

THE AUTHORS REPLY: Readers question our use of data obtained up to 2 years before patients were placed on the waiting list and our exclusion of transplantation-center experience and the 15% of patients with missing data. The median time from clinical measurements to placement on the waiting list was 183 days and was uncorrelated with the outcome. To avoid selection effects associated with the length of time since listing, our analyses implicitly compared patients who had undergone transplantation with patients who had been on the waiting list for about the same time and who had not received a transplant. We excluded patients with missing data instead of imputing values or attempting a review of original charts. Of the 88 patients who were excluded, 70 had missing clinical data during the 2 years before placement on the waiting list. Excluded patients were slightly younger but otherwise indistinguishable from included patients for modeled covariates. They were more likely to undergo transplantation, but had no difference in mortality after listing or transplantation. A preliminary analysis of pediatric lung transplantation showed reduced harm but no benefit at large centers.

In reply to Dawwas et al., we used all patients in our model development to maximize statistical power. We used bootstrapping to rebuild the model with randomly resampled populations and found the reported model to be robust. The high significance and magnitude of the effects establish discriminatory power. This is our second study with the use of a different patient population and markedly different methods to show a lack of survival benefit associated with lung transplantation in children with cystic fibrosis.¹ To assist clinicians in listing patients for transplantation, we excluded factors from analysis that were unknowable at the time of decision making; these

factors include donor characteristics and the future experience of transplantation centers.

Anbar and Sweet et al. suggest that healthier patients waited longer than sick patients for transplantation, perhaps biasing the results against transplantation. However, waiting times relative to health have not been carefully studied. Transplantation may also be deferred in patients who are deemed to be too sick to undergo the surgery, resulting in a different bias. Preliminary examination of center-specific data suggests that healthier patients at large centers had shorter times to wait before transplantation than sicker patients at small centers.

Sweet et al. report that the current lung-allocation score predicts that 69% of patients benefit from transplantation. This assertion of realized benefit constitutes a hypothesis that cannot be tested retrospectively. Under the lung-allocation scoring system, patient selection is based on the estimated survival benefit, confounding an analysis of the survival benefit of transplantation.

The question of the benefit of transplantation for children with cystic fibrosis cannot be resolved by retrospective study because of unobserved biases. The best solution is to positively answer our call for a prospective, randomized trial of lung transplantation.

Theodore G. Liou, M.D.
Frederick R. Adler, Ph.D.

University of Utah
Salt Lake City, UT 84132
ted.liou@utah.edu

David R. Cox, Ph.D.
Nuffield College
Oxford OX1 1NF, United Kingdom

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Outcomes of Care by Hospitalists

TO THE EDITOR: The article by Lindenauer and colleagues (Dec. 20 issue)¹ compares the outcomes of care by hospitalists with the outcomes of traditional models of care. As physicians who have practiced both as hospitalists and as primary care physicians, we believe that the authors failed to consider other pivotal variables. First, hospitalists are employed by either the hospital or a private contracting company; this variable affects both the

number of admissions and their appropriateness. Second, the authors did not compare physician experience and the rate of consultations per case when comparing hospitalist and traditional practice models. Third, sample homogeneity in regard to patient load per hospitalist per day should also have been examined. Another variable worth examining is the rate of patient satisfaction. Finally, what were the differences in level of service be-

tween the hospitalist and traditional practice models?

The above variables are essential for a correct assessment of the current practice environment and would help provide guidance in decision making with respect to the optimal setting and structure of a hospitalist service.

Moutasim H. Al-Shaer, M.D.

Cy-Fair Cardiovascular Associates
Houston, TX 77065
alshaermd@gmail.com

Ehab S. Suleiman, M.D.

Iowa Health Physicians
Waterloo, IA 50703

William P. Jerome, M.D.

Trinity Internal Medicine Specialists
Bettendorf, IA 52722

1. Lindenauer PK, Rothberg MB, Pekow PS, Kenwood C, Benjamin EM, Auerbach AD. Outcomes of care by hospitalists, general internists, and family physicians. *N Engl J Med* 2007;357:2589-600.

TO THE EDITOR: We believe that the conclusions reached by Lindenauer and colleagues may be based on an underestimate of the effect of hospitalists on outcomes of care. The “hospitalists” identified by the authors cared for a median of 70 patients per year with one or more of seven common inpatient medical diagnoses. A typical hospitalist admits 561 to 748 patients per year.¹ Approximately 22% of these admissions fall within the seven diagnoses studied.² This represents approximately twice the caseload of the median-volume hospitalists and almost four times the cutoff caseload for the comparison group of “high-volume” hospitalists (those with case volumes that met or exceeded the 25th percentile) identified in this study.

