Medical Officer

February 2005 – January 2006 & Continuing

PATIENT TRANSFER AGREEMENT
BY and Between
ANNE ARUNDEL MEDICAL CENTER, INC.
And
WASHINGTON HOSPITAL CENTER

THIS PATIENT TRANSFER AGREEMENT ("Agreement") is made this 2nd day of February 2005, by and between Anne Arundel Medical Center, Inc., a Maryland non-profit corporation and licensed acute care hospital ("Hospital") and Washington Hospital Center ("WHC"), a Delaware not-for-profit corporation and licensed acute care hospital.

Recitals

1. Hospital is an acute-care hospital that provides inpatient and outpatient services and operates an Emergency Room and from time to time has patients who require specialized services that are not within its capability;
2. WHC owns and operates a licensed acute care hospital located at 110 Irving Street, NW, Washington, DC 20010 that offers certain specialized services, which include but are not necessarily limited to, tertiary level cardiovascular services, including interventional cardiology and cardiovascular surgery, trauma center and burn center (hereinafter referred to as "Services"), and has physicians and other professional staff available who are qualified and competent to provide said specialized services; and
3. In order to ensure the certain continuity of care and treatment appropriate to the needs of patients, Hospital and WHC desire, by means of this Agreement, to set forth the responsibilities of each when a patient requires transfer to Washington Hospital Center.

NOW THEREFORE, in consideration of the mutual promises and covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties herein agree as follows:

1. **RESPONSIBILITIES OF HOSPITAL.** Hospital agrees to provide the following services to Patients who present with an emergency medical condition as defined by the Emergency Medical Treatment and Labor Act, 42 U.S.C. Sec. 1395dd ("EMTALA").

- 1.1 Treatment. Hospital agrees to provide medical treatment within its capacity in order to minimize risk to the patient.
- 1.2 Point of Contact. In the event the patient's physician determines that the patient is in need of additional specialized care, and the benefits of a transfer outweigh the risks, Hospital will contact WHC's designated points of contact for specialized care services to request a transfer and to confirm the availability of a bed.
- 1.3 Medical Information. Hospital agrees to send all medical records or copies thereof related to Patient's emergency medical condition to the extent the records are available at the time of transfer, including test results, preliminary diagnosis, and any treatment provided or an abstract thereof, together with essential identifying information necessary to continue the Patient's treatment without interruption.
- 1.4 Consent. Hospital will obtain Patient's or Patient's surrogate's informed consent to transfer to WHC, including the risks and benefits, along with alternatives to the proposed transfer, and whether the benefits of transfer are outweighed by the risks.
- 1.5 Transport. Hospital agrees to arrange for adequate transport, equipment, and personnel, consistent with Patient's medical condition, including life support measures if appropriate, to stabilize the patient before transport and to sustain the patient during transport.
- 1.6 Patient Valuables. Hospital agrees to send Patient's valuables with Patient or a family member.

2. RESPONSIBILITIES OF WHC

- 2.1 Acceptance of Patients. Subject to patient's meeting admission criteria, bed and other resource availability, all of which will be confirmed by WHC's point of contact in advance of the transfer, WHC agrees to accept Patients proposed to be transferred who require specialized Services where Hospital has certified that the benefits of transfer outweigh the risks and has obtained the Patient's or Patient's surrogate's informed consent. WHC agrees to accept transfers of patients in compliance with the EMTALA and EMTALA regulations.
- 2.2 Point of Contact. WHC agrees to establish and notify Hospital of the individual(s) who is the primary point of contact for transfers and a substitute.
- 2.3 Patient Valuables. WHC assumes the risk of loss with respect to Patient's valuables once Patient and said valuables have arrived at WHC's facility.

3. OTHER PERFORMANCE.

3.1 Compliance with Laws. Hospital and WHC agree to comply with all applicable federal, state, and local laws, rules, and regulations relating to the operation of their entities and warrant that they shall at all times during the term of this Agreement maintain all necessary licenses, permits, approvals and certifications from all governmental agencies to conduct their business. The parties further agree that each shall abide by accreditation guidelines in order to comply with the Joint Commission on Accreditation of Healthcare Organizations, or other such accreditation organizations, and appropriate governmental or industry standards, including Medicaid and Medicare certification. Each party hereby represents and warrants that it is not, nor at any time has been, excluded from participation in any federally funded health care program, including Medicare and Medicaid. Each party hereby agrees to notify the other immediately of any actual exclusion from any federally funded health care program, including Medicare and Medicaid. In the event that WHC or Hospital is excluded from participation in any federally funded health care program during the term of this Agreement, this Agreement shall, as of the effective date of such exclusion, automatically terminate.

3.2 Access to Records. If and to the extent required by section 1395x(v)(1)(I) of Title 42 of the United States Code, until the expiration of five (5) years after the termination of this Agreement, WHC shall make available, upon written request by the Secretary, or upon request by the Comptroller General of the United States General Accounting Office, or any of their duly authorized representatives, a copy of this Agreement and such books, documents and records as are necessary to certify the nature and extent of the costs of the services provided by WHC under this Agreement. WHC further agrees that in the event it carries out any of its duties under this Agreement through a subcontract with a related organization with a value or cost of Ten Thousand Dollars (\$10,000.00) or more over a twelve (12) month period, such subcontract shall contain a provision requiring the related organization to make available until the expiration of five (5) years after the furnishing of such services pursuant to such subcontract upon written request to the Secretary, or upon request to the Comptroller General of the United States General Accounting Office, or any of their duly authorized representatives, a copy of such subcontract and such books, documents and records of such organization as are necessary to verify the nature and extent of such costs provided pursuant to the subcontract.

3.3 Quality Assurance. The parties agree to participate in quality assurance, risk management, and peer review activities designed to monitor and improve the quality of care rendered to Patients.

3.4 Billing. Bills incurred with respect to services performed by the Hospital or WHC for Patient care shall be collected by the institution rendering such services directly from the Patient, third party insurance company, or other sources normally billed by the institution. No clause of this Agreement shall be interpreted to require Hospital or WHC to compensate the other for services rendered to a Patient transferred under this Agreement.

3.5 Mutual Respect. Each party will deal with the other publicly and privately in an atmosphere of mutual respect and support.

3.6 Patient Complaints. Each party will handle Patient complaints and inquiries promptly, professional and respectfully.

4. INSURANCE AND INDEMNIFICATION.

4.1 Insurance. Each party agrees to provide and maintain during the term of this Agreement professional liability insurance coverage with minimum limits of \$1 million per occurrence and \$3 million in the aggregate. Each party shall notify the other at least ten (10) days prior to cancellation, reduction, or material change in coverage.

4.2 Indemnification. Each party shall indemnify and hold harmless the other, its directors, officers, staff, agents, servants, and employees from and against any and all liabilities, claims, demands, actions, settlements or judgments, including fees and litigation expenses, based upon or arising out of the respective party's duties and responsibilities in this Agreement, where such liabilities, claims, demands, actions, settlements, or judgments relate to the negligence, action or omission of that party.

5. INDEPENDENT CONTRACTOR. The parties are independent contractors with respect to one another and each shall retain exclusive control over the policies, management, assets and affairs of their respective institutions. Neither is authorized or permitted to act as an agent or employee of the other. Nothing in this Agreement shall be construed as limiting the right of either party hereto to affiliate or contract with any other health care institution while this Agreement is in effect.

6. TERM AND TERMINATION. The effective date of the contract is the date of execution noted on the first page and it shall continue for one year. The Agreement shall renew automatically for successive twelve-month terms, provided that, either party may terminate by giving thirty (30) days notice, in writing to the other part of its intention to terminate this Agreement. The parties shall ensure continuity of care to patients involved in the transfer process. This Agreement shall terminate immediately in the event that either party becomes a sanctioned provider, or either party's license to operate is suspended or revoked by the State.

7. **DISPUTE RESOLUTION.** Any dispute that arises under this Agreement shall be attempted to be resolved in good faith directly by the appropriate department of the institutions. If the dispute cannot be resolved at this level, it shall be referred to the senior administrators or their designees for resolution.

8. **MISCELLANEOUS PROVISIONS.**

8.1 **Use of Name.** Neither party shall use the name of the other in any promotional or advertising material without the prior written consent of the other party.

8.2 **Notices.** All notices and other communications required or permitted by this Agreement shall be in writing and shall be deemed delivered personally or by registered or certified mail, return receipt requested to the parties as follows or to such other addressee as a party may designate in writing.

If to Hospital:
Anne Arundel Medical Center, Inc.
Vice President of Medical Affairs
2001 Medical Parkway
Sajak Pavilion, Suite 550
Annapolis, MD 21401

If to WHC:
Washington Hospital Center
Senior Vice President & Chief Medical Officer
110 Irving Street, NW
Washington, DC 20010

8.3 **Waiver.** No waiver of any term or condition of this Agreement by either party shall be deemed continuing or further waiver of the same term or condition or waiver of any other terms or condition of this Agreement.

8.4 **Non-Discrimination.** Neither party shall discriminate against any Patient on the basis of race, color, creed, national origin, gender, sexual orientation, health status, age, disability, or ability to pay.

8.5 **Amendment.** This Agreement may not be amended except by mutual written agreement, signed by the parties and shall be attached to and become a part of this Agreement.

8.6 **Assignment.** This Agreement shall not be assigned in whole or in part by either party without the express written consent of the other party. This Agreement shall be binding upon the successors or assigns of the parties hereto.

8.7 Changes in the Law. Notwithstanding any other provisions of this Agreement, if at any time during the term hereof any legislation is enacted by the federal government or the State of Maryland, or if any governmental agency that administers the Medicare or Medicaid programs, or any other payor or any other federal, Maryland, or local government agency passes, issues, or promulgates any law, rule, regulation, standard or interpretation which would render this agreement illegal, or which could cause significant and material adverse legal and/or economic consequences for any party hereto, inducing any such action that would adversely affect the tax-exempt status of Hospital or WHC or any of their nonprofit corporate affiliates, such party may give to the other party notice of intent to amend this agreement and such other agreements referenced herein in order to achieve the least burdensome alternative to the parties which still brings this Agreement into compliance with legislative or regulatory change and alleviate such legal or financial consequences. If this agreement is not so amended in writing within thirty (30) days after said notice is given, this agreement shall terminate as of midnight on the 30th business day after said notice is given.

8.8 Entire Agreement. This Agreement sets for the entire understanding and agreement of the parties with respect to the subject matter.

8.9 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Maryland.

IN WITNESS WHEREOF, the parties have executed this Agreement this 2nd day of February, 2005.

ANNE ARUNDEL MEDICAL CENTER, INC.

By: *Linda C. Helmgren*

Name: Linda C. Helmgren

Title: Senior Vice President, Chief Patient Care Officer

WASHINGTON HOSPITAL CENTER

By: *Janis M. Orlovski MD*

Name: Janis M. Orlovski, MD
 Title: Senior Vice President, Medical Affairs & Chief Medical Officer

By: *Mark Smith*

Name: Mark Smith, MD
 Title: Director of Emergency Services

**Addendum No. 1 to
Patient Transfer Agreement
By and Between
Anne Arundel Medical Center, Inc.
And
Washington Hospital Center**

This Addendum ("Addendum") is made this 21st day of February 2006 by and between Anne Arundel Medical Center, Inc., a Maryland non-profit corporation and licensed acute care hospital ("Hospital"), and Washington Hospital Center ("WHC"), a Delaware not-for-profit corporation and licensed acute care hospital.

RECITALS

WHEREAS, Hospital and WHC have entered into a Patient Transfer Agreement ("Transfer Agreement"), effective February 2, 2005, and wish to amend the terms as set forth below.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual promises and covenants contained herein, the parties agree as follows:

- 2.4 Transfer of Patients Enrolled in the Percutaneous Coronary Intervention Program. This addendum addresses the responsibility of WHC as the tertiary institution supporting the Percutaneous Coronary Intervention ("PCI") Program at Hospital. WHC agrees to accept unconditionally the transfer of patients enrolled in the PCI Program for any required additional care, including emergent or elective cardiac surgery or PCI, to provide timely transmission of required follow-up data on transferred patients.

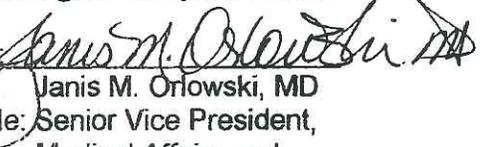
IN WITNESS WHEREOF, the parties have executed this Addendum as of the date first written above.

Anne Arundel Medical Center, Inc.

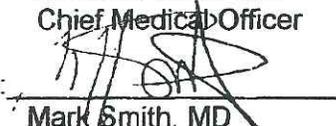
By: 

Linda C. Hoimgren
Title: Chief Operating Officer

Washington Hospital Center

By: 

Janis M. Orłowski, MD
Title: Senior Vice President,
Medical Affairs and
Chief Medical Officer

By: 

Mark Smith, MD
Title: Director of Emergency
Services

ATTACHMENT 7

HEALTH CARE REFORM

Case Volume, Quality of Care, and Care Efficiency in Coronary Artery Bypass Surgery

Andrew D. Auerbach, MD, MPH; Joan F. Hilton, ScD; Judith Maselli, MSPH; Penelope S. Pekow, PhD; Michael B. Rothberg, MD, MPH; Peter K. Lindenauer, MD, MSc

Background: How case volume and quality of care relate to hospital costs or length of stay (LOS) are important questions as we seek to improve the value of health care.

Methods: We conducted an observational study of patients 18 years or older who underwent coronary artery bypass grafting surgery in a network of US hospitals. Case volumes were estimated using our data set. Quality was assessed by whether recommended medications and services were not received in ideal patients, as well as the overall number of measures missed. We used multivariable hierarchical models to estimate the effects of case volume and quality on hospital cost and LOS.

Results: The majority of hospitals (51%) and physicians (78%) were lowest-volume providers, and only 18% of patients received all quality of care measures. Median LOS was 7 days (interquartile range [IQR], 6-11

days), and median costs were \$25 140 (IQR, \$19 677-\$33 121). In analyses adjusted for patient and site characteristics, lowest-volume hospitals had 19.8% higher costs (95% CI, 3.9%-38.0% higher); adjusting for care quality did not eliminate differences in costs. Low surgeon volume was also associated with higher costs, though less strongly (3.1% higher costs [95% CI, 0.6%-5.6% higher]). Individual quality measures had inconsistent associations with costs or LOS, but patients who had no quality measures missed had much shorter LOS and lower costs than those who missed even one.

Conclusion: Avoiding lowest-volume hospitals and maximizing quality are separate approaches to improving health care efficiency through reducing costs of coronary bypass surgery.

Arch Intern Med. 2010;170(14):1202-1208

IMPROVING QUALITY AND REDUCING costs of care are crucial goals for US health care. One approach to improving outcomes is to promote care at higher-volume sites,¹⁻³ while other efforts have focused on improving adherence to quality of care measures. Few data exist to describe the interaction between quality, case

For editorial comment see page 1189

volume, and costs or length of stay (LOS), even as we seek to constrain costs and increase the efficiency—and value—of health care.⁴ We have recently published findings suggesting that overall quality of care markedly influences patient outcomes following cardiac surgery,⁵ but higher volume has a weaker association with outcomes. These findings suggest that care quality may be a more important potential driver for value improvement based on outcome improvement regardless of case

volume. However, care value is improved if outcomes are unchanged but use of resources falls.

Understanding whether case volume or quality reduce costs or LOS has implications for health systems. If higher case volume were independently associated with lower costs or shorter LOS, this would provide a rationale for investing in infrastructure required to maximize access to high-volume hospitals or surgeons.³ However, a positive relationship between higher quality and efficiency might provide justification for investments in infrastructure needed to create high-reliability systems of care.⁶

To explore these issues, we analyzed data collected from adults undergoing coronary artery bypass surgery in a sample of US hospitals. Using these data, we first examined the relationship between surgeon and hospital volume, and costs and LOS. We then examined the relationships between case volume and costs and LOS after adjusting for individual measures of care quality, as well as overall care quality.

Author Affiliations: Division of Hospital Medicine (Dr Auerbach), Department of Epidemiology and Biostatistics (Dr Hilton), Division of General Internal Medicine (Ms Maselli), University of California, San Francisco; and Center for Quality of Care Research, Baystate Medical Center, Springfield, Massachusetts, and Department of Medicine, Tufts University School of Medicine, Boston, Massachusetts (Drs Pekow, Rothberg, and Lindenauer).

SUBJECTS

Our data were collected on 81 289 patients cared for by 1451 physicians at 164 hospitals participating in Perspective (Premier Inc, Charlotte, North Carolina), a voluntary, fee-supported database developed for measuring quality and health care utilization and which we have used in previous research.^{3,7-9}

In addition to standard hospital discharge file data, Perspective contains a date-stamped log of all materials (eg, serial compression devices used to prevent venous thromboembolism), and medications (eg, β -blockers) charged for during hospitalization. Perspective charge data are collected electronically from participating sites and audited regularly to ensure data validity. Perspective sites are representative of the US hospital population and perform similarly on publicly reported quality measures.¹⁰

Patients in our analysis were admitted between October 1, 2003, and September 1, 2005, were 18 years or older, and had coronary bypass grafting (CABG) as their principal procedure as defined by *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* code. The institutional review board at University of California, San Francisco, approved our study.

DATA

In addition to patient age, sex, race or ethnicity, marital status, insurance information, and principal diagnosis, we classified comorbidities using the method of Elixhauser et al.¹¹ Data regarding LOS and hospital costs were obtained from the Perspective discharge file. Three-quarters of hospitals that participate in Perspective report costs derived from their cost accounting systems, while others provide costs using Medicare cost to charge ratios. In addition, the database contains information about hospital size, teaching status, and location.

DEFINITION OF VOLUME MEASURES

Because some hospitals did not contribute data for the entire study period, we estimated the annual case volume by dividing each hospital's or physician's observed patient count by the total number of months that the hospital or physician contributed patients to the data set and then multiplied this number by 12. These "annualized" volumes were then divided into quartiles as has been done in previous work.^{1,12-14}

DEFINITION OF MISSED QUALITY MEASURES

Because diagnosis codes cannot reliably distinguish between complications and preexisting conditions, we measured the proportion of ideal candidates for each care process who failed to receive them—a missed quality measure. We developed these measures by translating recommendations from the Surgical Care Improvement Project¹⁵ and American Heart Association/American College of Cardiologists Guidelines¹⁶ into a series of dichotomous quality measures.³ These measures, many of which are also included in recently published recommendations,¹⁷ included whether antimicrobials were used to prevent surgical site infection on the operative day, whether that antimicrobial was discontinued in 48 hours, whether serial compression devices were used to prevent venous thromboembolism in the 2 days following surgery, and whether aspirin, β -blockers, or lipid-lowering statin drugs were administered in the 2 days follow-

ing surgery. Other measures (such as those related to glucose control) cannot be detected in Perspective data and were not targeted.

To provide a more sensitive measure of system-level ability to provide reliable care,¹⁸ we also counted the total number of individual quality measures missed during hospitalization.

STATISTICAL ANALYSIS

We first described study patients and hospitals using univariable methods. Mixed-effect models were used to account for clustering of patients within physicians and within hospitals. Length of stay and costs were log-transformed to account for skew and to stabilize variance of residuals in multivariable models. Beta estimates and 95% confidence intervals (CIs) were converted to percentage differences using the following formula: $100 \times (\exp[\text{estimate}] - 1)$.

Models were constructed using manual variable selection methods; volume and quality measures were entered manually, while additional covariates (confounding factors) were selected for inclusion if they were associated with the outcome at $P < .01$, if including them changed estimates for the primary predictors by more than 10%, or if they had face validity. Models of LOS were adjusted for age, sex, race, insurance type, diagnosis-related group severity of illness score, admission status, geographic area, comorbid illnesses (congestive heart failure, valvular disease, hypertension, paralysis, neurological disorders, chronic obstructive pulmonary disease, diabetes with complications, renal failure, obesity, weight loss, electrolyte disorder, blood loss, deficiency anemia, alcohol or drug abuse, psychoses, and depression), and whether an internal mammary graft was used during the procedure. Models of costs included age, sex, race, insurance type, admission status, number of beds, severity score, comorbid illnesses (congestive heart failure, valvular disease, hypertension, paralysis, neurological disorders, diabetes, diabetes with complications, renal failure, coagulopathy, weight loss, electrolyte disorder, blood loss, deficiency anemia, psychoses, and alcohol abuse), whether an internal mammary graft was used during the procedure, and source of costs (actual costs or cost to charge ratio).

Multivariable models first assessed the associations between hospital volume, physician volume, and individual (or overall) quality measures as single predictors in individual models for each predictor, after adjusting only for patient and hospital confounding factors. To determine the degree to which volume effects and missed quality effects were related, our next models included our volume and individual quality measures in one fully adjusted model; a separate fully adjusted model included volume and overall quality measures.

To assess potential collinearity between our key predictors (hospital volume, physician volume, and quality measures), we examined Pearson correlations between them. In view of the large number of observations, these analyses gave no evidence for collinearity (all correlations, <0.3). In addition, we examined models including only subsets of these variables, and found no evidence for instability. All analyses were carried out using SAS version 9.1 (SAS Institute Inc, Cary, North Carolina).

RESULTS

PATIENT CHARACTERISTICS

A total of 81 289 patients underwent CABG at one of our study sites between October 1, 2003, and September 30, 2005 (**Table 1**). Mean (SD) age of patients was 65.0 (10.9) years, and 72% were men. Most were white, mar-

Table 1. Characteristics of 81 289 Patients

Characteristic	Value ^a
Patient age, mean (SD), y	65.0 (10.9)
Male sex	58 398 (72)
Race	
White	61 621 (76)
Other	11 434 (14)
Black	5500 (7)
Hispanic	2734 (3)
Marital status	
Married	51 094 (63)
Single	8646 (11)
Widowed	8439 (10)
Other	6899 (8)
Divorced	6211 (8)
Primary payer	
Medicare	43 164 (53)
Managed care	21 987 (27)
Indemnity	8177 (10)
Medicaid	3614 (4)
Uninsured	2575 (3)
Other	1057 (1)
Capitated	715 (1)
Discharge status	
To home	43 588 (54)
Home health care	24 444 (30)
Skilled nursing facility	8028 (10)
Rehabilitation	2574 (3)
Death in hospital	1738 (2)
Transfer	399 (0.5)
Other	443 (0.5)
Hospice	75 (0.1)
Any ICU charges	60 392 (74)
APR-DRG severity	
1	8702 (11)
2	40 789 (50)
3	23 747 (29)
4	8051 (10)
APR-DRG risk of mortality	
1	27 388 (34)
2	32 065 (39)
3	15 883 (20)
4	5953 (7)

(continued)

ried, and had Medicare insurance. The most common comorbidities in our cohort were hypertension (72%), diabetes without chronic complications (31%), and chronic obstructive pulmonary disease (23%). Most received care at nonteaching hospitals in the South. Median LOS was 7 days (interquartile range [IQR], 6-11 days), and median costs were \$25 140 (IQR, \$19 677-\$33 121).

