Does Government Regulation Enhance Quality of Cardiovascular Procedures?

Robert H. Jones, MD

Cardiovascular specialists encumbered with excessive intrusion into the patient-doctor relationship will likely agree with the conclusion of DiSesa et al.1 that the coronary artery bypass grafting (CABG) mortality rate was not different between the 26 states with certificate-of-need (CON) programs and the 24 states without CON regulation. Data from the Society of Thoracic Surgeons’ (STS) National Cardiac Database (NCD) on 595,200 patients undergoing isolated CABG procedures for 4 consecutive years ending in 2003 used the STS NCD risk-stratification modeling to predict an equivalent occurrence of death after CABG during hospitalization or within 30 days for both the 280,512 patients treated in non-CON states and the 314,710 patients treated CON states (Table 5 in DiSesa et al.1). The observed perioperative CABG mortality rate was 2.52% for CON states and 2.62% for states without CON regulations (odds ratio [OR] = 0.97, P = 0.32).

Operative mortality and morbidity were compared for patients receiving CABG in CON and non-CON states in 2 separate hierarchical logistic regression analyses (Table 6 in DiSesa et al.1). When adjusted for patient risk factors, operative mortality still did not differ significantly (OR = 0.98, P = 0.52). However, patients in CON states had less renal failure (OR = 0.83, P < 0.001), although more patients stayed in the hospital more than 14 days after CABG (OR = 1.09, P = 0.02). With adjustment for risk factors and region, operative mortality becomes significantly lower in CON states (OR = 0.92, P = 0.05), with less renal failure (OR = 0.81, P < 0.001). The higher incidence of postoperative length of stay in CON states is no longer significant.

As an informed potential CABG patient, I assume that the higher perioperative renal failure in non-CON states reflects the occurrence of more frequent or more severe perioperative hypotensive episodes in non-CON states. Perhaps the 2-fold greater representation of minority patients in CON regions compared with non-CON regions explains why adjustment for both patient risk factors and region is required to demonstrate a lower operative mortality in CON states. It would be important for me as a potential CABG patient and concerned taxpayer to know why the costly and complicated CON process has such minimal benefit that a family of complex statistical models must be used to show minimal differences.

As the number of hospitals participating in the STS NCD rose from 431 in 2000 to 564 in 2003, the median annual CABG volume per hospital fell from 302 to 258 (~44) in CON and from 224 to 176 (~48) in non-CON hospitals (P = 0.0348, adjusted for region and state population density) (Table 1 in DiSesa et al.1). From 2000 to 2003, the percentage of low-volume hospitals performing 60 or fewer CABG operations per year increased from 6.7% to 7.4% of all CABG hospitals in non-CON states and decreased from 4.7% to 3.0% of all CABG hospitals in CON states (Table 2 in DiSesa et al.1). During the same interval, the percentage of low-volume hospitals performing 200 or fewer CABG operations per year increased from 42.5% to 57.5% of all CABG hospitals in non-CON states and from 25.7% to 35.5% of CABG hospitals in CON states (Table 3 in DiSesa et al.1). Although the number of low-volume hospitals performing 200 or fewer CABG operations rose during this 4-year

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

From the Department of Surgery/Duke, Clinical Research Institute, Duke University Medical Center, Durham, NC.

Correspondence to Robert H. Jones, MD, Duke Clinical Research Institute, PO Box 17969, Durham, NC 27715. E-mail jones060@mc.duke.edu

(Circulation 2006;114:2090-2091.)

© 2006 American Heart Association, Inc.

Circulation is available at http://www.circulationaha.org
DOI: 10.1161/CIRCULATIONAHA.106.657734

2090
interval in both CON and non-CON hospitals, growth was significantly slower in CON states, both with and without adjustment for state and region population density.

I was almost ready to concur with the conclusion of the authors of this article\(^1\) that CON regulation alone is not a sufficient mechanism to ensure quality of care for CABG operation and to even suggest that states with current CON programs might phase out CON regulations. The last data on recent emergence of more low-volume CABG hospitals are of concern, however. These data do suggest that CON programs decrease the numbers of hospitals with CABG rates below 60 per year (slightly more than 1 per week) and blunt the rise of programs in hospitals performing fewer than 200 CABG operations per year (4 or fewer CABG operations per week). A high CABG case volume would seem to maintain team skill among care providers (just as it does for athletic teams) and provide a plausible mechanism for higher mortality in patients who undergo CABG in low-volume hospitals. As a well-informed potential CABG patient, I have access to the Web and to friends and potential care providers to obtain information useful for choosing which institution and cardiac surgeon I will trust to provide excellent care. However, I fear that patients with less access to information will not fare as well. No rational person would praise government regulation as the best system of quality control. Some other system must be in place before all regulation is removed, however. The voluntary nature of the STS NCD seems to provide the best tool to standardize the quality of cardiac surgery. However, it is cause for concern that only about two thirds of hospitals in this country performing cardiac surgery voluntarily use this system. One can only wonder about the quality of outcomes in the large numbers of nonparticipating centers. Low participation would be expected especially at low-volume centers. Hesitancy to join the STS and voluntarily make program results public for a cardiac surgery program performing fewer than 60 operations a year is especially understandable if more than 1 death occurred in a year. Two deaths in 60 patients would raise operative mortality almost 2-fold above the national average. This suggests that the subsets of low-volume hospitals included in this report might not be representative of the entire low-volume CABG practice in this country. Perhaps this explains some of the weakness of the relationship between hospitals with low volumes of CABG cases and poor outcomes described in this article. I expect that my opinion as a prospective CABG patient is typical of that of others in that I must trust my doctors to produce a system that best measures the quality of cardiovascular care. Doctors have a large stake in supporting the core value that keeps their profession from becoming a guild. A profession places the welfare of those they serve above the welfare of individual members of the profession. Failure to seriously and rigorously monitor the competence of individual providers can quickly turn a profession into a guild. Those who pay for health care on my behalf also have power to influence the quality of care I receive, and provider reimbursement should be leveraged for my benefit. Close teamwork between the STS and other cardiovascular professional organizations that encourages providers to voluntarily participate in audited quality programs, combined with payer programs that provide financial incentives for maintaining high quality in appropriate ways, would seem to align the interests of the patient, provider, and payer to ensure development of quality-of-care partnerships that might render the need for governmental regulations obsolete in the future.

**Disclosures**

None.

**References**


---

**Key Words:** Editorials ■ bypass ■ morbidity ■ mortality ■ statistics
Does Government Regulation Enhance Quality of Cardiovascular Procedures?
Robert H. Jones

_Circulation_. 2006;114:2090-2091
doi: 10.1161/CIRCULATIONAHA.106.657734
_Circulation_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2006 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/114/20/2090

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in _Circulation_ can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to _Circulation_ is online at:
http://circ.ahajournals.org//subscriptions/