QUALITY AND VOLUME MEASURES

We have published details of our quality measures and their characteristics in our study population previously.⁵ Most patients (77%) did not have charges for serial compression devices, but few did not receive a β -blocker (22%), or had no antimicrobial charges on the operative day (6%) (eTable 1; <http://www.archinternmed.com>). Very few patients (12%) had no missed quality measures, and 44% missed 3 or more. The majority of hospitals and physicians in our cohort were lowest-

Table 1. Characteristics of 81 289 Patients (continued)

Characteristic	Value ^a
Comorbidities	
Hypertension	58 492 (72)
Diabetes without chronic complications	25 423 (31)
COPD	18 974 (23)
Fluid and electrolyte disorders	12 815 (16)
Deficiency anemia	11 981 (15)
Obesity	11 636 (14)
Peripheral vascular disease	11 034 (14)
Coagulopathy	6335 (8)
Hypothyroidism	6038 (7)
Diabetes with chronic complications	4623 (6)
Renal failure	4308 (5)
Depression	3781 (5)
Other neurological disorders	1882 (2)
Alcohol abuse	1663 (2)
Rheumatoid arthritis or collagen vascular disease	1191 (1)
Psychoses	1006 (1)
Paralysis	949 (1)
Solid tumor without metastasis	918 (1)
Congestive heart failure	443 (0.5)
Internal mammary graft not used (n, %)	9938 (12)
Site of care	
Teaching hospital	30 295 (37)
Urban hospital	76 079 (94)
Rural hospital	5210 (6)
Region	
South	46 768 (58)
Midwest	14 082 (17)
Northeast	11 201 (14)
West	9237 (11)
No. of beds	
100-199	2952 (4)
200-299	7469 (9)
300-399	16 678 (21)
400-499	13 373 (16)
\geq 500	40 817 (50)
Resource use	
Length of stay, median (IQR), d	7 (6-11)
Total costs, median (IQR), \$	25 140 (19 677-33 121)

Abbreviations: APR-DRG, all-patient refined–diagnosis related group; COPD, chronic obstructive pulmonary disease; ICU, intensive care unit; IQR, interquartile range.

^aData are given as number (percentage) unless otherwise specified.

volume health care providers (eTable 2). Hospital volume ranged from 112 (IQR, 80-154) per year in the lowest-volume quartile to 644 (IQR, 536-754) per year in the highest quartile. Physician volume ranged from 12 (IQR, 11-18) per year in the lowest-volume quartile to 155 (IQR, 141-173) per year in the highest quartile. The proportion of patients with 1 or more missed quality measure was slightly higher as volume rose.

ASSOCIATIONS BETWEEN VOLUME, INDIVIDUAL QUALITY MEASURES, AND CARE EFFICIENCY

Lowest-volume hospitals had substantially higher costs but similar LOS compared with other hospitals; these differences persisted whether volume measures were adjusted for patient factors alone or for individual care qual-

Table 2. Association Between Volume, Individual Quality Measures, and Resource Use

Variable	Difference, % (95% Confidence Interval)					
	Length of Stay			Costs		
	Unadjusted	Adjusted ^a	Adjusted ^b	Unadjusted	Adjusted ^a	Adjusted ^b
Hospital volume						
First quartile	-7.0 (-8.0 to -6.1)	1.1 (-5.9 to 8.7)	1.6 (-5.1 to 8.8)	13.2 (12.2 to 14.1)	19.8 (3.9 to 38.0)	18.3 (2.0 to 36.3)
P value	<.001	.75	.65	<.001	.01	.02
Second quartile	-7.6 (-8.6 to -6.7)	0.9 (-7.2 to 7.9)	0.2 (-6.7 to 7.5)	-6.9 (-7.7 to -6.0)	-0.2 (-14.1 to 16.0)	-1.0 (-14.7 to 15.0)
P value	<.001	.98	.96	<.001	.98	.90
Third quartile	-7.3 (-8.2 to -6.7)	-1.6 (-9.1 to 6.6)	-0.7 (-7.9 to 7.0)	-4.4 (-5.2 to -3.5)	0.3 (-14.4 to 17.5)	0.5 (-14.2 to 17.7)
P value	<.001	.70	.84	<.001	.97	.95
Fourth quartile	Referent	Referent	Referent	Referent	Referent	Referent
Physician volume						
First quartile	0.4 (-0.7 to 1.4)	1.1 (-1.1 to 3.4)	0.9 (-1.3 to 3.2)	10.7 (9.8 to 11.7)	3.4 (0.9 to 6.0)	3.1 (0.6 to 5.6)
P value	.49	.31	.44	<.001	.009	.01
Second quartile	-3.9 (-4.9 to -3.0)	-1.0 (-3.3 to 1.3)	-1.2 (-3.5 to 1.2)	3.5 (2.5 to 4.4)	1.1 (-1.6 to 3.9)	1.0 (-1.7 to 3.7)
P value	<.001	.40	.33	<.001	.43	.48
Third quartile	0.9 (-0.1 to 1.9)	0.6 (-1.7 to 3.0)	0.9 (-1.4 to 3.3)	-0.6 (-1.4 to 0.3)	-0.5 (-3.2 to 2.2)	-0.3 (-2.9 to 2.3)
P value	.08	.58	.44	.22	.70	.80
Fourth quartile	Referent	Referent	Referent	Referent	Referent	Referent
Measure						
Serial compression devices not used	-1.3 (-2.2 to -0.5)	12.9 (11.7 to 14.1)	12.5 (11.3 to 13.7)	-3.8 (-4.5 to -3.1)	6.0 (5.1 to 6.9)	6.0 (5.1 to 6.9)
P value	.002	<.001	<.001	<.001	<.001	<.001
Statin not administered	-9.9 (-10.6 to -9.2)	-9.8 (-10.4 to -9.1)	-9.8 (-10.5 to -9.2)	-7.9 (-8.4 to -7.3)	-3.6 (-4.1 to -3.1)	-3.6 (-4.1 to -3.1)
P value	<.001	<.001	<.001	<.001	<.001	<.001
Antibiotics not discontinued	44.9 (43.9 to 45.8)	23.1 (22.4 to 23.8)	23.1 (22.4 to 23.9)	32.2 (31.4 to 33.0)	14.7 (14.2 to 15.2)	14.7 (14.2 to 15.2)
P value	<.001	<.001	<.001	<.001	<.001	<.001
Aspirin not administered	-14.7 (-15.4 to -14.1)	-9.8 (-10.4 to -9.1)	-9.1 (-9.7 to -8.4)	-9.5 (-10.2 to -9.0)	-4.5 (-5.0 to -4.0)	-4.5 (-5.0 to -4.0)
P value	<.001	<.001	<.001	<.001	<.001	<.001
β-Blocker not administered	-9.6 (-10.4 to -8.8)	-1.1 (-1.8 to -0.4)	-1.2 (-1.9 to -0.5)	-5.5 (-6.2 to -4.8)	0.4 (-0.1 to 1.0)	0.4 (-0.1 to 1.0)
P value	<.001	<.001	<.001	<.001	.13	.14
Prophylactic antibiotics not administered	2.1 (0.6 to 3.6)	5.2 (3.6 to 6.9)	5.1 (3.4 to 6.8)	3.1 (1.7 to 4.4)	0.1 (-1.1 to 1.3)	0.1 (-1.1 to 1.3)
P value	.006	<.001	<.001	<.001	.90	.92

^aResults of 3 models examining volume and quality measures separately and adjusting for covariates described in the "Methods" section.

^bResults of a single model examining volume measures and quality and adjusting for covariates described in the "Methods" section.

ity measures (**Table 2**). Physician volume was not associated with LOS in individual models adjusting for clinical factors alone or clinical factors and quality measures. However, lowest-volume physicians had higher unadjusted costs, and these differences were not eliminated after adjusting for clinical factors or clinical factors and individual quality measures.

A number of individual quality measures were associated with unadjusted differences in LOS, many of which were altered substantially by adjusting for clinical risk factors. The addition of volume as another adjuster in our models did not appreciably alter the adjusted associations between individual quality measures and LOS or costs, suggesting that the associations between volume and resource use and between quality and resource use were independent of each other. In both individual and fully adjusted models, receiving antimicrobial prophylaxis was associated with longer LOS but not costs, and receipt of an antimicrobial after the first 48 hours and nonuse of serial compression devices for prevention of venous thromboembolism were associated with substantially longer LOS in individual or fully adjusted models.

ASSOCIATIONS BETWEEN VOLUME, OVERALL CARE QUALITY, AND CARE EFFICIENCY

Associations between hospital and physician volume and costs or LOS, adjusting for overall care quality, were essentially identical to those adjusting for individual quality measures, suggesting independence of the association between overall quality's and volume measures' associations with LOS or costs (**Table 3**). However, missing any quality measures was strongly associated with higher adjusted costs and LOS, whether or not volume measures were included.

SECONDARY ANALYSES

In preplanned analyses, we tested for statistical interactions between case volume measures and overall quality. In these analyses, we noted statistically significant interactions between hospital volume, overall quality, and LOS and costs, suggesting small incremental benefits of having higher quality care at a higher-volume hospital or from a busier surgeon.

Table 3. Association Between Volume, Overall Quality, and Care Efficiency

Value	% (95% Confidence Interval)					
	Length of Stay			Costs		
	Unadjusted	Adjusted ^a	Adjusted ^b	Unadjusted	Adjusted ^a	Adjusted ^b
Hospital volume						
First quartile	See Table 2		1.3 (-5.7 to 8.8)	See Table 2		18.3 (2.6 to 36.5)
P value	See Table 2		.71	See Table 2		.02
Second quartile	See Table 2		0.3 (-6.8 to 8.0)	See Table 2		-5.4 (-14.5 to 15.7)
P value	See Table 2		.93	See Table 2		.94
Third quartile	See Table 2		-1.2 (-8.6 to 6.8)	See Table 2		0.4 (-14.4 to 17.8)
P value	See Table 2		.77	See Table 2		.96
Fourth quartile	See Table 2		Referent	See Table 2		Referent
Surgeon volume						
First quartile	See Table 2		1.2 (-1.0 to 3.4)	See Table 2		3.3 (0.8 to 5.8)
P value	See Table 2		.28	See Table 2		.01
Second quartile	See Table 2		-0.9 (-3.1 to 1.5)	See Table 2		1.2 (-1.5 to 4.0)
P value	See Table 2		.47	See Table 2		.39
Third quartile	See Table 2		0.7 (-1.6 to 3.0)	See Table 2		-0.5 (-3.1 to 2.3)
P value	See Table 2		.55	See Table 2		.74
Fourth quartile	See Table 2		Referent	See Table 2		Referent
No. of missed quality measures						
None missed	Referent	Referent	Referent	Referent	Referent	Referent
1 Missed	21.5 (19.9 to 23.1)	11.9 (10.8 to 13.1)	11.9 (10.8 to 13.1)	13.7 (12.4 to 15.0)	7.8 (6.9 to 8.6)	7.8 (6.9 to 8.6)
P value	<.001	<.001	<.001	<.001	<.001	<.001
2 Missed	12.3 (10.9 to 13.7)	8.1 (6.9 to 9.3)	8.1 (6.9 to 9.3)	5.3 (4.1 to 6.4)	6.7 (5.8 to 7.6)	6.7 (5.8 to 7.6)
P value	<.001	<.001	<.001	<.001	<.001	<.001
3 Missed	8.0 (6.7 to 9.4)	5.0 (3.8 to 6.2)	5.0 (3.8 to 6.1)	4.6 (3.5 to 5.8)	6.7 (5.8 to 7.6)	6.7 (5.8 to 7.6)
P value	<.001	<.001	<.001	<.001	<.001	<.001
≥4 Missed	13.0 (11.5 to 14.5)	9.5 (8.2 to 10.8)	9.5 (8.2 to 10.8)	9.6 (8.3 to 10.9)	10.1 (9.1 to 11.1)	10.1 (9.1 to 11.1)
P value	<.001	<.001	<.001	<.001	<.001	<.001

^aResults of 3 models examining volume and quality measures separately and adjusting for covariates described in the "Methods" section.

^bResults of a single model examining volume measures and quality and adjusting for covariates described in the "Methods" section.

COMMENT

In this large cohort of patients undergoing CABG, hospitals with the lowest operative volumes tended to have higher costs but similar LOS compared with high-volume hospitals; a weak association between low-volume surgeons and higher costs was also observed. These findings persisted even after adjusting for observable patient characteristics and after adjustment for whether recommended care processes were missed. In contrast, missing 1 or more quality measure was strongly associated with higher costs and longer LOS, which was essentially independent of the volume of the surgeon or hospital. These findings suggest that efficiency can be improved in CABG by advising patients to avoid low-volume health care providers, while encouraging investment in improving the reliability of hospital care.

The relationship between higher volume of care and better outcomes of cardiac surgery is well established.^{13,19-21} Because cost savings attributable to volume-based referrals has generally been modest (<5%),²² the volume-based referrals have been thought to improve value largely based on improved clinical outcomes.²²⁻²⁴ Our data suggest that the bulk of savings would result if patients avoided low-volume hospitals (as high as 16% savings if quality is not taken into account), and that little savings would result from a shift of patients from second highest- to highest-volume centers (or third high-

est to highest). In our study, patients living near a lowest-volume hospital (approximately one-half of our hospitals) could choose from any of the 79 higher-volume hospitals rather than just the 19 in the highest quartile, saving between \$85 and \$171 million per year.

Our results more often suggest that promotion of adherence to process measures is a separate approach for improving care efficiency in cardiac surgery, but maximizing overall rather than individual measure performance is critical. While worse performance on individual measures in our study was inconsistently associated with costs or LOS and had a minimal impact on the association between volume and outcomes, the number of care processes missed was a strong and consistent predictor of longer LOS and costs. Differences in the associations between costs and LOS between individual and overall quality measures are important because overall quality and all-or-none measurement are thought to be a more valid measure of a systems' ability to deliver all aspects of care reliably to individual patients.¹⁸ Our data suggest that overall system performance in quality may have a direct effect on patient care efficiency and provide another rationale for "all or none" quality measurement as a method to compel widespread improvements in care,²⁵ or at the least efforts to standardize care.²⁶ Importantly, our overall quality measure was strongly associated with cost reductions even though it included individual measures with weak (or reversed) associations

with resource use. Refining this listing to just those measures or reweighting them (another proposed method for maximizing impact of quality reporting) is likely to only magnify the importance of overall quality in identifying optimal systems.

Our study has a number of limitations. First, because we used administrative data from the inpatient stay only, we cannot easily distinguish complications from preexisting disease. However, we constructed our quality measures to focus on patients who had no documented contraindications, and we did not use comorbidities to define outcomes. Our quality measures focus primarily on inpatient medications and cannot distinguish continuation of home medications and initiation of medications in hospital. This factor may be influencing the associations between resource use and aspirin, β -blockers, and statins but is less likely to affect antimicrobial or serial compression device use. In addition, our quality measures were collected from electronic billing systems rather than medical chart abstraction and have not been validated in a scientific study. However, because the business model of Premier Inc focuses on provision of accurate benchmarking data to their members, all charge and diagnosis data are regularly audited for accuracy. Our cost data include those incurred during hospitalization and may miss costs of posthospital care. Because we did not have these data available, our cost models did not adjust for differences in local wage index or share of low-income patients. As an observational study, the results are subject to biases related to nonrandom assignment of patients to receive medications or devices, as well as the documentation biases described herein. However, our results were robust even after adjusting for all available patient-level and hospital-level data associated with our measures of resource use. Although participating hospitals are similar to other US centers in terms of size, teaching status, and location, it is possible that they differ from non-Premier sites in subtle ways not captured in our data. Having said this, previous research in Premier sites has produced results useful to policy makers. In addition, while we constructed our volume measures to be consistent with those used in previous work, it is possible that they do not adequately represent expertise accrued if low-volume surgeons were performing other complex cardiovascular surgical procedures frequently or performed surgical procedures outside of our Premier hospitals. Finally, it is likely that some surgical procedures in our dataset were at least partially performed by fellows or residents. To address this potential concern, we adjusted for whether the surgery was performed at a teaching hospital.

Our results add to the literature by suggesting that one strategy to enhance the value of CABG is to direct patients away from lower-volume surgeons and hospitals to institutions and health care providers who perform the procedure regularly. However, our findings also suggest that quality improvement efforts focused on improving adherence to process measures as an all-or-none metric will also have beneficial effects on the value of care through reductions in cost and LOS. Health care reform efforts aimed at improving the value of care in the United States should examine whether strategies that incentiv-

ize systems to provide maximal care quality would be useful in this effort.

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Author Contributions: Dr Auerbach had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Auerbach and Lindenauer. *Acquisition of data:* Auerbach and Lindenauer. *Analysis and interpretation of data:* Auerbach, Hilton, Maselli, Pekow, Rothberg, and Lindenauer. *Drafting of the manuscript:* Auerbach, Maselli, and Lindenauer. *Critical revision of the manuscript for important intellectual content:* Auerbach, Hilton, Pekow, Rothberg, and Lindenauer. *Statistical analysis:* Auerbach, Hilton, Maselli, Pekow, and Lindenauer. *Obtained funding:* Auerbach. *Administrative, technical, and material support:* Auerbach and Lindenauer.

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Online-Only Material: eTables 1 and 2 are available at <http://www.archinternmed.com>.

Additional Contributions: Denise Remus, RN, PhD, and Kathy Belk assisted in assembling the data set used for this analysis.

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ATTACHMENT 8

Hospital volume, mitral repair rates, and mortality in mitral valve surgery in the elderly: An analysis of US hospitals treating Medicare fee-for-service patients

Christina M. Vassileva, MD,^a Christian McNeely, BS,^a John Spertus, MD,^b Stephen Markwell, MA,^a and Stephen Hazelrigg, MD^a

ABSTRACT

Background: The volume-outcome relationship has been suggested as a quality metric in mitral valve surgery and would be particularly relevant in the elderly because of their greater burden of comorbidities and higher perioperative risk.

Methods and Results: The study included 1239 hospitals performing mitral valve surgery on Medicare beneficiaries from 2000 through 2009. Only 9% of hospitals performed more than 40 mitral operations per year, 29% performed 5 or less, and 51% performed 10 or less. Mitral repair rates were low; 22.7% of hospitals performed 1 or less, 65.1% performed 5 or less, and only 5.6% performed more than 20 mitral repairs per year in those aged 65 years or more. Repair rates increased with increasing volume of mitral operations per year: 5 or less, 30.5%; 6 to 10, 32.9%; 11 to 20, 34.9%; 21 to 40, 38.8%; and more than 40, 42.0% ($P = .0001$). Hospitals with lower volume had significantly higher adjusted operative mortality compared with hospitals performing more than 40 cases per year: 5 or less cases per year, odds ratio (OR) 1.58 (95% confidence interval [CI], 1.40-1.78); 6 to 10 cases per year, OR 1.29 (95% CI, 1.17-1.43); 11 to 20 cases per year, OR 1.17 (95% CI, 1.07-1.28); 21 to 40 cases per year, OR 1.15 (95% CI, 1.05-1.26). Hospitals with lower mitral repair rates had an increased likelihood of operative mortality relative to the top quartile: lowest quartile, OR 1.31 (95% CI, 1.20-1.44); second quartile, OR 1.18 (95% CI, 1.09-1.29); and third quartile, OR 1.14 (95% CI, 1.05-1.24). Long-term mortality beyond 6 months was also higher in low-volume hospitals: 5 or less cases year, hazard ratio (HR) 1.11 (95% CI, 1.06-1.18); 6 to 10 cases per year, OR 1.06 (95% CI, 1.02-1.10) compared with hospitals performing more than 40 cases per year.

Conclusions: Most hospitals perform few mitral valve operations on elderly patients. Greater volume of mitral procedures was associated with higher repair rates. Both greater volume of mitral procedures and increasing mitral repair rates were associated with decreased mortality. (*J Thorac Cardiovasc Surg* 2015;149:762-8)

Operative mortality and mitral repair rates				
	OR	95%LL	95%UL	p-value
Hosp annual MV volume ≤5*	1.58	1.40	1.78	
Hosp annual MV volume >5-10*	1.29	1.17	1.43	0.0001
Hosp annual MV volume >10-20*	1.17	1.07	1.28	
Hosp annual MV volume >20-40*	1.15	1.05	1.26	
* versus >40 / year				
Repair rate - 1st quartile**	1.31	1.20	1.44	
Repair rate - 2nd quartile**	1.18	1.09	1.29	0.0001
Repair rate - 3rd quartile**	1.14	1.05	1.24	
** versus top quartile				
Repair rate (%)				
Hosp annual MV volume ≤5	30.5			
Hosp annual MV volume >5-10	32.9			
Hosp annual MV volume >10-20	34.9			
Hosp annual MV volume >20-40	38.8			
Hosp annual MV volume >40	42.0			

Odds ratios for adjusted operative mortality along with mitral valve repair rates.

Central Message

The majority of hospitals perform few mitral valve operations. Greater mitral procedural volume was associated with lower adjusted mortality, higher long-term survival, and higher repair rates. Lower hospital mitral repair rates were also independently predictive of higher mortality.

Author Perspective

Prior studies have found a relationship between volume and outcomes in cardiac surgery. We found that valve repair rates and mortality vary by hospital annual mitral procedure volume and that the majority of hospitals have a limited experience in treating elderly patients with mitral valve disease. We found a significant increase in mitral repair rates and a decrease in mortality as a function of hospital annual mitral procedure volume. Our findings support and extend prior reports suggesting that instituting specific volume thresholds for hospitals wishing to perform mitral valve surgery may lead to improved surgical outcomes.

See Editorial Commentary pages 769-70.

Supplemental material is available online.

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The management of elderly patients with mitral valve disease is complex. Options include medical management of heart failure symptoms and surgical intervention, consisting of either mitral repair or replacement. We recently found that outcomes after mitral surgery in the Medicare population are much better than previously reported; survival for those who underwent repair was similar to the age- and gender-matched US population.¹ Despite these favorable outcomes, mitral replacement is much more common in the elderly.² Hospitals vary dramatically in the number of mitral valve operations performed.

Previous studies have investigated the relationship between volume and outcome in mitral valve surgery.^{3,4} Using data from the Society of Thoracic Surgeons (STS) database, Gammie and colleagues³ analyzed data from

Abbreviations and Acronyms

BASF	= Beneficiary Annual Summary Files
CI	= confidence interval
CMS	= Centers for Medicare and Medicaid Services
HR	= hazard ratio
MEDPAR	= Medicare Provider Analysis and Review
NIS	= Nationwide Inpatient Sample
OR	= odds ratio
STS	= Society of Thoracic Surgeons

575 participating hospitals from 2000 to 2003 and found that a higher volume of mitral procedures was associated with lower adjusted operative mortality and increased repair rates.³ Because the mean age of the patient population included in that report was lower than 65 years, it is unclear if these findings can be extrapolated to older patients. In addition, far fewer hospitals participated in the STS at that time and it is possible that participating hospitals differed from nonparticipating hospitals. A more representative analysis of contemporary treatment in the elderly is needed to support this previously reported volume-outcome relationship.

Birkmeyer and colleagues⁴ used the Medicare database to examine the relationship between hospital volume and surgical mortality for a variety of procedures in the United States, including aortic and mitral valve replacement and found an inverse relationship. This methodology was limited by not taking into account the interhospital variability in the proportion of Medicare cases performed (ie, it was assumed that hospitals do not differ in the number of Medicare patients they see) as well as any variability of the proportion of Medicare cases performed at each hospital over time. Moreover, it did not include information on mitral repair, a procedure that has been used with increasing frequency in mitral valve surgery. The purpose of this investigation was to extend these previous efforts by providing a descriptive analysis of the association between hospital volume of mitral procedures, mitral valve repair rates, and mortality in the Medicare population.

METHODS**Data Sources**

The data files used for the present study included the Medicare Provider Analysis and Review (MEDPAR) files and corresponding Beneficiary Annual Summary Files (BASF) from 1999 to 2009. The MEDPAR files contain institutional claims for inpatient services covered under Part A. The BASF files contain information on patient demographics, eligibility, enrollment, summarized service utilization and payment, and chronic condition flags for eligible beneficiaries. The Vital Status file for February 2012 was used to calculate long-term survival.

The study was approved by the Institutional Review Board of Southern Illinois University, which waived the requirement for informed consent. In

addition, beneficiary confidentiality data was protected through a rigorous data use agreement with Centers for Medicare and Medicaid Services (CMS).

Patient Cohort

All Medicare beneficiaries aged 65 years or older who underwent mitral valve repair (International Classification of Diseases, Ninth Edition, Clinical Modification [ICD-9-CM] code 35.12) or replacement (35.23 or 35.24) from 2000 through 2009 were considered for inclusion. Figure 1 provides a flowchart outlining patient selection for the analysis. The ICD-9 codes used for the exclusions are provided in Table E1. Patients with significant concomitant procedures or other nonvalvular procedures were excluded to more directly assess the relationship between the volume of more straightforward mitral valve operations and outcomes. In addition, to ensure a more complete assessment of patient risk factors, patients were excluded if they did not have 12 months of Medicare Part A and Part B coverage in the year preceding their index admission, or if they had a period of enrollment under a Medicare managed plan at any point in the year before their index admission. Patients with emergency admission status were also excluded from the analysis.

Data Variables

The index admission was defined as the first hospitalization documenting a mitral valve repair or replacement during the 10-year period from 2000 through 2009. Demographic and comorbidity data were obtained from the MEDPAR file, using ICD-9-CM diagnostic codes from both the index admission and any hospitalizations during the 12-month period before the index admission. Operative mortality was defined as hospital or 30-day mortality, whichever was longer, in accordance with the standard STS definition. Long-term mortality was calculated from the Vital Status file for February 2012. Hospital annual volume of mitral procedures was calculated as the average number of mitral valve operations per year, that is, the total number of mitral valve operations paid for by Medicare over the 10-year study period, divided by the number of years that the hospital reported performing mitral valve operations. Thus, if a hospital had claims only in 6 of the 10 years, the total number of claims would be divided by 6. After examining the distribution of annual mitral valve volumes across hospitals, we identified clinically and statistically relevant categories of annual volumes. Similarly, the hospital annual volume of mitral repairs was defined as the average number of mitral valve repairs per year. The average annual mitral repair rates for each hospital were categorized into quartiles of the distribution across the hospitals.

Statistical Analysis

Categorical patient characteristics were compared across the volume groups using the χ^2 test, including observed mitral repair rates. A Cochran-Armitage trend test was used to assess the influence of the volume of mitral procedures on mitral repair rates. In order to account for clustering of patients within hospitals, hierarchical logistic regression was used to model operative mortality. Adjusted odds ratios (ORs) are presented, accounting for the clustering of patients within hospitals, the hospital characteristics of annual volume of mitral valve procedures and mitral valve repair rates, as well as the baseline patient and surgery characteristics. Similarly, Cox proportional hazards models, specifying hospital as a random effect to account for patients being nested within hospitals, were used to examine the impact of patient and hospital characteristics on long-term mortality beyond 6 months. After inspecting mortality curves, we chose to look at the impact of these factors on long-term mortality after the initial 6-month period after surgery because there is a high mortality phase immediately after surgery followed by a fairly constant hazard of death thereafter. Adjusted hazard ratios (HRs) reflecting the relative increase/decrease in the likelihood of death over the follow-up period from more than 6 months to 10 years are presented. All analyses were performed using SAS v 9.3 (SAS Institute Inc, Cary, NC).

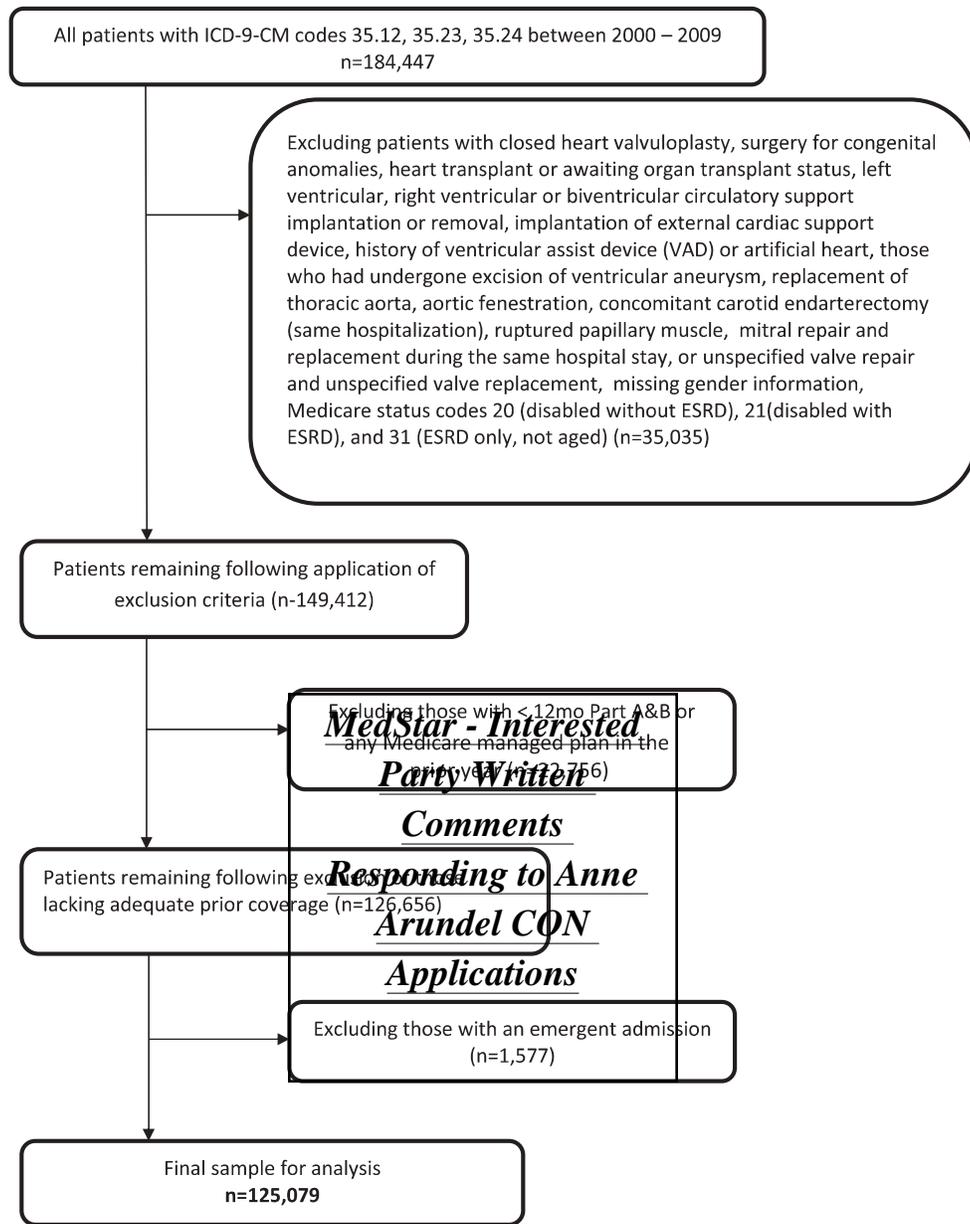


FIGURE 1. Flowchart of patient selection. ICD-9-CM, International Classification of Diseases, Ninth Edition, Clinical Modification; ESRD, end-stage renal disease; VAD, ventricular assist device.

TABLE 1. Distribution of annual hospital volumes of Medicare mitral procedure (n = 1239)

All mitral procedures			Mitral repairs		
Range	No. of hospitals	%	Range	No. of hospitals	%
			0	36	2.9
≤5	354	28.6	1	245	19.8
6-10	276	22.3	2-5	525	42.4
11-20	313	25.3	6-10	233	18.8
21-40	188	15.2	11-20	130	10.5
>40	108	8.7	>20	70	5.6

RESULTS

Distribution of Mitral Valve Operations

This study included all US hospitals using the Medicare fee-for-service system that performed any mitral operations on Medicare patients during the study period. A total of 1239 hospitals were included in the study. The number of mitral valve operations performed on Medicare patients at most of the hospitals was low (Table 1). More than one quarter (28.6%) of the hospitals performed 5 mitral operations or less per year and 50.9% of the hospitals performed 10 or less mitral valve operations per year. In contrast, only

TABLE 2. Baseline characteristics by hospital volume

Characteristics	Overall % (n = 125,079)	% ≤5 (n = 4897)	% >5-10 (n = 11,765)	% >10-20 (n = 27,618)	% >20-40 (n = 33,318)	% >40 (n = 47,481)	P value
Patient characteristics							
Age ≥75 y	55.6	51.4	54.1	55.6	56.6	55.8	.0001
Female	53.2	56.7	55.1	53.7	52.9	52.4	.0001
Hypertension	53.7	52.8	52.9	52.4	53.9	54.5	.0001
Diabetes	20.7	21.7	20.2	20.6	20.8	20.6	.2791
PVD	3.9	3.6	3.6	3.9	3.8	4.1	.0615
Stroke	9.7	9.7	9.5	9.8	9.6	9.9	.7135
Heart failure	63.8	65.9	64.0	62.9	64.2	63.7	.0002
CAD	59.1	57.0	59.0	58.7	59.6	59.1	.0066
COPD	20.7	22.9	23.0	20.8	20.2	20.2	.0001
Respiratory failure	12.8	16.9	14.8	13.9	12.8	11.4	.0001
Renal failure	11.0	24.6	24.1	23.6	24.2	22.5	.0001
Atrial fibrillation	46.8	44.3	45.0	45.0	46.8	48.5	.0001
Anemia	17.0	18.3	17.3	16.7	16.8	17.0	.0606
History of MI	19.8	19.0	19.6	19.8	20.1	19.7	.3432
Previous cardiac surgery	3.7	2.7	2.9	3.5	3.8	4.1	.0001
Surgery characteristics							
Urgent admission	58.0	58.6	55.4	56.4	58.3	59.2	.0001
Mitral valve repair	38.3	30.5	32.9	34.9	38.8	42.0	.0001
CABG	46.8	46.8	48.4	48.3	47.8	44.9	.0001
Other valve surgery	24.5	17.9	18.5	23.1	25.2	27.0	.0001

PVD, Peripheral vascular disease; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; CABG, coronary artery bypass graft.

8.7% of the hospitals performed more than 40 mitral operations per year.

The annual hospital rate of mitral repairs ranged from 0% to 100%. The median annual hospital repair rate was 32.9% (interquartile range [IQR], 21.8% to 44.4%). The 10th and 90th percentiles were 12% and 54%, respectively. Furthermore, the distribution of mitral repair volumes among the hospitals revealed that almost one quarter of the hospitals (22.7%) performed only 1 or no mitral repairs per year and that most hospitals (65.1%) performed 5 or fewer mitral repairs per year. Only 5.6% of the hospitals performed more than 20 mitral repairs per year on Medicare patients.

Patient Characteristics

The study population included a total of 125,079 patients; 47,897 (38.3%) underwent mitral valve repair and 77,182 (61.7%) underwent mitral valve replacement. The median age was 75 years. The baseline characteristics for the overall cohort of patients undergoing mitral valve surgery as well as by hospital volume are presented in Table 2. Higher-volume hospitals treated patients with a higher incidence of atrial fibrillation, a higher proportion of patients who required concomitant other valve surgery, and a higher percentage of reoperations (Table 2). Mitral repair rates increased significantly with increasing hospital annual volume of mitral procedures ($P = .0001$), from 30.5% for hospitals performing 5 or fewer mitral operations per year to 42.0% for hospitals performing more than 40 mitral operations per year.

Hospital Mortality

The overall hospital mortality rate was 10.7%. The results of the hierarchical logistic regression model for adjusted operative mortality are presented in Table 3. In this model, each hospital mitral volume category was used as a separate covariate. Similarly, mitral repair rates were divided into quartiles and each quartile was examined as an independent covariate. Because preoperative profiles differed among patients presenting to different volume centers, adjusted operative mortality was calculated to account for these differences. After adjustment for baseline characteristics and hospital repair rates (quartiles), the lower-volume hospitals all exhibited increased likelihood of operative mortality relative to those hospitals performing more than 40 cases per year: 5 or less cases per year, OR 1.58 (95% confidence interval [CI], 1.40-1.78); 6 to 10 cases per year, OR 1.29 (95% CI, 1.17-1.43); 11 to 20 cases per year, OR 1.17 (95% CI, 1.07-1.28); 21 to 40 cases per year, OR 1.15 (95% CI, 1.05-1.26).

When hospitals were divided into 4 quartiles according to their annual repair rates, the hospitals with the lowest annual repair rates also had an increased likelihood of operative mortality relative to those in the top quartile: lowest quartile, OR 1.31 (95% CI, 1.20-1.44); second quartile, OR 1.18 (95% CI, 1.09-1.29); and third quartile, OR 1.14 (95% CI, 1.05-1.24). The median repair rates and the range for each quartile were as follows: first quartile, median 14%, range 0% to 22%; second quartile, median 28%, range 22% to 33%; third quartile, median 38%, range 33% to 44%; fourth quartile, median 52%, range 44% to 100%.

TABLE 3. Operative mortality

Characteristics	Odds ratio	95% Lower limit	95% Upper limit	P value
Age \geq 75 y	1.60	1.53	1.66	.0001
Female	1.28	1.23	1.33	.0001
Hypertension	0.69	0.66	0.72	.0001
Diabetes	1.06	1.02	1.11	.0092
PVD	1.33	1.22	1.45	.0001
Stroke	1.66	1.57	1.75	.0001
Heart failure	1.33	1.27	1.39	.0001
CAD	0.83	0.79	0.87	.0001
COPD	1.12	1.07	1.17	.0001
Respiratory failure	2.49	2.39	2.61	.0001
Renal failure	1.78	1.69	1.88	.0001
Atrial fibrillation	0.76	0.73	0.79	.0001
Anemia	0.94	0.90	0.99	.0189
History of MI	1.44	1.38	1.51	.0001
Previous cardiac surgery	1.03	0.92	1.14	.6557
Urgent admission	1.76	1.68	1.85	.0001
CABG	1.37	1.31	1.44	.0001
Other valve surgery	1.61	1.55	1.68	.0001
Hospital annual volume of mitral valve procedures				
\leq 5*	1.58	1.40	1.78	
6-10*	1.29	1.17	1.43	.0001
11-20*	1.17	1.07	1.28	
21-40*	1.15	1.05	1.26	
Repair rate				
First quartile**	1.31	1.20	1.44	
Second quartile**	1.18	1.09	1.29	.0001
Third quartile**	1.14	1.05	1.24	

PVD, Peripheral vascular disease; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; CABG, coronary artery bypass graft. *Versus $>$ 40 per year. **Versus top quartile.

Important surgical characteristics that were associated with increased operative mortality included urgent admission status and concomitant coronary artery bypass graft (CABG) or other valve surgery. Important patient baseline characteristics that were predictive of increased operative mortality included respiratory failure, stroke, renal failure, history of previous myocardial infarction and age 75 years or more.

Long-Term Mortality

The overall long-term mortality rates were 20.1% at 1 year, 29.0% at 3 years, 39.0% at 5 years, and 66.4% at 10 years. The 6-month mortality rates for the volume groups were 21.5% for patients in the hospitals with the lowest volume (\leq 5 cases per year), 19.3% for those in the hospitals with 6 to 10 cases per year, 17.7% for those in the hospitals with 11 to 20 cases per year, 17.5% for those in the hospitals with 21 to 40 cases per year, and 15.4% for those in hospitals with more than 40 cases per year. After adjustment for baseline characteristics and hospital repair rates (quartiles), patients in the lower-volume hospitals exhibited greater long-term mortality beyond 6 months relative to those

TABLE 4. Long-term mortality

Characteristics	Hazard ratio	95% Lower limit	95% Upper limit	P value
Age \geq 75 y	1.54	1.51	1.57	.0001
Female	0.96	0.94	0.98	.0001
Hypertension	0.94	0.92	0.96	.0001
Diabetes	1.37	1.34	1.40	.0001
PVD	1.20	1.15	1.26	.0001
Stroke	1.24	1.20	1.28	.0001
Heart failure	1.40	1.37	1.43	.0001
CAD	1.06	1.04	1.09	.0001
COPD	1.52	1.48	1.55	.0001
Respiratory failure	1.26	1.23	1.30	.0001
Renal failure	1.78	1.72	1.83	.0001
Atrial fibrillation	1.09	1.07	1.12	.0001
Anemia	1.13	1.10	1.16	.0001
History of MI	1.11	1.08	1.14	.0001
Previous cardiac surgery	1.22	1.16	1.27	.0001
Urgent admission	1.10	1.08	1.13	.0001
CABG	1.14	1.11	1.16	.0001
Other valve surgery	1.20	1.18	1.23	.0001
Hospital annual volume of mitral valve procedures				
\leq 5*	1.11	1.06	1.18	
6-10*	1.06	1.02	1.10	.0002
11-20*	1.02	0.98	1.05	
21-40*	1.01	0.98	1.04	
Repair rate				
First quartile**	1.12	1.08	1.16	
Second quartile**	1.08	1.05	1.12	.0001
Third quartile**	1.07	1.04	1.10	

PVD, Peripheral vascular disease; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; CABG, coronary artery bypass graft. *Versus $>$ 40 per year. **Versus top quartile.

hospitals performing more than 40 cases per year: 5 cases or less per year, HR 1.11 (95% CI, 1.06-1.18); and 6 to 10 cases per year, HR 1.06 (95% CI, 1.02-1.10). A statistically significant relationship between repair rate and long-term mortality was also noted ($P = .0001$). Hospitals with the lowest annual repair rates had an increased likelihood of long-term mortality relative to those in the top quartile: lowest quartile, HR 1.12 (95% CI, 1.08-1.16); second quartile, HR 1.08 (95% CI, 1.05-1.12); third quartile, HR 1.07 (95% CI, 1.04-1.10) (Table 4).

Although low hospital volumes were associated with long-term mortality beyond 6 months, patient characteristics were also strongly associated with survival. Patients undergoing concomitant CABG or other valve surgery (HR, 1.14; 95% CI, 1.11-1.16; and HR, 1.20; 95% CI, 1.18-1.23) were also at increased risk for long-term mortality. Similarly, patients presenting with an urgent admission status were at greater risk (HR, 1.10; 95% CI, 1.08-1.13) (Table 4). Additional patient characteristics predictive of long-term mortality included history of COPD (HR, 1.52; 95% CI, 1.48-1.55), renal failure (HR, 1.78; 95% CI,

1.72-1.83), and age 75 years or more (HR, 1.54; 95% CI, 1.51-1.57).

DISCUSSION

In this large, national study using the Medicare database, we examined the association between hospital annual volume of Medicare mitral procedures, mitral repair rates, and mortality. A critically important observation in this study was the relatively small number of mitral valve procedures performed in elderly patients at most US hospitals. Most of these hospitals (83.9%) performed 10 or less mitral repairs per year in this cohort of Medicare beneficiaries with a median age of 75 years. After accounting for several patient and treatment characteristics associated with 30-day and long-term mortality, we found a significant association between hospital volume of mitral procedures and outcomes. The hospital groups with the lowest volume (≤ 5 and 6-10 mitral procedures per year) had substantially worse short- and long-term survival than higher-volume hospitals (>40 mitral cases per year). Similarly, lower annual hospital mitral valve repair rates were also independently predictive of higher operative and long-term mortality in this Medicare population.

Our findings support and extend previous reports suggesting specific volume thresholds for hospitals wishing to perform mitral valve surgery. Bridgewater and colleagues⁵ recommended a minimum annual volume of 50 mitral valve repairs for hospitals performing mitral valve repair. In a previous study using data from the Nationwide Inpatient Sample (NIS) database,⁶ we found that less than 20% of the hospitals performed more than 50 mitral procedures per year, and only 7% of the hospitals performed more than 50 mitral repairs per year. High-volume mitral valve centers are not evenly distributed across the United States, raising concerns that volume restrictions could limit access to care unless regional referral networks are developed. Such networks would affect the elderly in particular, because those in more geographically isolated areas might have to travel hundreds of miles to undergo surgery.

The low repair rates in this cohort are disappointing. This study included all hospitals in the United States that use Medicare. Most hospitals in the United States perform a limited number of mitral valve operations, and especially mitral valve repair, on elderly patients. Although the prevalence of mitral valve disease increases with age such that by age 75 years, it affects a significant portion of the population, only 5.6% of the hospitals in our study cohort performed more than 20 mitral repairs per year.⁷ The reasons for these findings cannot be studied using this administrative database.

Beyond our observations of overall mitral valve procedures, we also found significant variations in the use of mitral valve repair, with greater rates of repair observed in hospitals with higher annual volumes of mitral procedures. The ability to perform mitral valve repair is

considered an important quality measure in mitral valve surgery. We found that lower repair rates were independently predictive of higher operative mortality and lower long-term survival. These data bear direct relevance to the recently proposed CMS guidelines for coverage for transcatheter mitral valve repair. The proposed guidelines of at least 25 total mitral valve procedures in the previous year of which at least 10 must be mitral valve repairs, is an exceedingly low threshold that will likely allow dissemination of this technology to centers with suboptimal mitral experience and higher mortality rates. Whether patients seen at these centers are more likely to be referred to transcatheter mitral repair because of a lack of expert mitral repair surgeons remains to be seen.

The results of this investigation should be interpreted in the context of several potential limitations. The volumes of mitral procedures reported here are only reflective of mitral valve operations in the Medicare population. This offers a partial explanation for the low volumes of mitral procedures, especially mitral repairs, in this cohort. Nevertheless, because most patients in this age group have Medicare as a primary payer, this is an excellent representation of the true repair rates in the elderly, especially because the median age of this cohort was 75 years. We also examined the annual volume of mitral valve procedures across hospitals from the NIS data (all payers) for patients 65 years of age or older. The median across these hospitals ($n = 891$) was 11 (IQR, 5-23; 10th percentile, 2; 90th percentile, 42). For the MedPar data ($n = 1239$), the median annual volume was 10 (IQR, 4.5-19.5; 10th percentile, 2.4; 90th percentile, 37.3). Therefore, although without a doubt, the Medicare volumes represent a fraction of the hospital volumes of mitral procedures, these data would suggest that for patient age 65 years and older the Medicare database captures most of the mitral valve operations in the United States. In order to more accurately gauge the true level of experience level, we then looked at the NIS data to determine annual volumes of mitral procedures based on patients of all ages. The median annual volume across these hospitals ($n = 904$) was 20.5 (IQR, 9.0-40.4; 10th percentile, 4; 90th percentile, 78). The correlation between annual volumes based on patients of all ages and based on patients aged 65 years or more having Medicare as the primary payer was $r = 0.96$. Thus, on average, the real volume of mitral procedures (experience level) at hospitals may be almost twice that calculated from the MedPar data; however, it would seem that hospitals with a higher overall volume of mitral procedures also tend to have higher volumes of Medicare patients undergoing mitral procedures.

The greater burden of comorbidities and higher perioperative risk in the elderly would support the development of volume thresholds as a marker of quality in this population. Nevertheless, our description of low volumes of procedures in this Medicare cohort may not be a good indication of the

quality of programs that provide substantial numbers of mitral valve procedures to younger patients. Despite this potential limitation, we did observe a strong volume-outcome relationship for the older population. An additional concern is that we relied on administrative data to assess comorbidities and could not account for the severity of various comorbidities or the cause of mitral valve disease. Given that different causes of disease, such as degenerative mitral regurgitation, can be associated with significantly higher repair rates than other causes such as endocarditis, end-stage renal disease, rheumatic disease, or lupus,^{2,8-10} we are limited in our ability to explain the reasons why replacement rather than repair was chosen as the treatment strategy. We also did not have access to the patients' preprocedural health status, which has previously been shown to be associated with periprocedural mortality.¹¹ Future studies that incorporate echocardiographic and intraoperative information may better address the potential selection biases between alternative treatment strategies. We were, however, able to account for some patient characteristics that are negatively associated with the performance of mitral valve repair, such as older age, urgent or emergency status, race, socioeconomic status, and female gender.¹²⁻¹⁵

The purpose of an administrative database such as Medicare is to gather billing data and therefore it does not provide as much clinical detail compared with the STS database. However, it does have the potential to capture most patients aged 65 years and older and provides data that are free of inclusion bias related to differing hospital outcomes for participating versus nonparticipating hospitals in the STS database. In addition, we cannot exclude potential unmeasured confounders associated with hospital volumes that might account for some of our observations. We cannot provide a specific volume that may be used as a cut-off to examine and compare hospital outcomes. Professional societies and health care planners will need to consider these data in the context of other economic, access to care, and health planning issues to develop rational criteria for using treatment volumes in the elderly as a potential performance measure of quality.

Although we have performed a descriptive analysis of the association between hospital volume of mitral procedures, repair rates, and outcomes in the Medicare population, we cannot make any conclusions regarding causation. Although it is plausible that higher volumes lead to improved outcomes (the learning curve), it is also possible that hospitals with improved outcomes gain volume over time (the selective referral mechanism).¹⁶

In conclusion, we found that mitral valve repair rates and mortality in the Medicare population vary by hospital annual volume of mitral procedures and that most hospitals have a limited experience in treating elderly patients with mitral valve disease. We found a significant increase in mitral repair rates and a decrease in mortality as a function of

hospital annual volume of mitral procedures. After accounting for differences in hospital volume of mitral procedures, annual hospital mitral repair rates were also independently predictive of operative mortality. Future work is needed in order to consider performance measures or regional health care planning as potential vehicles for improving outcomes.

Conflict of Interest Statement

Authors have nothing to disclose with regard to commercial support.

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Key words: mitral valve, surgery, hospital volume, outcome research

TABLE E1. ICD-9-CM codes used for exclusions

Exclusions	ICD-9-CM codes
Closed heart valvuloplasty	35.00, 35.01, 35.02, 35.03, 35.04
Congenital anomaly	35.8, 35.4, 35.53, 35.54, 35.62, 35.63, 35.9, 39.0, 39.21
Heart transplant	37.51
Awaiting transplant	V49.83
History of heart transplant	V42.1
History of ventricular support procedures	37.52, 37.62, 37.64, 37.65, 37.66, 37.68, 39.65, 39.66, 97.44
Implantation of external support device	37.41
History of ventricular assist device or artificial heart	V43.21, V43.22
Excision of ventricular aneurysm	37.32, 37.35, 37.49
Replacement of thoracic aorta	38.45
Aortic fenestration	39.54
Concomitant carotid endarterectomy	38.12
Rupture of papillary muscle	429.6
Repair or replacement, unspecified valve	35.10, 35.20

ICD-9-CM, International Classification of Diseases, Ninth Edition, Clinical Modification.

ATTACHMENT 9

VII. HOSPITAL VOLUME AND CORONARY ARTERY BYPASS GRAFT SURGERY OUTCOMES

The association between the quantity of care that a physician or hospital provides and the quality of care that patients receive has been intensely investigated by clinicians and health services researchers. In the majority of the published data investigating this relationship, researchers have generally found that the higher the number of patients a physician or hospital treats with a specific condition, the better, on average, the patients' health outcomes. This "volume-outcome" relationship has been documented for a wide variety of medical conditions and surgical procedures at several levels of care, including the physician, clinical team, and hospital level. In a report reviewing the volume-outcome relationship, published by the Institute of Medicine (Hewitt, 2000), the author noted that 77% of the published volume-outcome studies demonstrate a significant relationship between higher physician and hospital volumes and better health outcomes. In fact, in this Institute of Medicine review, no studies were found to demonstrate a significant negative relationship between higher volumes and outcomes (i.e., resulted in worse health outcomes).

The volume-outcome relationship has been most extensively studied for patients receiving coronary artery bypass graft (CABG) surgery. This observed relationship could imply that regionalizing services, thereby increasing average physician and hospital volumes, would improve the quality of healthcare. Whereas most of these studies found that hospitals performing more CABG surgeries had better outcomes, the policy significance of this relationship remains controversial. Many question the magnitude of the CABG volume-outcome association since several recent studies using more robust statistical methods have failed to find a clinically significant relationship (Peterson, 2004; Shahian, 2001; Christiansen, 1997; Kalant, 2004; Panageas, 2003).

CCMRP 2000-2002 Analyses

The following analyses and report examine the volume-outcome relationship in CABG surgery using the California CABG Mortality Reporting Program (CCMRP) data from 2000 to 2002. The primary goal of these analyses is to use the most current methodological techniques to determine whether hospitals performing more CABG surgeries have lower risk-adjusted mortality than hospitals performing fewer CABG surgeries in California.

First, a patient-level risk-adjusted mortality prediction model was developed using a hierarchical or multi-level technique. Hierarchical models (also referred to as multi-level models, random or mixed-effect models, and random coefficient/intercept regression models) are increasingly used in health services research to analyze multi-level data, particularly when analyses are done on patient data from many hospitals. These models are more appropriate than traditional patient-level models for making inferences at the hospital level because they adjust for the "clustering" of patients (Shahian, 2001; Christiansen, 1997; Leyland, 2003; Burgess, 2000). Specifically, it is known that patients are not randomly distributed among all hospitals and that similar patients are cared for at similar hospitals. These techniques adjust for non-randomly distributed, unmeasured characteristics that contribute to a patient's CABG mortality rate. All of these characteristics could contribute to a hospital's observed CABG mortality rate that may not be accounted for in a traditional patient-level logistic regression model. Not accounting for some of these factors, particularly patient-level factors, may cause a hospital's CABG mortality rate to appear better or worse than it should be. For example, if one hospital treats more patients from lower socioeconomic neighborhoods (a factor not accounted for in the mortality risk model but

known to be associated with CABG mortality), this so called “clustering” of such patients may increase the observed mortality rate of this hospital, thereby resulting in a higher than expected “observed-to-expected” (O/E) mortality ratio.

To demonstrate the validity and reliability of the hierarchical model, it was compared to the mortality prediction model developed using traditional logistic regression. Then, to assess the relationship between hospital CABG volume and mortality, annual hospital volume was first included as a continuous independent variable in both the traditional logistic regression and the hierarchical logistic regression models (using a random intercepts model). Second, to visualize the hospital volume-outcome relationship, the hierarchical model was used to plot the O/E ratio for each hospital against its annualized volume over the three years. Third, hospitals were grouped into volume categories depending upon the number of CABG procedures performed on average over the three years. Then, these categories were included as indicator variables in the hierarchical logistic regression to determine whether the different volume categories were significantly associated with higher or lower mortality.

Results

The CCMRP CABG database contains detailed patient-level clinical data on 57,388 isolated CABG surgery procedures in 83 hospitals in California from 2000 to 2002.⁷ The average annual hospital CABG volume was 251 cases, with a range among individual hospitals of 39 to 1,277. The overall inpatient mortality rate was 2.71%, and the average hospital mortality rate was 3.30%, with a range among individual hospitals of 0.86% to 12.12%. On average, mean predicted mortality rates were higher among low-volume hospitals than among high-volume hospitals, which is consistent with previous data.

The hierarchical model resulted in very little change of the patient-level coefficients from the standard logistic regression model. None of the independent variables changed with respect to the direction of their association with mortality. In the hierarchical model, when annualized hospital volume was entered into the analysis as a continuous variable, it was significantly associated with risk-adjusted mortality (coefficient of -0.0007, odds ratio of 0.9994, and p-value of 0.0026 for every additional patient). For example, for a hospital with state average volume per year (n=251), adding 100 more CABG procedures would reduce the in-hospital mortality rate by 0.08%.

The expected number of deaths at each hospital was calculated by summing the probabilities of death for all patients at each hospital, using the hierarchical model. The observed-to-expected (O/E) ratios were then plotted against annualized volume for the three years of data. These plots are shown in Figure 4. Each dot in the figure identifies a single hospital. The mean O/E ratio computed using the hierarchical logistic regression model was 1.021, with a range of 0.426 to 1.512. Figure 4 reveals that higher volume CABG hospitals tend to cluster around an O/E of 1.0, with less variation in performance as compared to hospitals with annual volumes below 200, where there is significant variation in performance results. Further, Figure 4 demonstrates that not all low volume hospitals have higher severity-adjusted mortality rates, and in fact, some low volume hospitals have very low severity-adjusted mortality rates.

⁷ Six hospitals submitted data for at least one complete year but did not want their results published.

Figure 4: Plot of Observed to Expected (O/E) Ratio Versus Annualized Hospital Volume Using Results from the Hierarchical Logistic Regression Model

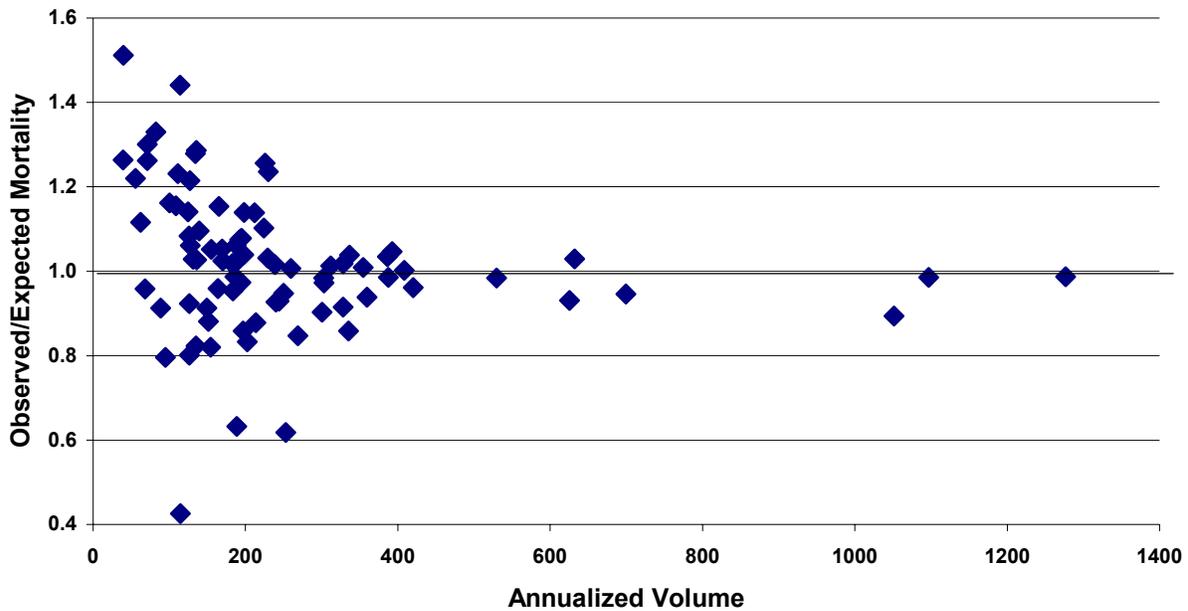


Table 6 presents the summary statistics when hospital volume was categorized into quartiles (<200, 200-299, 300-599, >=600) and dichotomized (>=450 and <450; and >=250 and <250). The quartiles were chosen because these volumes were used in the previous CCMRP report and because these cut-points split the data into four groups with a similar numbers of cases in each group. The split point of 450 procedures per year was chosen because of current recommendations by The Leapfrog Group (www.leapfroggroup.org). Again, the data show that patients face a reduced risk of dying from a CABG procedure in hospitals with higher annual volumes of CABG surgeries.

Table 6: Hospital Volume Groups and Predicted Mortality Outcomes

Volume Group	Hospitals (n=83) N (%)	Patients (n=57,387) N (%)	OR (95% CI)
>=600	6 (7)	16,145 (28)	0.56 (0.40, 0.79)
300-599	16 (19)	17,052 (30)	0.80 (0.63, 1.02)
200-299	14 (17)	8,168 (14)	0.74 (0.57, 0.97)
<200	47 (57)	16,022 (28)	Reference
>=450	7 (8)	17,734 (31)	0.65 (0.47, 0.89)
<450	76 (92)	39,653 (69)	Reference
>=250	26 (31)	35,286 (61)	0.73 (0.59, 0.89)
<250	57 (69)	22,101 (39)	Reference

What are the policy implications of these results? If, for example, all CABG patients went to hospitals with an annual volume of ≥ 250 cases, an overall reduction in predicted mortality of 0.51% would result. In other words, assuming 25,000 CABG procedures are conducted each year, 50 lives would be saved annually. If all CABG patients went to hospitals in the ≥ 450 volume group, a reduction in predicted mortality of 0.64% would result, or 110 lives saved annually. These projections assume that the higher-volume hospitals would continue to perform at their current standard of quality given increased volume.

ATTACHMENT 10

Welcome Back, Volume—the Original Quality Measure

Cheryl Clark, for HealthLeaders Media , May 21, 2015

After a decade in which physicians and observers focused on processes and outcomes, the pendulum is swinging back toward viewing volume as the best barometer of hospital quality.

Welcome back, Procedural Volume.

Your popularity as a way to measure hospital quality—that the more procedures a hospital or doctor does, the lower risk of complications and vice versa—has been on the wane. But now you're trending back up. Good for you.

Here's why:

- On Wednesday, *U.S. News & World Report* published, as part of its annual Best Hospitals report, a special new set of ratings that evaluate hospital performance in five common surgical procedures and medical conditions. The expanded report, [Best Hospitals for Common Care](#), found that patients who receive these procedures at low-volume hospitals have a much higher risk of death or complications, while patients at higher-volume facilities have a reduced risk.
- On Tuesday, Dartmouth-Hitchcock Medical Center, The Johns Hopkins Hospital and Health System, and the University of Michigan Health System announced their ["Take the Volume Pledge" program](#). They will restrict their 20 hospitals and surgeons from performing any of 10 procedures if they don't do a minimum amount per year. They also encourage other hospitals to adopt similar policies, perhaps as a condition for granting physician staff privilege.
- The Centers for Medicare & Medicaid Services has begun posting on a [new Hospital Compare tab](#) the number of Medicare beneficiaries who received care for any of 64 medical conditions or surgeries at various levels of complexity. The idea is that an especially fragile patient may require a hospital with experience treating a more complex case.

"There is a pendulum swing back toward paying attention to the volume/outcome story now," says John Birkmeyer, MD, a surgeon, outcomes researcher, and executive vice president for enterprise support services at Dartmouth-Hitchcock.

So procedural volume is officially back in the game. Or maybe we're just re-recognizing volume with much more appreciation for the important role it plays.

Volume has had an interesting journey since it first came on the scene in 2001.

That's when the Leapfrog Group's survey, in an effort to help employers and patients make better choices about hospital care, became the first advocacy group to include procedural volume as a proxy for quality of care.

Leapfrog scored reporting hospitals on how often they performed six procedures, setting minimum numbers for each necessary for proficiency: coronary artery bypass grafts, coronary angioplasty, carotid endarterectomy, esophageal cancer surgery, abdominal aortic aneurysm repair, and high-risk obstetrics. Later came aortic valve repairs and pancreatectomies.

Leapfrog's move, which President Leah Binder says garnered criticism at the time, was based on numerous studies published in the *New England Journal of Medicine* and other journals showing that procedure volume was just about the best quality measure going at the time, other than mortality, the ultimate outcome measure. Dozens of other quality measures were added in later years, diluting the impact of volume, but procedural volume persisted.

Birkmeyer, who has written many papers linking higher volume to better outcomes and advised Leapfrog in its move to use volume to guide choice of care, recalls those days as having "a huge flurry of attention to this from the lay media and professional [physician] societies. But over the next few years, volume as a measure for outcomes moved to the back burner."

That was partly because "the professional societies—the physician guilds—were successful in arguing that volume is just a proxy of quality and we should really measure outcomes and more direct measures of quality," for example infection rates or reoperation rates, "rather than getting so distracted with volume."

What followed was a new emphasis on process measures, such as timely administration of clot-busting drugs to heart attack patients, or giving surgical patients timely antibiotics, which correlate with greater success.



John Birkmeyer, MD

With the passage of the Patient Protection and Affordable Care Act in 2010, new penalty programs added readmission rates, patient experience survey scores, and infections to the equation of what determines high quality. And today, those measures are associated with adjustments to hospital pay that can represent nearly 6% of a hospital's annual reimbursement from Medicare.

Today, many of those measures are under fire as hospital officials point out bias or flaws. Counting avoidable 30-day readmission rates is controversial because it lacks an adjustment for socioeconomic status and unfairly punishes hospitals that treat the poor. Thirty-day mortality is important, but carries a low weight in the scoring formula, and may be more sensitive to patient comorbidities than the adjustment factor shows, some argue.

Last year, the Centers for Disease Control and Prevention acknowledged, and corrected this year, its measures for counting central line bloodstream and catheter-associated urinary tract infections. Previously, they were too vague and allowed too much interpretation and subjectivity, leaving hospitals to interpret what qualified and what didn't. Plus, thousands of hospitals didn't have enough cases to reach statistical significance.

Now, the CDC has [clarified those infection reporting definitions](#). But hospital officials still argue they'll never get to zero, and what is a reasonable rate of hospital-acquired infections for different kinds of facilities remains in dispute.

So we're back to volume.

"Despite all the best intentions, consumers/patients still have a real paucity of information about comparative quality of surgeons and hospitals for elective but high-risk things," Birkmeyer says. "So the promise of better quality measures never really got there, certainly in any way that's meaningful to patients or leads to better choices."

So what is it about volume that makes it such a good measure for quality?

Ashish Jha, MD, director of the Harvard Global Health Institute, and a hospitalist at the *VA Boston* Healthcare System, agrees that volume is on the rebound. "But we're swinging back with a far greater sophistication of why volume is important than just 'practice makes perfect,' which is what we thought 15 years ago. It may be related more toward other components that come with larger volumes, such as more nurses per patient, better nutrition programs, or even having important equipment like a PET scanner."

Birkmeyer says Jha is "exactly right."

"It may have to do, too, with having a more coordinated team that surrounds the surgeon and is there after surgery," Birkmeyer says. "It means the scrub nurses and the anesthesiologists and other teams work well."

"And that if you're seeing a condition often enough, you're able to make good judgments about who needs surgery in the first place, and obviously making sure you do those surgeries well."

"It may be the team is good at not just avoiding complications but in rescuing patients when things start to go sour. With greater procedural volume, you become more adept in seeing when something isn't right, and taking the right steps toward pulling a patient out of the fire."

That's why for Birkmeyer and Binder—and perhaps patients—volume never really went away.

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ATTACHMENT 11

6/3/15 U.S. News & World Rep. (Pg. Unavail. Online)
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U.S. News & World Report
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June 3, 2015

Section: Opinion

Low Volume Hospitals Create Big Risks for Surgery Patients

Peter Pronovost

Correction 06/04/15: An earlier version of this blog post misstated the number of hip replacements and the resulting mortality rates at low-volume hospitals.

Imagine you were seeking major surgery, and the hospital's consent form contained this surprise statement, which you were asked to initial: "I understand that this surgeon and hospital have not performed this procedure in the last 12 months. As such, I accept the greater risk of complications and even death."

It's hard to believe that you would sign the form and move forward with the surgery.

However, that's the decision that some patients unwittingly make when they agree to high-risk procedures by surgeons with insufficient experience in performing them, or in hospitals where they are not commonly done. For decades, evidence has shown that mortality is lower, and outcomes are better, when you seek certain procedures from physicians and hospital teams with more practice doing them. And yet, complex surgeries such as pancreas and esophagus resections are done too often in hospitals that may have done none or one in the previous year.

Recent articles in U.S. News & World Report highlighted this connection between volume and outcomes, focusing on five common procedures and conditions. For example, as many as 11,000 lives of Medicare patients could have been saved between 2010 and 2012 if patients received treatment at the highest-volume fifth of the hospitals instead of the lowest-volume fifth.

READ: [[When Health Care Cost Studies Get the Facts Wrong](#)]

The differences in volumes and outcomes are staggering. For example, low-volume hospitals perform about 35 hip replacements a year and have mortality rates that are 48 percent higher than expected, according to U.S. News. High-volume hospitals, on the other hand, performed 430 hip replacements a year, with mortality rates 15 percent lower than expected.

Nobody has done anything about this problem -- not hospitals, individual surgeons or regulatory organizations such as The Joint Commission or Centers for Medicare and Medicaid Services. But last week, the leaders of three health care systems -- Dartmouth-Hitchcock Medical Center, University of Michigan Health System and Johns Hopkins Medicine -- announced that we planned to take action. We selected 10 high-risk procedures for which the link between volume and mortality is strongest

and decided that we would not perform them if our hospitals did not meet certain thresholds. Likewise, we would not allow our surgeons to do these surgeries unless they performed a minimum number of them every year.

These are conservative thresholds, which would remove hospitals and surgeons in the lowest fifth by volume of procedures. And yet doing so for these 10 procedures alone would save 1,300 lives a year, according to an analysis by Dartmouth surgical outcomes expert John Birkmeyer.

READ: [[How the Uber Model Could Transform U.S. Health Care](#)]

Without a doubt, surgery is complicated, requiring the skilled coordination of teams in the operating room, recovery unit, intensive care unit and elsewhere. We can't reduce surgical quality to the person holding the scalpel or a hospital's name. Yet we also can't ignore what the evidence tells us about the importance of meeting minimum volumes for certain procedures.

At each of our hospital systems, the chairs of the departments of surgery and the division leads of the surgeons for each type of surgery all agreed that this change needs to happen. And you would think that we can just make it so, but we can't. There's a hitch: We need the vote of our hospital's physicians.

Regulations by CMS and The Joint Commission give a hospital's medical staff the power to place constraints on physicians such as meeting certain volume requirements. These rules require that physicians be self-governing, meaning that for every hospital wishing to adopt these standards, the chair of surgery must make a recommendation to their medical executive committee -- the physician leadership of the hospital -- who must vote to approve this change. This process would need to be repeated at each of the nation's more than 5,000 hospitals. (One exception: Hospital leaders may decide that their facility will not perform certain elective procedures under any circumstance, in which case physician approval is not required.)

READ: [[Why Doctors Still Perform Unnecessary Medical Tests](#)]

On one hand, letting physicians govern themselves is wise. It respects their unique knowledge of their field. Indeed, when I discussed these thresholds with surgeons and other physicians, they identified important nuances that must be included in the plan. For example, we must make accommodations for new surgeons by having them mentored. Perhaps we could apply the surgeries that they do under mentors toward meeting the minimum number of cases. We must account for surgeons who performed high volumes of a surgery for many years and then take a yearlong sabbatical.

Yet on the other hand, relying solely on physician committees to police themselves is at best a long, slow and uncertain process. The evidence for a strong volume-outcome relationship has been around since 1979, and yet some physicians categorically oppose any constraints on practice. Further, it may be in the financial interest of the doctors and hospitals to keep doing these high-revenue procedures. Such factors reduce the likelihood that medical executive committees will approve new rules. Perhaps we need a balanced approach, in which corporate health systems gain power to create policies for volume thresholds within their hospitals, and hospital leaders can support policies that reduce risks to patients.

Hospital leaders who pursue these volume thresholds should do so thoughtfully and with caution. They should reserve such constraints for procedures in which the evidence of patient benefit is strongest. They should work collaboratively with medical staff on these policies and actively seek to identify and mitigate any unintended consequences.

READ: [[America Is Neglecting Its Addiction Problem](#)]

Can we expect hospitals and physicians to place constraints on themselves? If we're skeptical, an alternative would be for CMS or The Joint Commission to require that hospitals have minimum volume thresholds for high-risk procedures, when the evidence supports it. There is precedent for such a move: No hospitals can perform organ transplants without obtaining CMS approval.

I've seen the need for this revolution first hand. Several years ago I cared for "Mrs. K," an elderly patient who had been transferred to Johns Hopkins after an esophagus cancer resection at a nearby hospital and eventually died. The surgery had gone terribly wrong, and she had not been informed that the hospital had performed just one esophagectomy the year before.

If you think this is a rare occurrence, think again. In the Leapfrog Group's annual Hospital Survey, one-third of the hospitals that reported that they offered elective esophagectomies in 2013 performed either one or two that year. It's doubtful that those hospitals' patients were informed that they were taking a risk. Just 10 percent of the hospitals did 20 or more esophagectomies -- the hospital-level threshold that our three health systems announced that they would adopt for this procedure. While the Leapfrog survey's respondents are a self-selected group, representing about a third of all U.S. hospitals, these numbers hint at the extent of the problem.

READ: [The Republicans' King v. Burwell Problem]

This issue brings up a consistent challenge when it comes to patient safety. Even though thousands of people may die one at a time, alone in a hospital, it gets less attention from the public and policymakers than a smaller number of deaths from train accidents, mining accident or defective car parts. When these other tragedies occur, they receive immediate congressional and public attention, and actions are taken as a result. Twisted metal gets more attention than twisted bodies, it seems.

Perhaps this is because, unlike in Mrs. K's case, we don't always see firsthand when patients could have fared better if they went to high-volume hospitals for procedures. Statistically, the low-volume providers have higher mortality, more complications and higher readmission rates. But because these providers have so few cases, it may be years before they get a stable estimate of their facility's mortality or complication rates -- if they're looking.

It shouldn't matter. It is time that these often faceless victims get the same public outrage and attention of policymakers as other causes of preventable harm.

Peter Pronovost is director of the Armstrong Institute for Patient Safety and Quality and senior vice president for patient safety and quality at Johns Hopkins Medicine. A practicing anesthesiologist and critical care physician dedicated to making hospitals and health care safer for patients, Pronovost also posts on the Armstrong Institute blog, Voices for Safer Care .

---- Index References ----

Industry: (Clinical Outcomes (1CL11); Healthcare (1HE06); Healthcare Service Providers (1HE78); Healthcare Services (1HE13); Hospital Administration (1HO60); Hospitals (1HO39); Medical Devices (1ME31); Mortality Rates (1MO15); Orthopedic Devices & Instrumentation (1OR11))

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NewsRoom

ATTACHMENT 12



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Risks Are High at Low-Volume Hospitals

Patients at thousands of hospitals face greater risks from common operations, simply because the surgical teams don't get enough practice.



As many as 11,000 deaths may have been prevented between 2010 and 2012 if patients who went to the lowest-volume fifth of the hospitals had gone to the highest-volume fifth.

By [Steve Sternberg](#) and [Geoff Dougherty](#)

May 18, 2015 | 12:01 a.m. EDT

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Like other hospitals in thinly populated areas, Sterling Regional Medical Center does a bit of everything. The 25-bed Colorado hospital has its own heliport, delivers about 200 babies a year and admits more than 1,200 patients for a variety of conditions and procedures. Replacing worn and painful hips and knees is among them. To patients, the surgery may seem perfectly routine.

Joint replacements are anything but routine at hospitals that don't do many of them, a new U.S. News analysis shows. Sterling is among thousands of U.S. medical centers whose patients face a greater risk of death and complications because their surgical teams do too few procedures, even common ones, for doctors, nurses and technicians to maintain their skills.

These large numbers of low-volume hospitals, the analysis found, continue to put patients at higher risk even after three decades of published research have demonstrated that patients are more likely to die or suffer complications when treated by doctors who only occasionally see similar patients rather than by experienced teams at hospitals with more patients and established protocols.

Elective hip and knee replacements are a prime example. Many urban centers routinely do hundreds a year. At Sterling, the three-year total for Medicare inpatients from 2010 through 2012 was 29 hips and 52 knees. And while the death rate for these operations is about 1 in 1,000 nationally, Medicare data in the U.S. News analysis show that the relative risk of death for the hospital's elective knee replacement patients was 24 times the national average and three times the national average for hip replacement patients.



RELATED

Low Volume Hospitals: What to Ask

"You can save your life by picking the right place," says Leah Binder, director of the Leapfrog Group, a consortium of major employers that emphasizes safety in measuring hospital performance.

A calculation by Dr. John Birkmeyer, a surgeon who has produced pioneering research on the effect of patient volume, underscores the point. Using the U.S. News analysis, he determined that as many as 11,000 deaths nationally might have been prevented from 2010 through 2012 over the three years analyzed if patients who went to the lowest-volume fifth of the hospitals had gone to the highest-volume fifth.

The data Birkmeyer used for his calculations covered only five common procedures and conditions. If a full range of commonplace operations and medical conditions had been included, adds Birkmeyer, executive vice president for enterprise services and the chief academic officer at Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire, "tens of thousands" of deaths could potentially have been averted.

The U.S. News analysis was conducted as part of a new set of hospital ratings, Best Hospitals for Common Care, to be launched Wednesday. The first set of ratings will evaluate hospital performance in caring for traditional Medicare fee-for-service patients, in five procedures: bypass surgery without valve repair or replacement, elective hip and knee replacement, congestive heart failure and chronic obstructive pulmonary disease. The project's goal is to enable users to see how well their local hospitals care for patients who do not require the highest level of medical expertise and technology.

The analysis, conducted in collaboration with Dr Foster, a London-based global health analytics firm, unearthed low volumes and troubling outcomes at hospitals many times larger than Sterling. At 331-bed Lawnwood Regional Medical Center & Heart Institute in Ft. Pierce, Florida, the relative risk of dying following a hip replacement was nine times the national average. At 316-bed Jersey City Medical Center in New Jersey, the risk for patients who had heart bypass surgery (none involving valve replacement or repair) was four times higher than average.

Representatives from Sterling Regional and the other higher-risk hospitals highlighted in the analysis responded that they could not confirm any of the deaths. It is possible that all of the deaths occurred elsewhere, or at other hospitals, after the patients had been discharged from the facilities where they received initial care but within 30 days of their original admission. But attributing treatment-related deaths to the hospitals where patients were first admitted and adjusting for differences in each hospital's mix of patients is standard practice in analyzing health data.

Sterling spokeswoman Sara Quale said the hospital declined to comment on the specifics of the analysis because officials could not track the patients in the hospital's records. Lawnwood spokeswoman Ronda Wilburn said the hospital's "30-day post-discharge outcomes are in line with national mortality rates" posted on Medicare's [Hospital Compare website](#). The mortality rates published there, however, reflect overall mortality, not the relative risk of death from low-volume procedures.

Joseph Scott, CEO of Jersey City Medical Center, acknowledged that the hospital may have had problems with its bypass surgery program during the years evaluated by U.S. News. "We have a different cardiac surgeon today than we did [then]," he says. "While [the findings] may be true between 2010 and 2012, we're always about continuous improvement and making things better."

The first large study showing an indisputable link between low volumes and poorer outcomes appeared in 1979 as a special report in the *New England Journal of Medicine*. Regardless, large numbers of hospitals continue to do small numbers of procedures. Part of the U.S. News analysis identified every

hospital across the nation that operated on or treated fewer than 25 traditional Medicare inpatients from 2010 through 2012 for nearly 20 frequent procedures and conditions.

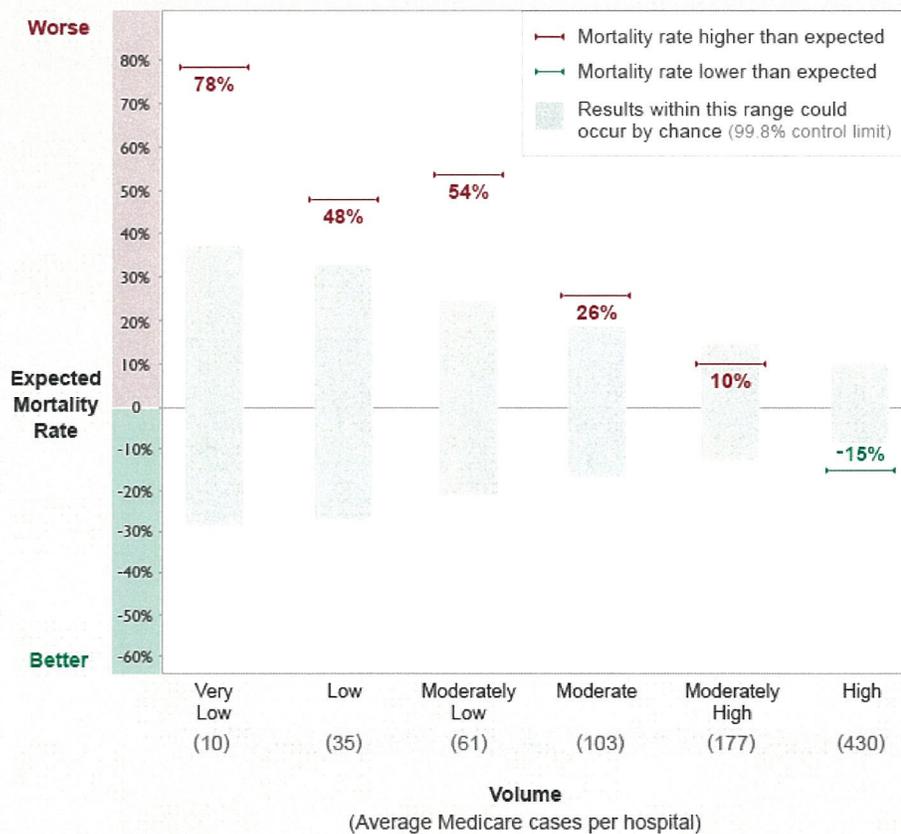
Among the findings for those ultra-low-volume hospitals:

- 1,071 performed 10,686 hip replacements, an average of 3.3 per year per hospital.
- 608 performed 6,707 knee replacements, an average of 3.7 per year.
- 124 performed basic heart bypass surgery on 1,538 patients, an average of 4.1 per year.
- 254 hospitals performed heart bypass surgery involving valve replacement or repair on 3,203 patients, an average of 4.2 per year.
- 396 hospitals treated 4,626 cases of heart failure, an average of 3.9 per year.
- 558 hospitals treated 7,174 cases of chronic obstructive pulmonary disease, an average of 4.3 per year.

Because a single death more or less would make the calculated odds jump or plummet at these hospitals, U.S. News chose not to display their overall ratings in Best Hospitals for Common Care unless such a hospital had had five or more deaths in a procedure or condition.

Nevertheless, taken together, the risk posed by ultra-low-volume hospitals is unmistakable. In the U.S. News analysis, knee-replacement patients at the hospitals had double the national average death risk, a 25 percent higher rate of readmission because of post-discharge complications. Hip-replacement patients faced a 77 percent higher risk of death and a 25 percent higher risk of readmission.

More Cases, Fewer Deaths: Hip Replacement

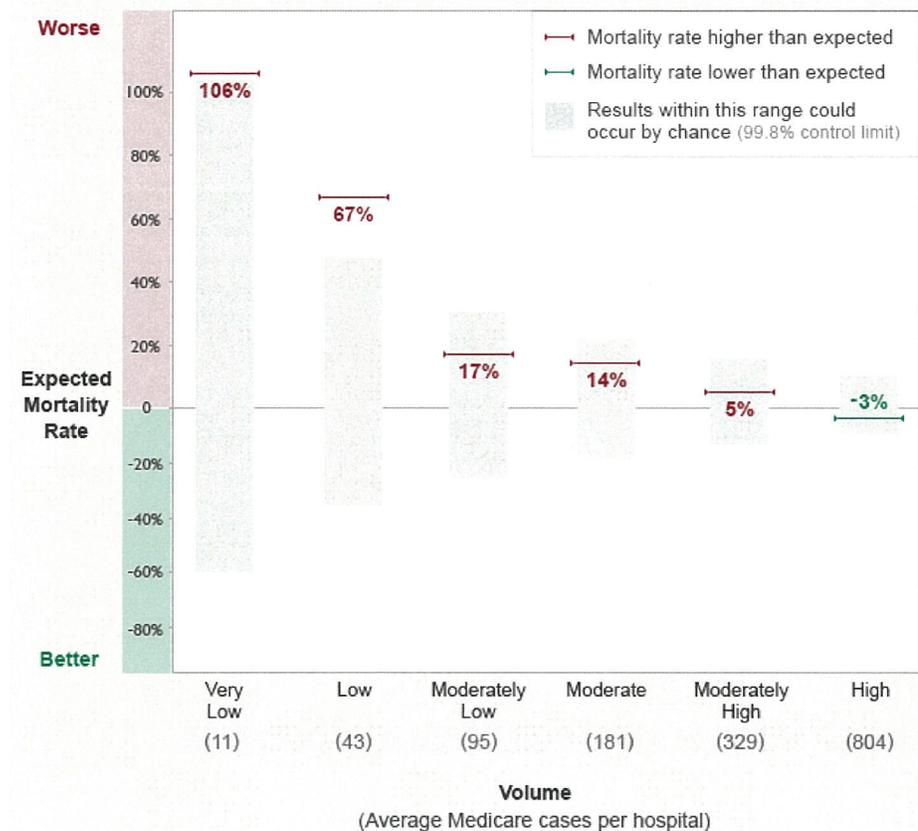


To analyze the risks presented by hospitals with volumes high enough to allow them to be individually rated, U.S. News divided all centers that treated at least 25 patients in one or more of the operations and conditions analyzed for the project into five roughly equal bands by volume. Rates of death and complications were then calculated for each band as well as an overall rating. Hospitals in the lowest-

volume quintile for knee replacement, for example, had average total volume of about 43 joints over the three years of analysis and those in the highest-volume quintile an average of 806.

Across all five operations and conditions, nearly 120,000 patients were treated at hospitals in the lowest-volume band – 39,483 for elective hip or knee replacement, 7,898 for cardiac bypass, 36,711 for heart failure patients and 34,181 for COPD.

More Cases, Fewer Deaths: Knee Replacement



Overall, knee replacement patients who had their surgery in in the lowest-volume centers were nearly 70 percent more likely to die than patients treated at centers in the top quintile. For hip replacement patients, the risk was nearly 50 percent higher. Patients with congestive heart failure and chronic obstructive pulmonary disease had a 20 percent increased risk of dying.

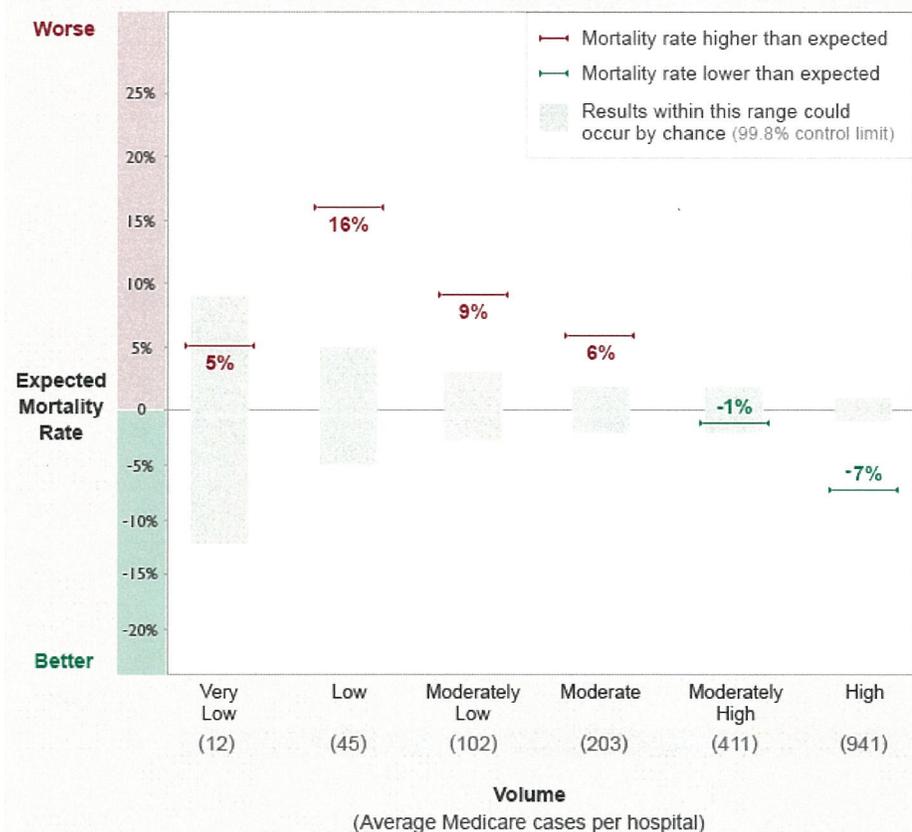
Few patients ask how many similar cases a hospital, let alone an individual doctor, has treated, says Dr. David Jevsevar, an orthopedic surgeon at Dartmouth-Hitchcock. "Are patients aware that they're going to a hospital that has done three of these [procedures] in the last year?" he asks. "Would they feel differently if they knew?"

Perhaps not. Most patients, doctors say, feel that the more local the care, the better. Even if other hospitals are just an hour or two away, nearby care is comfortingly familiar. It avoids negotiating with a health insurer and the expense and stress, to the patient and to family members, of out-of-town care.

A study led by Dr. Samuel Finlayson of the University of Utah bears this out, showing that nearly one-fifth of patients would choose to have surgery at a local hospital with a death rate of 18 percent rather than drive two hours to a regional hospital with a death rate of 3 percent.

Besides, most of the time nothing goes wrong. But if there is a problem, good options may be few. "We can't always predict very well who's going to get into trouble," says Dr. Steven Nissen, chief of cardiology at the Cleveland Clinic. "If you're in a local institution with limited experience and things go wrong, there's no going back."

More Cases, Fewer Deaths: Heart Failure



While death is the ultimate poor outcome, low-volume care has other hazards. Patients at low-volume hospitals need to come back more often after joint replacement for revision surgery due to deep infection or mechanical failure, for example. One-year revision rates are nearly 20 percent higher among knee patients and 20 percent higher for hip patients operated on at the lowest-volume fifth of rated hospitals, the U.S. analysis found.

"If you don't do something very often and it's complicated, you're not going to do it as well as someone who makes their living doing it," says anesthesiologist Dr. Peter Pronovost, director of the Armstrong Institute for Patient Safety and Quality at Johns Hopkins Medicine.

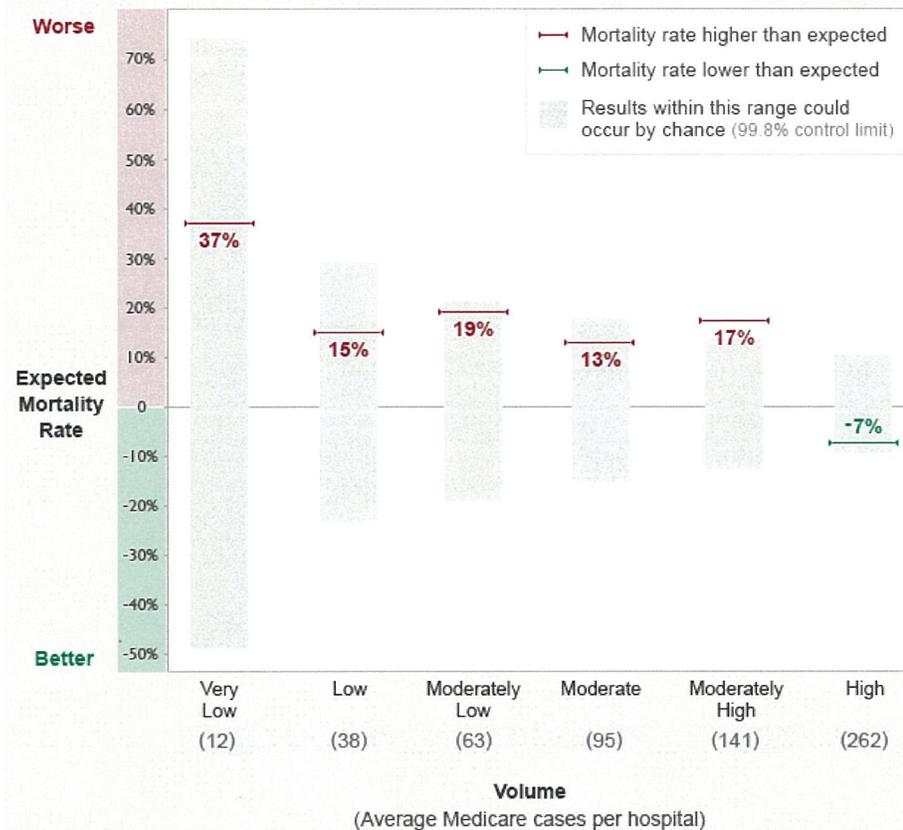
He recalls a case involving a woman who had had a diseased portion of her esophagus inexpertly removed at a hospital that does only one or two esophagectomies a year. She was transferred to Johns Hopkins, but it was too late to save her. Studies have shown that mortality for the procedure is significantly lower for patients treated in hospitals that perform as few as a dozen a year. Less than two miles away, Pronovost says, were two hospitals that each averaged about 40 a year.

"She was butchered," he says. "There's no other word for it. Yet when I asked whether the patient was told that she was at higher risk [because of the hospital's low volume], the answer was 'No.'"

The lack of accountability makes Pronovost fume. "Who's responsible for this?" he says. "Is it the physician? The hospital? State regulators? The [hospital-accrediting body] Joint Commission? Where's the accountability for informing people?"

Dr. Mark Chassin, president and CEO of the Joint Commission, the not-for-profit organization that accredits hospitals and other health care institutions, agrees that many studies, including his own, have shown a relationship between low volumes and worse outcomes. But he balks at using accreditation to discourage low-volume hospitals or surgeons from doing procedures. "I don't think thresholds or minimum requirements will change things for the better," he says. "It will reduce supply and indiscriminately remove both good and bad performers. That's not a prescription for improvement."

More Cases, Fewer Deaths: Heart Bypass Surgery



The Joint Commission's stance, says Chassin, is to leave it to individual hospitals to assure that their physicians provide high quality care. "What we've urged, and what we require, is that all hospital clinical departments set up criteria for credentialing of physicians or surgeons and take into account how well they do — track their performance" he says.

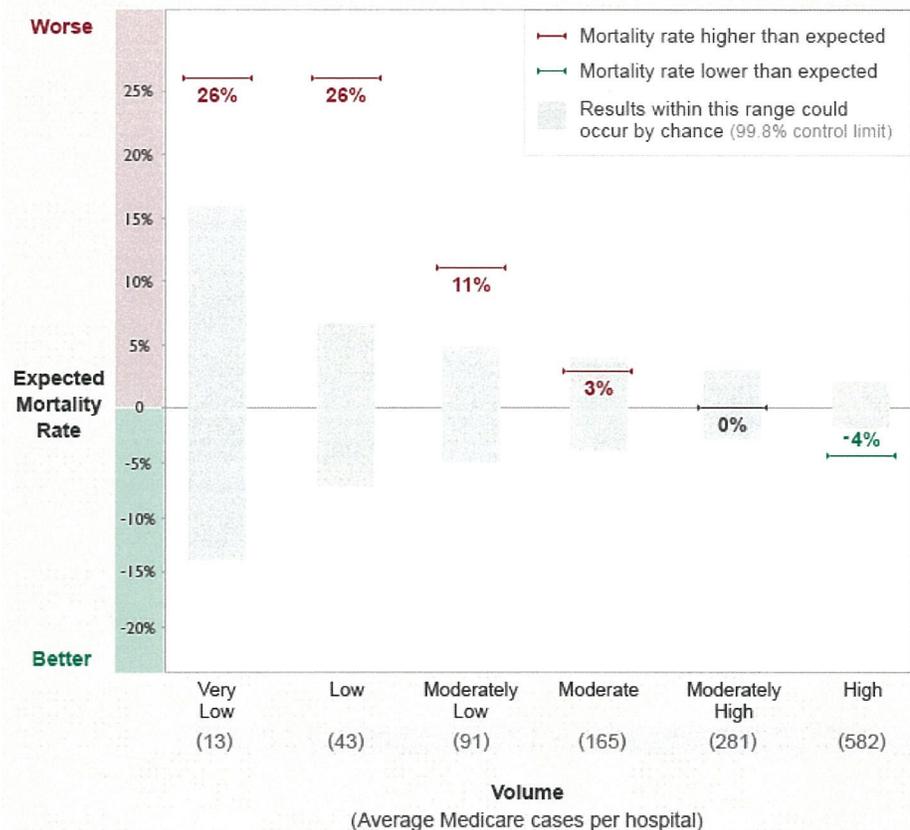
The absence of firmer measures carries consequences, says Dr. Robert Wachter, author of "The Digital Doctor: Hope, Hype and Harm at the Dawn of Medicine's Computer Age" and chief of medical service and chief of the division of hospital medicine at UCSF Medical Center in San Francisco. "In the U.S., we've traditionally propped up [low-volume] hospitals because we've felt that every city that wants a hospital should have one. These [U.S. News] data indicate that this isn't a benign choice."

Over the decades, other studies have extended the findings beyond hospitals to individual surgeons, demonstrating the Carnegie Hall principle: The more they practice, the better they do. In some procedures, such as aortic-valve replacement, says Dartmouth's Birkmeyer, physician volume is a better yardstick of performance than hospital volume.

Yet hospitals with few cases and marginally or inexperienced physicians often "discourage doctors from sending patients to other facilities," says the Cleveland Clinic's Nissen. "I frequently encounter patients who come in for a second opinion, and they'll often be pretty open about being discouraged from going somewhere else." Hospitals often depend on big-ticket procedures like heart bypass surgery and joint replacement for financial survival. A Blue Cross-Blue Shield report published in January showed that the typical joint replacement procedure is billed at more than \$30,000.

In its ratings, Leapfrog has pioneered reporting of volume-based proficiency standards for certain surgeries—the number required for a doctor, surgical team and hospital to keep skills sharp. "The average hospital does about 400 heart cases per year, and typically those hospitals would have an average of two or three surgeons," says Birkmeyer, who helped draw up the Leapfrog standards. "It would be reasonable to say that you'd want surgeons who did at least 100 [heart] cases a year and hospitals, depending on where you want to draw the line, that do 200 or 300 cases a year."

More Cases, Fewer Deaths: COPD



The relationship between higher volume and better outcomes is strong but not absolute or even a straight line. Although the risk of dying at one hospital may be far higher than at another, a patient's risk may still be low. Some low-volume centers, moreover, consistently do well; some high-volume centers do not. And some high-volume centers may operate on people who don't need surgery, says Dr. Kevin Bozic, chairman of surgery and professor of orthopedic surgery at the University of Texas in Austin. Even if such a center is highly proficient, any surgery exposes patients to risks, so someone having an unneeded operation is automatically in a higher-risk category.

Evaluation of hospital care, say Bozic and other researchers, should include volume along with other factors, preferably information derived from outcomes data like rates of deaths and complications. U.S. News has designed Best Hospitals, Best Children's Hospitals and the new Best Hospitals for Common Care around that principle. But the relationship between low volume and poor outcomes is easily strong enough to raise questions about seeking care at a hospital where few patients in a procedure or condition of interest are treated.

The current massive consolidation of larger and smaller hospitals may winnow out some low-volume hospitals. "Thousands of hospitals may close, many of them smaller," says Wachter. "Some of them are already living on the edge." He believes the casualties are likely to be driven more by economics than quality. They could include both high-mortality hospitals and excellent small hospitals with a couple of dozen beds that he knows from visits in states like Iowa and South Dakota, "God bless them," says Wachter of the small strivers. "They're doing the best they can."

Putting the onus on patients to identify riskier healthcare settings may be asking too much, says Wachter. Perhaps, he says, centers that only do a few heart bypasses, hip replacements or other procedures a year should carry a "black-box warning" on their web pages and elsewhere, as risky medications do – a statement that provides information but leaves it to patients to decide what to do with it.

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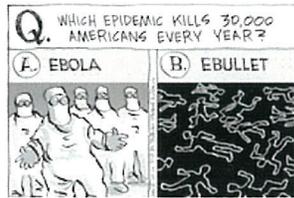
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ATTACHMENT 13



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Hospitals Move to Limit Low-Volume Surgeries

Three of nation's leading hospital systems say they will limit low-volume surgeries.



Patients who undergo knee-replacement procedures at the lowest-volume fifth of hospitals are nearly 70 percent more likely to die than those treated at the highest-volume fifth, according to a U.S. News analysis.

By [Steve Sternberg](#)

May 19, 2015 | 12:01 a.m. EDT

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Three of the nation's top academic medical systems – Dartmouth-Hitchcock Medical Center, Johns Hopkins Medicine, and the University of Michigan – say they are planning to impose minimum-volume standards that will bar hospitals in their systems from performing certain procedures unless both the hospitals and their surgeons do them often enough to keep their skill level up.

The move comes in the wake of [a story released Monday by U.S. News](#) showing that hospitals that do small numbers of common procedures place patients at far greater risk than those that do lots of them.

The voluntary standards, which are expected to go into effect before the end of the year, represent the first coordinated effort to place limits on hospitals and on surgeons, who traditionally have been allowed to perform virtually every procedure within the scope of their specialty training, even if only once a year.

"It's a promising, bold move. I hope other hospitals across the country follow," says Leah Binder,

director of the Leapfrog Group, a consortium of major employers that has championed using hospital and surgeon volume as part of a comprehensive assessment of hospital safety.

The aim of the new initiative is to prevent deaths and complications that occur at the hands of less-practiced providers. For three decades, researchers have been pointing out the hazards of having surgery at hospitals that only care for a small number of similar patients each year. Despite the mounting evidence of higher death and complication rates, the studies have largely been ignored.



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Risks Are High at Low-Volume Hospitals

"Low-volume hobbyists are bad for patients and we have to stop them," says Dr. John Birkmeyer, a surgeon and chief academic officer at Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire. Birkmeyer helped to draft the new standards with Dr. Peter Pronovost, director of the Armstrong Institute for Patient Safety and Quality at Johns Hopkins University, in consultation with surgeons at both institutions.

The minimums will apply to up to 20 hospitals in the three systems. Two flagship Harvard University teaching hospitals in the Partners Healthcare system, Massachusetts General Hospital and Brigham and Women's Hospital, and their sister institutions in the system say they are considering the new standards but are not ready to sign on without considerably more deliberation.

"Everybody I've talked to [at Massachusetts General Hospital] buys the importance of volume related to outcomes, and most of us could live very nicely with the numbers put forth by Peter and John in their proposal," says Dr. Keith Lillemoe, chief of surgery at Massachusetts General. "But this is too fast for us to make a commitment." He wants to look closely at the specific volume thresholds. He and his colleagues at Brigham and Women's plan to take the proposal up with the hospitals' executive leadership.

Dartmouth-Hitchcock and Johns Hopkins decided to act after Birkmeyer and Pronovost were asked to comment on the findings from the U.S. News analysis. "Within two weeks, we got consensus on something that hasn't been acted on in 30 years," says Pronovost. "Not just consensus – people realized that this is something we have to do, the direction in which we have to go."

Overall, the U.S. News analysis found, knee-replacement patients who had their surgery in the lowest-volume fifth of the centers were nearly 70 percent more likely to die than patients treated at centers in the highest-volume fifth. For hip replacement, the risk was nearly 50 percent higher. Patients with congestive heart failure and chronic obstructive pulmonary disease had a 20 percent increased risk of dying.

The analysis was conducted as part of a new set of hospital ratings, Best Hospitals for Common Care, to be launched on May 20. It will enable users to identify local hospitals that do the best job of caring for patients whose needs are relatively commonplace.

The ratings, developed in collaboration with Dr. Foster, a London-based global health analytics firm, evaluated how hospitals perform in caring for Medicare fee-for-service patients in five procedures: bypass surgery without valve repair or replacement, elective hip and knee replacement, congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD).

Across all five operations and conditions, nearly 120,000 patients received care at hospitals in the lowest-volume band – 39,483 for elective hip or knee replacement, 7,898 for cardiac bypass, 36,711 for heart failure and 34,181 for COPD.

Even at major medical centers, surgeons sometimes tackle cases that they don't ordinarily perform. "You might think it's only a problem with very small hospitals that are trying to run with the big dogs," Birkmeyer says, "but we see this within our own health system, when surgeons whose primary interests are elsewhere do that [operation] just because it showed up on their doorstep."

As a starting point, the three centers have agreed on a list of 10 procedures that have repeatedly been demonstrated in research studies to be riskier when they're performed at hospitals and by surgeons

that do them only occasionally. The list includes bariatric surgery, lung cancer surgery, esophagus surgery and joint replacement.

Birkmeyer says the minimums are "very conservative," based on a combination of scientific publications and recent analyses of Medicare data by his team. The volume thresholds were selected based on the surgical judgment and consensus of surgeons at Dartmouth and Johns Hopkins. They represent approximate median figures, meaning that half of U.S. hospitals and surgeons do more and half do fewer than the selected thresholds. Between 10 percent and 20 percent of hospital patients in the U.S. have one or more of the procedures at hospitals that fail to meet those standards.

Taken together, Birkmeyer says, approximately 1.3 million people in the U.S. undergo the 10 procedures on the minimums list annually; about 264,000 of them are treated in hospitals with below-average volume.

If patients treated in those hospitals were in more experienced hands, he says, more than 1,300 deaths could be averted each year.

Health policy experts have debated how to address the risks posed by low-volume hospitals for decades, ever since a 1979 landmark report in the *New England Journal of Medicine* linked low volumes of certain procedures with higher mortality and proposed that patients should be referred to regional centers of excellence.

Patients' desire to be treated closer to home, in familiar surroundings, with easy access to friends and family, has made the centers of excellence concept a hard sell. A solution has been further stalled by hospitals' reluctance to give up profitable procedures. Nearly 30 percent of hospitalizations involve surgery, and those operations make up almost 50 percent of a hospital's revenue, according to an analysis by the Agency for Healthcare Research and Quality.

Surgeons' and hospitals' interests align. The amount of revenue surgeons generate gives them the clout to resist almost any threat to their autonomy, including putting the brakes on their power to perform any operation within the scope of their clinical training, whether they perform one procedure a year or a thousand, and whether the procedure is necessary or not.

That's one weakness of the minimum-volume standard, says Leapfrog's Binder: "It can't account for surgeons who do unnecessary procedures."

Another is that many higher-volume hospitals don't have the capacity to care for a major influx of patients from smaller community hospitals. "A lot of big hospitals, mine included, are really full," says Dr. Michael Mulholland, chairman of surgery at the University of Michigan.

The federal Centers for Medicare & Medicaid Services sets the rules for payments to hospitals for care of Medicare and Medicaid patients, but deliberately hasn't stepped in to set volume requirements. A detailed plan for implementing the new standards still must be worked out at all three hospital systems, Birkmeyer says. Dartmouth has decided to "hard-wire" the standards into their credentialing procedures; doctors who fail to meet the minimum standards will not be granted privileges to perform the listed procedures at Dartmouth hospitals.

Special rules will address emergency procedures, newly minted surgeons transitioning into staff positions and surgeons who have been away from the operating room due to illness or because they were on sabbatical. Surgeons seeking to obtain, regain or expand their privileges may be required to perform a certain number of supervised procedures to increase their volumes, Birkmeyer says.

However the plan is implemented, Pronovost says, it's likely to generate opposition. The CEOs and boards at both Dartmouth and Johns Hopkins have agreed to adopt the new standards, but each hospital's medical executive committee, which represents the physician leadership, must also sign on. "There are going to be strong critics of this," says Pronovost. "We just have to be ready for that."

TAGS: surgery, medicine, hospitals

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ATTACHMENT 14

Proposed Requirements for Comprehensive Cardiac Center Certification Program

Comprehensive Cardiac Center Certification

1 **Comprehensive Cardiac Center Management (CCCM)**

2

3 **CCCM.1**

4 The comprehensive cardiac center's leaders secure support from the organization.

5

6 **EP 1**

7 The center's philosophy is aligned with the organization's mission.

8

9 **EP 2**

10 The center's leaders are empowered by the organization's leaders to provide care, treatment, and
11 services.

12

13 **EP 3**

14 Center leaders integrate the care, treatment, and services provided by the center with those of the
15 organization.

16

17 **EP 4**

18 Center leaders secure the resources the center requires in order to support the scope of care,
19 treatment, and services provided.

20

21 **EP 5**

22 Center leaders evaluate care, treatment, and services provided to ascertain whether the scope and
23 level of care, treatment, and services are consistently provided.

24

25 **EP 6**

26 Center leaders create opportunities for the interdisciplinary team to participate in the design of the
27 care, treatment, and services provided. (See also CCCM.7, EP 3)

28

29 **EP 7**

30 The center assumes an active role in the development and coordination of cardiac education
31 programs at the community level based on the needs of the population served.

32

Comprehensive Cardiac Center Certification Program

33 **EP 8**

34 The center sponsors at least one community education program annually that focuses on
35 cardiovascular disease prevention. (See also CCCPC5, EP7)

36
37 **CCCM.2**

38 The center defines its leadership roles.

39
40 **EP 1**

41 The center has dedicated executive leadership and staff necessary to meet the scope of care,
42 treatment, and services it provides across the continuum of care.

43
44 **EP 2**

45 The center has a designated leader who is accountable for the comprehensive cardiac center. This
46 leader makes certain that the center does the following:

- 47 - Provides integrated, coordinated, patient-centered care
- 48 - Provides early identification of patients' risk levels and provides care at a level that
- 49 corresponds to the center's capabilities
- 50 - For identified or unanticipated high-risk/high-complexity patient needs, provides direct
- 51 care or stabilizes and safely transfers patients who require care beyond the scope of services
- 52 provided by the organization
- 53 - Patient education and information about comprehensive cardiac care services is made
- 54 available to patients so they can make informed decisions about their care
- 55 - Implements ongoing performance improvement processes that include program-specific
- 56 performance improvement requirements in addition to any required measures

57
58 **EP 3**

59 The center's executive leadership team includes, at a minimum, the following members:

- 60 - A qualified physician(s) (doctor of medicine or osteopathy) who has specialized training in
- 61 cardiology, and is privileged in cardiology
- 62 - A qualified cardiothoracic surgeon who has specialized training and is privileged in
- 63 cardiothoracic surgery
- 64 - Registered nurse(s) and/or advanced practice nurses(s) who have cardiovascular training or
- 65 clinical experience in cardiac care, or are certified/certification eligible
- 66 - Organization executive

67

Comprehensive Cardiac Center Certification Program

68 **EP 4**

69 A qualified physician with medical cardiology privileges is responsible for management of the
70 center's cardiology services.

71

72 **EP 5**

73 A qualified physician with interventional cardiology privileges is responsible for management of the
74 interventional cardiology services.

75

76 **EP 6**

77 A qualified surgeon with cardiothoracic surgery privileges is responsible for management of the
78 center's cardiac surgical services.

79

80 **EP 7**

81 A qualified cardiac anesthesiologist with cardiac anesthesiology privileges is responsible for the
82 center's cardiac anesthesia services.

83

84 **EP 8**

85 A qualified physician with electrophysiology privileges is responsible for management of the center's
86 electrophysiology services.

87

88 **EP 9**

89 A qualified physician with emergent cardiovascular care training and emergency room privileges is
90 responsible for the management of the center's emergency room services.

91

92 **EP 10**

93 A nursing leader with cardiovascular nursing care experience is responsible for management of the
94 center's cardiovascular nursing care services.

95

96 **EP 11**

97 The comprehensive cardiac center's executive leaders define both the shared and unique
98 responsibilities and accountabilities of its leadership and staff.

99

100 **EP 12**

101 Center leaders share best practices with leaders of other comprehensive cardiac centers and other
102 organizations providing cardiac care, treatment, and services.

**Comprehensive Cardiac Center Certification
Program**

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EP 13

The center complies with applicable law and regulation.

EP 14

The center executive leaders make certain that practitioners practice within the scope of their licensure, certification, training, and current competency.

CCCM.3

The comprehensive cardiac center provides services that meet the needs of its patient population.

EP 1

The center defines its scope of care, treatment, and services. At a minimum, these include the following:

- Management of ischemic heart disease, including medical and interventional/surgical management, including management of acute coronary syndrome (STEMI and NSTEMI), percutaneous coronary interventions, and coronary bypass graft surgery
- Management of cardiac valve disease, including valve replacement/repair procedures
- Management of arrhythmias, including electrophysiology services and outpatient device clinic.
- Advanced heart failure management, including outpatient services
- Management of cardiac arrest, including resuscitation and therapeutic hypothermia/temperature management for cardiac arrest
- Cardiac rehabilitation of patients, as indicated, either on site or by referral
- Cardiovascular risk factor identification and cardiac disease prevention

EP 2

The center provides care, treatment, and services to meet the needs of the population served based on the scope of services offered.

EP 3

The center provides the patient and family education or information about care, treatments, and services, and alternative options available to meet the patient's needs and preferences. (See also CCCPC.2, EP 3)

Comprehensive Cardiac Center Certification Program

138 **EP 4**

139 The center demonstrates its capability to provide medical and interventional/surgical cardiovascular
140 critical care services in designated beds 24 hours a day, 7 days a week.

141 Note: Cardiovascular critical care units can be defined and implemented in a variety of ways. The
142 cardiovascular critical care unit must be a specific enclosed area with beds designated for acute
143 cardiovascular patients.

144

145 **EP 5**

146 The center provides the following 24 hours a day, 7 days a week (suitable backup systems and plans
147 are in place that meet the emergent needs of the patient, while also taking into account the
148 characteristics and needs of the population served):

149 - Anesthesia services

150 - Perfusion services

151 - Respiratory care services

152 - Radiology services

153 - Cardiac imaging services

154 - Cardiac computed tomography

155 - Nuclear cardiology

156 - Echocardiography

157 - Transthoracic echocardiography (TTE)

158 - Transesophageal echocardiography (TEE)

159 - Electrocardiogram

160 - Laboratory services

161 - Blood bank services

162 - Emergency department

163 - Cardiac catheterization and interventional lab

164 - Cardiac surgical services

165 - Electrophysiology services for emergency cardiac pacing and device interrogation

166 - A process for recognizing and responding to changes in a patient's condition based on
167 early warning risk criteria

168 - Resuscitation services

169 |

170 **EP 6**

171 The center provides early risk identification and manages the patient's risks at a level that
172 corresponds to the center's capabilities.

**Comprehensive Cardiac Center Certification
Program**

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EP 7

The center performs emergency cardiovascular diagnostic, imaging, and interventional/surgical services within an interval of time that meets the needs of the patient and is consistent with current clinical practice guidelines.

EP 8

The center demonstrates its capability to perform cardiopulmonary resuscitation, including intubation and therapeutic hypothermia/temperature management, 24 hours a day, 7 days a week. This is performed according to the most current national guidelines. (See also CCCM.4, EP 1; CCCM.6, EP 4; CCCM.9, EP 1)

EP 9

In the event of unanticipated patient complications, the center provides direct care; otherwise, the center stabilizes and transfers a patient who requires care beyond the scope of services provided by the organization.

EP 10

The center has internal guidelines regarding consultation with a physician who is board-certified or board-eligible in the required cardiac specialty 24 hours a day, 7 days a week.

EP 11

The center follows its written policies for consultation and transfer arrangements. The needs of the population served guide decisions about which services will be provided directly or through referral, consultation, contractual arrangements, or other agreements. (See also CCCM.4, EP 1)

EP 12

The center demonstrates the capability to immediately receive, process, and report results for urgent or emergent laboratory requests with consideration for the acuity of the patient and the integrity of the samples.

EP 13

The center demonstrates the capability to provide emergent pacing and device interrogation services 24 hours a day, 7 days a week, based on the patient's individual needs and according to current clinical practice guidelines.

Comprehensive Cardiac Center Certification Program

210 **CCCM.4**

211 The center uses clinical practices originating from evidence-based national guidelines or expert
212 consensus to deliver or facilitate care, treatment, and services.

213

214 **EP 1**

215 The center has policies and procedures that support its clinical practices management of common
216 conditions that may occur. At a minimum, this includes policies and procedures for the following:

217 - Providing direct care, or stabilizing and transferring patients who require care beyond the
218 scope of services provided by the organization

219 - Providing continuous mechanical circulatory support

220 - Planning for consultation, referral, and transfer arrangements (See also CCCM.3, EP 11)

221 - Managing unexpected complications

222 - Performing cardiopulmonary resuscitation according to current national guidelines (See
223 also CCCM.3, EP 8)

224 - Providing therapeutic hypothermia after cardiac arrest

225 - Planning for discharge, follow-up, and transitions of care

226 - Managing an acute myocardial infarction—ST segment elevation myocardial infarction
227 (STEMI) and non-ST segment elevation myocardial infarction (NSTEMI)

228

229 **EP 2**

230 The center's interdisciplinary team members and staff have access to reference materials, including
231 clinical practice guidelines, in either hard copy or electronic format. At a minimum, these include the
232 following:

233 - Evidence-based guidelines and reference materials.

234 - Protocols/care pathways and guidelines for the acute workup, management, and transitions
235 of care for cardiac patients.

236 - Complete description of the emergency medical services (EMS) with available treatment
237 guidelines for prehospital personnel, including EMS patient routing plans that direct
238 transport of acute cardiac ST segment elevation myocardial infarction (STEMI) patients to a
239 STEMI-receiving center

240

241 **EP 3**

242 The center has a process to regularly review its clinical practice guidelines and order sets.

243

**Comprehensive Cardiac Center Certification
Program**

244 **EP 4**

245 The center implements modifications to its clinical practices in response to changes in evidence-
246 based national guidelines, up-to-date systematic review of existing evidence, or results of its
247 performance improvement activities. (See also CCCPI.3, EP 5)

248

249 **EP 5**

250 The center demonstrates that the clinical practice guidelines and policies and procedures that apply
251 to its patient population are coordinated and unified throughout the center.

252

253 **CCCM.5**

254 The center identifies and minimizes risks to patients.

255

256 **EP 1**

257 Staff implements activities for managing medications, including following protocols for, at a
258 minimum, anticoagulants, nitrates, vasopressors, antibiotics, hemorrhage management/medications,
259 and emergency resuscitation medications. (See also CCCM.6, EP 2)

260

261 **EP 2**

262 Staff implement activities for preventing and controlling infection in the center's patient population,
263 which include reducing health care-acquired infections and following standardized wound care
264 protocols.

265

266 **CCCM.6**

267 Center leaders are responsible for selecting, orienting, educating, and training comprehensive cardiac
268 center staff.

269

270 **EP 1**

271 Center staff have education, experience, training, and/or certification consistent with the center's
272 philosophy and scope of care, treatment, and services.

273

**Comprehensive Cardiac Center Certification
Program**

274 **EP 2**

275 Center leaders, or their designees, evaluate the qualifications, training, and experience of
276 comprehensive cardiac center staff to determine whether practitioners are knowledgeable about the
277 following:

278 - Pathophysiology, presentation, assessment, diagnostics, and treatment of patients with
279 acute coronary syndromes, heart failure, cardiogenic shock, cardiac arrhythmias, structural
280 heart disease, adult congenital heart disease, cardiovascular prevention, and other cardiac
281 disease states

282 - Surgical treatment of coronary artery disease, heart failure, structural heart disease, and
283 other cardiac disease states

284 - Cardiac imaging

285 - Communication with an inbound emergency medical services (EMS) for cardiac
286 emergencies, activation of the ST segment elevation myocardial infarction (STEMI) team,
287 and location and application of STEMI protocols

288 - Indications and contraindication for use of IV thrombolytic therapy and direct
289 percutaneous coronary intervention (PCI)

290 - Indications and contraindications of advanced cardiac life support and mechanical
291 circulatory support

292 - Signs and symptoms of cardiovascular deterioration

293 - Recognition, assessment, and management of cardiac complications

294 - Managing medications, including following protocols for, at a minimum, anticoagulants,
295 nitrates, vasopressors, antibiotics, hemorrhage medications, and emergency resuscitation
296 medications (See also CCCM.5, EP 3)

Comprehensive Cardiac Center Certification Program

297 **EP 3**

298 The center requires the following specific training and education for physicians and staff members,
299 including cardiac care unit staff and emergency department staff:

300 - Registered nurses working in the emergency department, cardiovascular critical care units,
301 cardiac surgery, cardiac stepdown/telemetry nursing units, and cardiac
302 catheterization/interventional/electrophysiology laboratories are formally educated and
303 experienced in the provision of evidence-based acute cardiac nursing care.

304 - Registered nurses working in the above areas are knowledgeable about cardiac assessment
305 and nursing management of cardiovascular patients.

306 - Advanced practice nurses (clinical nurse specialists or nurse practitioners) have specific
307 expertise in cardiac advanced nursing management.

308 - Physician assistants have specific expertise in cardiac patient management

309 - Advanced practice nurses, physician assistants and nurse educators providing acute cardiac
310 care to patients or educating registered nurses who provide that care are required to attend
311 one or more local, regional, or national meetings every other year related to cardiovascular
312 care.

313 - Registered nurses working in the emergency department complete at least two hours of
314 continuing education per year on acute cardiac nursing assessment and patient management.

315 - Registered nurses working in a cardiac care unit or a cardiovascular critical care unit
316 providing acute cardiac patient care are required to complete ten or more hours of education
317 per year on cardiovascular disease, nursing assessment, and patient management.

318 - Medical staff members of the interdisciplinary team receive at least eight hours annually of
319 continuing education on providing interdisciplinary care to cardiovascular patients, or other
320 equivalent educational activity, as determined by the center physician leadership, the
321 organization's medical staff requirements, and as appropriate to the physician's level of
322 responsibility.

323 - Other direct patient care members of the interdisciplinary team receive at least two hours
324 of continuing education annually on cardiovascular patient care.

Comprehensive Cardiac Center Certification Program

325 **EP 4**

326 Center leaders identify critical competencies and education for the center's interdisciplinary team
327 members, which, at a minimum, include the following as appropriate to the patient care area and
328 patient population:

- 329 - Pathophysiology, presentation, assessment, diagnostics, and treatment of cardiac patients,
330 including acute coronary syndromes, cardiac arrhythmias, acute heart failure, cardiogenic
331 shock, cardiac arrest, syncope, tamponade, structural heart disease, and other acute
332 cardiovascular disease presentations.
- 333 - Use of new patient equipment or technology
- 334 - Use of auscultation and electronic cardiac monitoring, including use of current terminology
335 for interpretation of the results
- 336 - Identification and management of cardiac arrhythmias
- 337 - Providing care for patients on continuous mechanical circulatory support
- 338 - Skills for caring for patients on intra-aortic balloon pump counter pulsation
- 339 - Preparation for emergency cardiovascular management, including medical management,
340 interventional/surgical procedures, and postprocedure/postoperative care
- 341 - Use of intravenous vasopressor and antihypertensive and positive inotropic agents
- 342 - Methods for hemodynamic monitoring
- 343 - Methods for invasive and noninvasive ventilator management
- 344 - Postanesthesia and recovery care
- 345 - Nursing care of patients post cardiovascular procedures
- 346 - Providing resuscitation according to current national guidelines
- 347 - Use of therapeutic hypothermia protocols following cardiac arrest
- 348 - Identification and care of the ST segment elevation myocardial infarction (STEMI) patient
349 (out-of hospital and inpatient)
- 350 - Cardiovascular patient assessment and care
- 351 - Location and application of STEMI, advanced cardiac life support (ACLS), and
352 arrhythmia-related protocols, activation of the cardiac catheterization team, and
353 communications with inbound emergency medical services (EMS).
- 354 - Clinical drills to help staff prepare for unanticipated complications or high-risk events with
355 a low rate of occurrence
- 356 - Clinical drill debriefings to evaluate team performance and identify areas for improvement
- 357 - Patient safety drills

358 **EP 5**

359 Center leaders assess each team member's identified critical competencies through observation on
360 an ongoing basis. This assessment is documented.

Comprehensive Cardiac Center Certification Program

361

362 **EP 6**

363 The center provides or facilitates access to orientation for the interdisciplinary team members, center
364 staff, and volunteers. The orientation plan and specific content are defined by the center leaders, and
365 include, but are not limited to, the following areas:

- 366 - The domains of comprehensive cardiac care
- 367 - Assessment and management of pain and other physical symptoms
- 368 - Assessment and management of psychological symptoms and psychiatric diagnoses
- 369 - Communication skills
- 370 - Cross-cultural knowledge and skills
- 371 - Information on specific population(s) served
- 372 - Grief and bereavement
- 373 - Ethical principles that guide provision of comprehensive cardiac care
- 374 - Community resources for patients and families
- 375 - Palliative and hospice care

376 Note: Orientation may be provided over a period of time and in a variety of methods,
377 including live and video presentations; electronic or written materials; clinical experience
378 with a preceptor or mentor; or education at a seminar or other organization.

Comprehensive Cardiac Center Certification Program

379 **EP 7**

380 The orientation process for the center's clinical direct patient care interdisciplinary team members
381 includes information and training necessary to perform their responsibilities. Completion of the
382 orientation is documented. This includes, but is not limited to, information and training on the
383 following:

- 384 - Performing a comprehensive assessment that includes documentation in the medical record
385 and plan of care
- 386 - Identifying common cardiovascular signs and symptoms
- 387 - Identifying and responding to changes in the patient's clinical condition or risk factors
- 388 - Using standardized terminology to communicate with other team members (See also
389 CCCPC.4, EP 4)
- 390 - Using cardiovascular clinical practice guidelines (See also CCCPM.4, EP 1–5)
- 391 - The treatment and care of routine cardiovascular problems
- 392 - The treatment and care of unanticipated high-risk events
- 393 - Cardiopulmonary resuscitation according to current national guidelines
- 394 - Transferring or transporting the patient
- 395 - Pain management
- 396 - Care practices that promote patient and family-centered care
- 397 - Clinical drills to help staff prepare for high risk events with a low rate of occurrence
- 398 - Clinical drill debriefings to evaluate team performance and identify areas for improvement
- 399 - Safety and security of the patient (See also CCCM.5, EP 7)

400

401 **EP 8**

402 Leaders support the interdisciplinary team members' participation in continuing education, including
403 in-services, training, and other activities, relevant to the program's scope of services.

404

405 **EP 9**

406 The center develops cardiovascular educational initiatives for all cardiovascular personnel including
407 those involved in prehospital care.

408

409 **EP 10**

410 The center interdisciplinary team prepares and presents two or more educational programs annually
411 for the center staff or for those staff in the organization outside the cardiac center.

412

Comprehensive Cardiac Center Certification Program

413 **EP 11**

414 The center provides opportunities for emotional support of leaders, the interdisciplinary team, staff,
415 and volunteers.

416 Note: Emotional support is especially important in helping manage the stress of caring for critically
417 ill, chronically ill, and palliative care cardiac patients and their families.

418

419 **CCCM.7**

420 The comprehensive cardiac center has an interdisciplinary team that includes individuals with
421 expertise in and/or knowledge about the program's specialized care, treatment, and services.

422

423 **EP 1**

424 The center's interdisciplinary team includes the following individuals and services to meet the needs
425 of the patient population:

426 Direct patient care staff, including but not limited to, the following:

427 - A qualified provider with medical cardiology privileges and appropriate training and
428 expertise

429 - A qualified provider with interventional cardiology privileges and appropriate training and
430 expertise

431 - A qualified provider with cardiothoracic surgery privileges and appropriate training and
432 expertise

433 - A qualified provider with electrophysiology privileges and appropriate training and
434 expertise

435 - A qualified internist or family practitioner with privileges and appropriate training and
436 expertise

437 - A qualified provider with cardiac anesthesia privileges

438 - Qualified nursing personnel in adequate numbers to meet the needs of each patient in
439 accordance with the care setting

440 - Cardiac diagnostics staff

441 - Cardiac imaging staff

442 - Cardiac catheterization laboratory or interventional laboratory staff

443 - Cardiac surgery staff

444 - Electrophysiology staff

445 - Cardiac rehabilitation staff

446 - Respiratory care staff

447 - Radiology staff

448 - Registered pharmacist with expertise in cardiology

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449 Non-direct patient care staff, including but not limited to, the following:

- 450 -Leadership/management of cardiac care units and cardiovascular critical care units
- 451 - Laboratory services for immediately obtaining and processing appropriate samples and
- 452 reporting urgent/emergent laboratory requests
- 453 - Blood bank services for determining ABO blood group and Rh type, cross-matching
- 454 blood, and performing antibody testing
- 455 -Data collection personnel

456

457 **EP 2**

458 Based on the care, treatment, and services provided, the population served, and the patient's and
459 family's needs, the interdisciplinary team may utilize additional individuals including, but not limited
460 to, the following:

461

- 462 - Additional physicians to support members of the interdisciplinary team
- 463 - Additional nursing staff to support members of the interdisciplinary team
- 464 - Case managers and social workers with expertise in cardiac care coordination
- 465 - Clinical pharmacists
- 466 - Gerontologists
- 467 - Dietitians
- 468 - Psychiatrists
- 469 - Psychologists
- 470 - Recreational therapists
- 471 - Exercise physiologists
- 472 - Rehabilitation therapists, including physical, occupational, and speech therapists
- 473 - Supervised volunteers

474

475 **EP 3**

476 The center defines in writing the interdisciplinary team members' responsibilities. (See also CCCM.1,
477 EP 6)

478

Comprehensive Cardiac Center Certification Program

479 **EP 4**

480 Adequate numbers and types of practitioners are available to deliver or facilitate the delivery of care,
481 treatment, and services as follows:

482 - The center has a written and adhered to call schedule for physicians with expertise in
483 cardiac critical care, coronary interventions, advanced heart failure care, cardiac imaging,
484 arrhythmia management, and cardiothoracic surgery providing coverage 24 hours a day, 7
485 days a week.

486 - The center demonstrates coverage of the emergency department, cardiovascular critical
487 care units, catheterization laboratories, and operating rooms 24 hours a day, 7 days a week by
488 physicians with expertise in critical cardiovascular care, coronary interventions, and
489 cardiothoracic surgery.

490 - The center's program/unit medical directors or designees are available by phone within 20
491 minutes and available in-house within 45 minutes, 24 hours a day, 7 days a week.

492

493 **EP 5**

494 The following practitioners and staff members are available as follows:

495 Physicians:

496 - At least one cardiac interventionist is available by phone within 10 minutes and available in
497 house within 30 minutes, 24 hours a day, 7 days a week.

498 - Other cardiac catheterization/interventional suite personnel are available within 30
499 minutes, 24 hours a day, 7 days a week, to perform emergency cardiac
500 catheterization/interventional procedures.

501 - At least one cardiologist with cardiac imaging experience is available 24 hours a day, 7 days
502 a week.

503 - At least one board-certified electrophysiologist is available 24 hours a day, 7 days a week.

504 - At least one diagnostic radiologist is available 24 hours a day, 7 days a week.

505 - Physicians with critical care and cardiovascular experience staff the cardiovascular critical
506 care units and are available 24 hours a day, 7 days a week.

507 - In addition to the cardiac interventionist, one or more additional cardiologists are to be
508 available by phone within 20 minutes and available in house within 45 minutes, 24 hours a
509 day, 7 days a week.

510 - One or more cardiothoracic surgeons are available within 30 minutes, 24 hours a day, 7
511 days a week.

512 - One or more cardiac anesthesiologists are available within 30 minutes, 24 hours a day, 7
513 days a week

514 - Surgeons with expertise in vascular surgery are available.

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- 515 Advanced Practice Nurses (APNs) and Physician Assistants (PAs):
- 516 - APNs and PAs support delivery of evidence-based acute cardiac care, assessment, and
517 management.
- 518 - APNs provide expert nursing consultation and practice oversight.
- 519 - APNs and PAs develop and deliver cardiovascular care education programs.
- 520 - APNs and PAs participate in performance improvement processes.
- 521 - APNs and PAs participate in cardiovascular research.
- 522 Imaging Staff:
- 523 - One or more qualified radiology technologists are available 24 hours a day, 7 days a week.
- 524 - One or more qualified radiology technologists are available 24 hours a day, 7 days a week
525 to assist with cardiac procedures.
- 526 - One or more qualified computed tomography (CT) and magnetic resonance imaging (MRI)
527 technologists are available 24 hours a day, 7 days a week.
- 528 Cardiac Rehabilitation:
- 529 - Cardiac rehabilitation services are directed by a clinician with expertise and experience in
530 cardiac rehabilitation.
- 531 - Physical therapists, nutritionists, and cardiac rehabilitation staff are available to perform
532 patient assessment during the inpatient acute cardiac phase.
- 533
- 534 **EP 6**
- 535 The following individuals and support services are available to the center's interdisciplinary team:
- 536 - Licensed social worker or nurse case manager for discharge planning and education,
537 community follow-up, referral process, home care or foster care arrangements, and
538 socioeconomic and psychosocial problems
- 539 - Infection control personnel responsible for surveillance of infections, as well as
540 development of an appropriate infection control program
- 541 - Genetic diagnostic and counseling services or written consultation and referral agreements
542 for these services
- 543 - Behavioral or mental health services or written consultation and referral agreements for
544 these services
- 545 - Nurse(s) or licensed independent practitioner(s) with appropriate training or experience in
546 cardiovascular care to conduct staff education and development
- 547 - Personnel for assisting surgical procedures, such as surgical assistants
- 548 - At least one staff member with expertise in grief and bereavement counseling and palliative
549 care who is responsible for these activities
- 550

**Comprehensive Cardiac Center Certification
Program**

551 **EP 7**

552 Suitable backup systems and plans are in place that take the following into account:

- 553 - Emergent needs of the patient
- 554 - Characteristics and needs of the population served
- 555 - Skill set of the staff providing the services

556

557 **CCCM.8**

558 The center promotes collaboration among center staff and with the organization staff who are
559 involved in the patient's care.

560

561 **EP 1**

562 The center and the organization promote and support a collaborative and trusting environment.

563

564 **EP 2**

565 Center leaders facilitate communication among the interdisciplinary team members and other
566 organization staff who are involved in the patient's care.

567

568 **EP 3**

569 The center demonstrates teamwork among the interdisciplinary team members and other
570 organization staff who are involved in the patient's care.

571

572 **CCCM.9**

573 The program has essential cardiovascular emergency equipment, supplies, and medications stocked
574 and readily available.

575

576 **EP 1**

577 The center has equipment and supplies immediately available to provide, at minimum, for the
578 following functions:

- 579 - Monitoring, hardwire, and telemetry, based on the patient's needs and protocols
- 580 - Resuscitation and stabilization of the patient
- 581 - Infection control and isolation, if necessary
- 582 - Initiation of an emergency call system

583

**Comprehensive Cardiac Center Certification
Program**

584 **EP 2**

585 Emergency medications needed to initiate and maintain resuscitation, per national guidelines, are
586 present or immediately available in patient care areas.

587

588 **CCCM.10**

589 The comprehensive cardiac center participates in cardiovascular research.

590

591 **EP 1**

592 The center currently participates in patient-centered cardiovascular research approved by the
593 Institutional Review Board (IRB).

594 Note: Patient-centered research includes research focusing on clinical patient studies. Participating in
595 laboratory-based research or a registry does not meet this requirement.

596

597 **EP 2**

598 The center has a written research protocol for current cardiovascular research.

599

600 **Provision of Care, Treatment, and Services (CCCPC)**

601

602 **CCCPC.1**

603 Patients and families know how to access and use the center's care, treatment, and services.

604

605 **EP 1**

606 The center has a process to identify patients for whom cardiac care services are indicated and
607 communicates this to appropriate organization staff and interdisciplinary team members.

608

609 **EP 2**

610 The center informs patients and families on how to access care, treatment, and services during
611 business hours.

612

613 **EP 3**

614 The center informs patients and families on how to contact staff in the case of an emergent situation
615 during or after business hours.

616

**Comprehensive Cardiac Center Certification
Program**

617 **EP 4**

618 The center informs patients and families about patient rights and responsibilities while receiving
619 care, treatment, or services.

620

621 **EP 5**

622 The center informs patients and, as appropriate, families of their responsibilities for providing
623 information that is important to care, treatment, and services.

624

625 **EP 6**

626 The center informs patients and, as appropriate, families about a patient's right to refuse any or all of
627 the care, treatment, and services offered by the center.

628

629 **EP 7**

630 The center assists patients and, as appropriate, families with accessing health care services and
631 providers that are available to meet patients' health care needs. This includes supportive referrals to
632 social service programs, health care systems and settings, and health care specialists.

633

634 **EP 8**

635 Comprehensive cardiac centers that do not provide highly specialized aspects of cardiovascular care
636 (for example, heart transplant) have a process for making referrals to one or more centers that will
637 accept patient referrals.

638

639 **CCCPC.2**

640 The center communicates with and involves patients and, as appropriate, families in decision
641 making.

642

643 **EP 1**

644 The center discusses with patients and, as appropriate, families how they want to receive
645 information, including the type and extent of information, and their preferred language.

646

647 **EP 2**

648 Patients' and, as appropriate, families' wishes about how they want to receive information is
649 communicated to staff who are involved in the patient's care.

650

**Comprehensive Cardiac Center Certification
Program**

651 **EP 3**

652 Patients' and, as appropriate, families receive the information they need to make informed decisions
653 about their care, including, but not limited to, information about treatment, tests, medications, and
654 procedures. Information includes related risks, benefits, and alternatives. (See also CCCM.3, EP 3)

655

656 **EP 4**

657 The center actively involves patients and, as appropriate, families in decisions about clinical care.

658

659 **EP 5**

660 Patients, families (as appropriate), and staff mutually agree upon patient-centered goals of care. (See
661 also CCCPC.7, EP 3)

662

663 **EP 6**

664 As appropriate to the patient's clinical status, center staff provide information and education about
665 advance care planning to the patient and family, based on the patient's expressed values, religious or
666 spiritual beliefs, cultural practices, and preferences for care. This information is documented in the
667 medical record.

668

669 **EP 7**

670 If the patient has an advance directive, a copy is included in the patient's medical record.

671

672 **EP 8**

673 The center documents in the patient's medical record whether the patient has a designated surrogate
674 decision-maker. When the patient has a surrogate decision-maker, the center documents the
675 surrogate decision-maker's name and contact information in the medical record.

676

677 **EP 9**

678 The center has a process to provide surrogate decision-makers with guidance on legal and ethical
679 decision-making, when needed.

680

**Comprehensive Cardiac Center Certification
Program**

681 **EP 10**

682 Center staff educate the patient and family on disease processes and prognosis so that they are able
683 to make informed care decisions.

684

685 **EP 11**

686 If the patient has expressed preferences for treatment as his or her disease progresses, the
687 interdisciplinary team will document these preferences in the medical record.

688

689 **CCCPC.3**

690 The center tailors care, treatment, and services to meet the lifestyle, needs, and values of the patient
691 and, as appropriate, family.

692

693 **EP 1**

694 The documented plan of care is developed together with the patient, family (as appropriate), and
695 care provider(s) based on the patient's assessed needs, strengths, limitations, and goals.

696

697 **EP 2**

698 The plan of care is based on an understanding of the patient's and, as appropriate, family's values
699 and preferences.

700

701 **EP 3**

702 The center provides care, treatment, and services in a manner that meets the patient's and, as
703 appropriate, family's communication needs. This includes recognizing and addressing their level of
704 understanding and health literacy needs.

705

706 **EP 4**

707 The center demonstrates a patient- and family-centered approach to all aspects of care based on the
708 individual needs and/or preferences of the patient and family.

709

710 **EP 5**

711 The center incorporates the patient's and, as appropriate, family's cultural preferences while
712 providing care, treatment, and services. (See also CCCPC.4, EP 3)

713

714 **EP 6**

715 The center communicates the plan of care to staff involved in the patient's care. (See also CCCPC.6,
716 EP 1)

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Program**

717

718 **EP 7**

719 The center informs the patient and, as appropriate, family about the outcomes of the patient's care,
720 treatment, and services, including unanticipated outcomes and sentinel events.

721

722 **EP 8**

723 The center continually evaluates, revises, and implements revisions to the plan of care to meet the
724 patient's ongoing needs and preferences. Revisions are documented in the medical record.

725

726 **CCCPC.4**

727 The center's interdisciplinary team assesses and reassesses the patient's needs.

728

729 **EP 1**

730 The plan of care is developed using an interdisciplinary approach and the patient's and, as
731 appropriate, family's participation.

732

733 **EP 2**

734 The center's interdisciplinary team performs an initial patient assessment and documents the
735 assessment in the patient's medical record. The initial assessment includes, but is not limited to, the
736 following:

- 737 - A physical, psychological, and psychosocial assessment of the patient
- 738 - A detailed clinical examination and assessment of the patient performed by a qualified
739 provider(s) and center staff
- 740 - Cardiovascular risk factors, including family history, smoking history, and dietary habits
- 741 - Appropriate tests and review of results
- 742 - Ongoing, pertinent patient education
- 743 - Environmental barriers to care

744 (See also CCCIM.2, EP 3) (For more information, see PC.01.02.01, EPs 1–4, and PC.01.02.03, EPs
745 1–2 and EPs 6–8, in the Comprehensive Accreditation Manual for Hospitals.)

746

747 **EP 3**

748 The interdisciplinary team obtains information about cultural, spiritual, or religious beliefs and
749 practices important to the patient and family that influences care, treatment, and services. (See also
750 CCCPC.3, EP 5)

751

**Comprehensive Cardiac Center Certification
Program**

752 **EP 4**

753 The interdisciplinary team assesses and documents the patient's clinical symptoms and, when
754 available, uses standardized scales.

755

756 **EP 5**

757 As part of the initial assessment, the interdisciplinary team assesses and documents the patient's
758 pain, dyspnea, and other symptoms using standardized scales when they are available. The scope of
759 this assessment is defined by the center and based on patient needs.

760

761 **EP 6**

762 As part of the initial assessment, the interdisciplinary team assesses and documents the patient's
763 anxiety, stress, grief, coping, and other psychological symptoms using standardized scales when they
764 are available. The scope of this assessment is defined by the center and based on patient needs.

765

766 **EP 7**

767 The interdisciplinary program team assesses and documents the need for grief, bereavement, and
768 palliative care services for the patient and family, when needed. (See also CCCPC.5, EP 9)

769

770 **EP 8**

771 The interdisciplinary team completes the initial assessment within its defined time frame.

772

773 **EP 9**

774 The interdisciplinary team reassesses the patient on a regular basis, including whenever there is a
775 change in the patient's condition or goals, when there is a change in the patient's or family's
776 preferences, and as defined by the center. The reassessment is documented in the patient's medical
777 record.

778

779 **EP 10**

780 The interdisciplinary team documents the patient's wishes regarding his or her own care across care
781 settings and fulfills the patient's preferences when possible.

782

783 **EP 11**

784 The interdisciplinary team uses established criteria and guidelines for early and ongoing
785 identification of cardiovascular risk factors in patients along the entire continuum of care.

786

**Comprehensive Cardiac Center Certification
Program**

787

788 **CCCPC.5**

789 The center provides care, treatment, and services according to the plan of care.

790

791 **EP 1**

792 The center delivers care, treatment, and services according to the patient's plan of care.

793

794 **EP 2**

795 The center revises plans and goals for care, treatment, and services based on a reassessment, the

796 patient's needs, and achievement of goals.

797

798 **EP 3**

799 The interdisciplinary team manages the patient's physical symptoms according to the patient's plan

800 of care.

801

802 **EP 4**

803 The patient's mental health conditions and psychological symptoms, including anxiety, stress, coping

804 strategies, depression, delirium, behavioral changes, and anticipatory grief are managed according to

805 the patient's plan of care.

806

807 **EP 5**

808 The patient is monitored for the effects of medications.

809

810 **EP 6**

811 The center provides services, consultations, or referrals for its patients, if indicated.

812

**Comprehensive Cardiac Center Certification
Program**

813 **EP 7**

814 The center provides education, training, and support to the patient and family based on the
815 population served. This includes, but is not limited to, the following:

- 816 - Information regarding the patient's condition/illness
- 817 - Medications
- 818 - Lifestyle changes
- 819 - Self-management
- 820 - Cardiovascular risk factors
- 821 - Cardiovascular disease prevention
- 822 - Identification of any needs the patient, and, as appropriate, family may have for physical or
- 823 psychosocial care, treatment, and services after discharge or transfer (See also, CCCPC.7,
- 824 EP2)

825

826 **EP 8**

827 The center provides education, training, and support to the patient and family in a way that they can
828 understand and in a way that respects their culture.

829

830 **EP 9**

831 The center provides referrals for grief, bereavement, and palliative care services for patients and/or
832 families, if indicated. (See also CCCPC.4, EP 7)

833

834 **EP 10**

835 The center provides education and support to the patient and family based on their needs and the
836 plan of care.

837

838 **EP 11**

839 The center identifies and manages patients who must be transferred to another setting that provides
840 care outside the scope of the organization's level of care.

841

842 **CCCPC.6**

843 The patient's care is coordinated across the continuum of care.

844

845 **EP 1**

846 The center implements its process of exchanging patient health information among internal and
847 external staff who are involved in the patient's care, in addition to other health care organizations
848 involved in the patient's care. (See also CCCIM.1, EP 2; CCCPC.3, EP 6)

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Program**

849

850 **EP 2**

851 The center coordinates the patient's care, treatment, and services within a time frame that meets
852 their patient needs.

853

854 **EP 3**

855 The center assists staff in obtaining knowledge-based information resources and references that are
856 necessary for the patient's care and self-management and that support the patient's and staff's ability
857 to make decisions.

858

859 **EP 4**

860 Patients' co-occurring conditions, if present, are managed. This includes coordinating care with their
861 specialists and obtaining medical tests when necessary.

862 Note: If the patient's co-occurring conditions are managed by staff or a setting(s) outside the center,
863 the information necessary for its management is communicated to the staff and at setting(s) across
864 the continuum of care. (For more information, refer to Standard CCCIM.3, EP 4)

865

866 **EP 5**

867 The center conducts regular patient care conferences with members of the interdisciplinary team to
868 discuss patient-centered goals of care, disease prognosis, and advance care planning. The frequency
869 of these patient care conferences is defined by the center.

870

871 **EP 6**

872 The center assists the patient and family in collecting, organizing, and communicating important
873 health information.

874

875 **EP 7**

876 The center coordinates care with the primary care providers. This includes integrating clinical care
877 with consultations, referrals, and/or coordinated links to relevant programs such as, but not limited
878 to, the following:

879 - Community resources

880 - Mental health

881 - Nutrition

882 - Psychosocial counseling

883 - Social support

884

**Comprehensive Cardiac Center Certification
Program**

885 **EP 8**

886 At the time a patient is transferred to a different care setting, information about the patient's goals,
887 preferences, and values and the patient's clinical condition are communicated to staff in the new
888 setting.

889

890 **CCCPC.7**

891 The patient's need for continuing care, treatment, and services after discharge or transfer is
892 addressed.

893

894 **EP 1**

895 The center begins the discharge/transition planning process with the patient early in the period of
896 care, treatment, and services. At a minimum, this includes an individualized written
897 discharge/transition plan addressing the following:

- 898 - Factors from the inpatient episode or outpatient encounter that identify any potential
899 problems for the patient
- 900 - Details of the health care professionals involved in the patient's care, including roles and
901 contact details
- 902 - Support for the patient and family as needed

903

904 **EP 2**

905 The center identifies any needs the patient, and, as appropriate, family may have for physical or
906 psychosocial care, treatment, and services after discharge or transfer.

907 For the patient, this process includes assessing the patient's capacity to do the following:

- 908 - Self-report
- 909 - Manage medications
- 910 - Identify variances that may require further medical assessment
- 911 - Make a follow-up appointment(s) with a primary care provider and/or other health care
912 provider
- 913 - Access support systems, including psychosocial support
- 914 - Know what to expect at home, resources available, when to be concerned, and when to call
915 the provider (See also CCCPC.5, EP 7)

916

917 **EP 3**

918 The center discusses and plans with the patient and, as appropriate, the family, the care, treatment,
919 and services that are needed in order to achieve the mutually agreed upon plans and goals. (See also
920 CCCPC.2, EP 5)

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Program**

921

922 **EP 4**

923 The comprehensive cardiac center addresses the patient's and, as appropriate, the family's questions
924 that arise after discharge.

925

926 **Information Management (CCCIM)**

927

928 **CCCIM.1**

929 The comprehensive cardiac center maintains and protects the privacy and security of health
930 information.

931

932 **EP 1**

933 The center has a written policy that addresses privacy and security of health information.

934

935 **EP 2**

936 The center defines which individual staff or staff positions have access to what types of health
937 information. (See also CCCPC.6, EP 1)

938

939 **EP 3**

940 The center's written policy on privacy and security of health information addresses how it retrieves
941 health information without compromising privacy and security.

942

943 **EP 4**

944 The center's written policy on privacy and security of health information addresses how it will
945 safeguard records and information against loss, unintentional destruction, tampering, and
946 unauthorized access or use.

947

948 **EP 5**

949 The center defines the process to follow when privacy or security of health information is breached.

950

951 **EP 6**

952 The center implements its policy on privacy and security of health information.

953

954 **EP 7**

955 The center informs staff and patients about its policy on privacy and security of health information.

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Program**

956

957 **EP 8**

958 The center informs patients and, as appropriate, family about its uses and disclosure of health
959 information and obtains his or her consent for release of information when required.

960

961 **EP 9**

962 The center discloses health information only as authorized by the patient and, as appropriate, family
963 or as otherwise consistent with law and regulation.

964

965 **CCCIM.2**

966 The comprehensive cardiac center maintains complete and accurate medical records.

967

968 **EP 1**

969 The medical record contains sufficient information to identify the patient.

970

971 **EP 2**

972 The center documents in the patient's medical record information about his or her care, treatment,
973 and services.

974

975 **EP 3**

976 The center documents in the patient's medical record any additional information that would help
977 promote continuity of care, including the patient's ongoing cardiovascular risk assessment,
978 procedures/surgeries, test results, plan of care, and education.

979

980 **EP 4**

981 The center reviews its medical records within its defined time frames for completeness and accuracy.

982

983 **EP 5**

984 The center retains records, data, and health information in accordance with law and regulation.

985

986 **EP 6**

987 The center has a process in place to make sure that medical records are up-to-date, complete, and
988 available outside office hours.

989

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990

991 **CCCIM.3**

992 Continuity of information is maintained.

993

994 **EP 1**

995 The center has a plan for maintaining continuity of health information, which includes disaster
996 recovery.

997

998 **EP 2**

999 The center's plan for continuity of health information includes an assessment of the potential impact
1000 of a severe interruption of information systems on the center and patients.

1001

1002 **EP 3**

1003 The center's plan for continuity identifies what health information is most critical for the patient's
1004 care, treatment, and services.

1005

1006 **EP 4**

1007 The center's plan for continuity of health information includes sharing ongoing information about
1008 the patient's health status with health care providers and health care organizations involved in the
1009 patient's care. This includes making sure that assessments and plans of care are accessible at
1010 locations where the patient is planning to receive care, and the providers' offices have post-discharge
1011 information.

1012

1013 **EP 5**

1014 The center implements its plan for maintaining continuity of health information, whenever
1015 necessary.

1016

1017 **Performance Improvement (CCCPI)**

1018

1019 **CCCPI.1**

1020 The comprehensive cardiac center plans an organized, comprehensive approach to performance
1021 improvement.

1022

1023 **EP 1**

1024 The center has a written performance improvement plan.

1025

**Comprehensive Cardiac Center Certification
Program**

1026 **EP 2**

1027 The center implements its performance improvement plan.

1028

1029 **EP 3**

1030 The center leaders and staff participate in the review, evaluation, and revision of its annual
1031 performance improvement plan.

1032

1033 **EP 4**

1034 The center adjusts its current performance improvement plan in response to unusual or urgent
1035 events. (See also CCCPI.5, EP 8)

1036

1037 **EP 5**

1038 The center's performance improvement plan, including its data analysis, is communicated at least
1039 annually to the organization's leaders.

1040

1041 **EP 6**

1042 The performance improvement plan is annually reviewed and approved by the Board of Directors.

1043

1044 **EP 7**

1045 The center has an interdisciplinary and inter-specialty cardiovascular performance improvement
1046 committee that meets a minimum of twice a year to evaluate clinical care practices and protocols.

1047

1048 **EP 8**

1049 Patients and families have a defined role in the evaluation of the provision of care, treatment, and
1050 services.

1051

1052 **EP 9**

1053 The center plans process and performance improvement activities to encompass multiple specialties,
1054 disciplines, and/or settings.

1055

1056 **EP 10**

1057 Upon request, the center provides the public with information about its commitment to
1058 performance improvement.

1059 Note: This information can be general in nature and consist of patient satisfaction data or general
1060 information about how the program improves its performance.

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1061
1062 **EP 11**
1063 The center leaders, interdisciplinary team, and staff participate in the evaluation of the provision of
1064 care, treatment, and services.

1065
1066

1067 **CCCPI.2**
1068 The comprehensive cardiac center collects data to monitor its performance.

1069
1070 **EP 1**
1071 The center collects the data it needs to improve processes and outcomes.

1072
1073 **EP 2**
1074 The center monitors periprocedure complication and mortality rates for key cardiac interventions
1075 and surgical procedures including, but not limited to, the following:

- 1076 - Coronary artery bypass surgery
1077 - Valve replacement/repair procedures
1078 - Percutaneous coronary interventions
1079 - Implantable cardioverter defibrillator (ICD) insertions

1080

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1081 **EP 3**

1082 The center demonstrates sufficient quality and/or maintenance of experience through:

1083 - Coronary artery bypass grafting of 125 patients/annual volume requirement (alone or in
1084 combination with other procedures). Hospitals with less than annual volume of 125 patients
1085 must participate in a nationally audited registry and demonstrate risk adjusted outcomes that
1086 meet or exceed the national average.

1087 - Valve replacement/repair of 50 patients/annual volume requirement. Hospitals with less
1088 than annual volume of 50 patients (undergoing valve replacement/repair) must participate in
1089 a nationally audited registry and demonstrate outcomes that meet or exceed the national
1090 average for risk-adjusted outcomes.

1091 - Percutaneous Coronary Intervention of 200 patients/annual volume requirement.
1092 Hospitals with less than annual volume of 200 patients must participate in a nationally
1093 audited registry for catheterization and interventional procedures and demonstrate outcomes
1094 that meet or exceed the national average for risk adjusted outcomes.

1095 - Primary PCI for ST segment elevation myocardial infarction (STEMI) of 36
1096 patients/annual volume requirement. Hospitals with less than annual volume of 36 patients
1097 must participate in a nationally audited registry for catheterization and interventional
1098 procedures and a nationally audited registry for acute myocardial infarction and demonstrate
1099 outcomes that meet or exceed the national average for risk adjusted outcomes.

1100

1101 **EP 4**

1102 The center has a process to monitor appropriateness for cardiac procedures. At minimum, these
1103 procedures include:

1104 - Percutaneous coronary interventions

1105 - Cardiac stress tests

1106

1107 **EP 5**

1108 The center uses consistent data sets, definitions, codes, classifications, and terminology.

1109

1110 **EP 6**

1111 Data collection is timely, accurate, complete, and relevant to the center.

1112

1113 **EP 7**

1114 The center collects individual patient data related to processes and outcomes.

1115 Note: Measurement data must be internally trended over time and may be compared to an external
1116 data source for comparative purposes.

1117

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1118 **EP 8**

1119 The center collects data that is specific to a patient's experience of the care, treatment, and services
1120 he or she receives.

1121

1122 **EP 9**

1123 The center monitors the quality of data collected.

1124

1125 **EP 10**

1126 The center reports aggregated data results for minimum data sets specified in CCCPI.2 EPs 1–7 to
1127 The Joint Commission at defined intervals.

1128

1129 **CCCPI.3**

1130 The center analyzes and uses its data.

1131

1132 **EP 1**

1133 The center analyzes its data and compares it against regional, state, and national target ranges, when
1134 they exist.

1135

1136 **EP 2**

1137 The center uses statistical tools and techniques to analyze data.

1138

1139 **EP 3**

1140 The center identifies and evaluates variables that affect outcomes.

1141

1142 **EP 4**

1143 The center uses data that are specific to the care, treatment, and services it provides.

1144

1145 **EP 5**

1146 The center uses its data analysis to improve and sustain performance. (See also CCCPI.5, EP 8)

1147

1148 **EP 6**

1149 The center shares its data analysis with the interdisciplinary team at defined intervals.

1150

1151

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1152 **CCCPI.4**

1153 The center analyzes and uses its performance measurement data to identify opportunities for
1154 performance improvement.

1155

1156 **EP 1**

1157 The center prioritizes the identified improvement opportunities based on performance data and
1158 compares it against regional, state, and national target ranges.

1159

1160 **EP 2**

1161 The center takes action on improvement opportunities and has documentation to reflect outcomes
1162 that determine whether improvements have been achieved or sustained.

1163

1164 **EP 3**

1165 The center evaluates its actions to confirm that they resulted in improvements. The center also has
1166 documentation to reflect outcomes that determine whether improvements have been achieved or
1167 sustained.

1168

1169 **EP 4**

1170 The center takes action when it does not achieve or sustain planned improvements.

1171

1172 **CCCPI.5**

1173 The center addresses sentinel events that occur and takes steps to prevent future occurrences.

1174

1175 **EP 1**

1176 The center has a process for preventing sentinel events.

1177

1178 **EP 2**

1179 The center implements its process for preventing sentinel events.

1180

1181 **EP3**

1182 The center has a process for identifying and reporting sentinel events through established channels,
1183 both internally and externally.

1184

1185 **EP 4**

1186 The center implements its process for identifying and reporting sentinel events.

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1187

1188 **EP 5**

1189 The center has a process for analyzing sentinel events when they occur.

1190

1191 **EP 6**

1192 The center implements its process to conduct a thorough analysis of sentinel events.

1193

1194 **EP 7**

1195 The center documents its analysis of sentinel events.

1196

1197 **EP 8**

1198 The center implements changes based on its analysis of sentinel events. (See also CCCPI.1, EP 4;

1199 CCPI.3, EP 5)