This discrepancy could have biased the results in two ways. First, the lower-than-expected case volume suggests misclassification of nonhospitalist physicians as hospitalists, which would bias the results toward the null hypothesis. Second, on the basis of what is known about the improved outcomes seen when physicians perform a higher volume of work in a specific area,³⁻⁵ the study might have underestimated the potential beneficial effects of hospitalists on length of stay and cost of care.

Eugene S. Chu, M.D.

Richard K. Albert, M.D.

Denver Health Medical Center
Denver, CO 80204

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of hospital medicine: highlights/executive summary. (Accessed March 28, 2008, at <http://www.hospitalmedicine.org/AM/Template.cfm?Section=Survey&Template=/CM/ContentDisplay.cfm&ContentID=14352>.)

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5. Moscucci M, Share D, Smith D, et al. Relationship between operator volume and adverse outcome in contemporary percutaneous coronary intervention practice: an analysis of a quality-controlled multicenter percutaneous coronary intervention clinical database. *J Am Coll Cardiol* 2005;46:625-32.

TO THE EDITOR: The study by Lindenauer et al. investigated the outcomes of hospitalist care among 76,926 patients at 45 hospitals. As compared with the outcomes associated with hospitalist care in previous studies based on single hospitals,^{1,2} the cost savings were lower and favorable inpatient mortality was not found in the study by Lindenauer et al. However, I would like to see some analysis with regard to the homogeneity of the outcomes among the hospitals in their study. The cost for the same therapy could be quite different among hospitals. Although the authors have considered some variables, such as number of beds and location of the hospitals, the outcomes could vary among the hospitals even after adjustment for these factors. The authors' primary explanation for the discrepancy between their findings and the results of previous studies was that they included many community-based hospitals in the study. If this is the case, hospitalist care may have a weak favorable effect, no effect, or a negative effect on the outcomes in community-based hospitals. A subgroup analysis will be needed.

Ming Wei, M.D.

Holy Hospital
Mechanicsburg, PA 17050

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TO THE EDITOR: The discussions by Lindenauer et al. and by McMahon,¹ in the accompanying edito-

rial, present the hospitalist movement as one driven by cost and quality concerns. Having been involved in physician credentialing at several national health plans over the past dozen years, I see the shift to hospitalists as a cultural one as well on the part of physicians who no longer view the hospital as the axis of their professional activities. I will remember how the request by an allergist to become a part of our plan's panel, yet not maintain hospital privileges, flummoxed our credentialing committee at the time. Now it is routine to see most primary care physicians and many specialists present to the committee without hospital affiliations. They no longer see the hospital as offering services or value to them that justifies joining a medical staff with its attendant obligations. This change has also been facilitated by the explosive growth in freestanding ambulatory centers, owned and managed by physicians and usually in direct competition with hospitals, that are supplanting hospital-based services in many communities.

Derek van Amerongen, M.D.

Humana of Ohio
Cincinnati, OH 45202
dvanamerongen@humana.com

1. McMahon LF Jr. The hospitalist movement — time to move on. *N Engl J Med* 2007;357:2627-9.

THE AUTHORS REPLY: We agree with Al-Shaer and colleagues that factors such as employment arrangements for hospitalists (employed by the hospital or by a private group), staffing ratios (e.g., the ratio of patients to physicians), and number of years in practice may explain variations in outcome among hospitalist programs. Similar structural factors are likely to influence outcomes of care by family physicians or general internists as well. However, the aim of our study was to compare outcomes across representative groups of physicians, not to assess factors associated with intraspecialty variation.

Although we acknowledged the risk of misclassification in our article, we disagree with Chu and Albert about the presence of large differences between the annual volume estimates we produced and those based on productivity data from the Society of Hospital Medicine (SHM).¹ Our median volume estimates are based on the number of cases for which each hospitalist was the attending physician of record in our data set, whereas SHM data are derived from surveys, include consultative encounters, and are normalized to a 1.0

full-time-equivalent job description. Despite Chu and Albert's comments about the relationship between volume and outcome, volume was not independently associated with any of the outcomes we studied. Although this may seem to be at odds with the experience in cardiac surgery or cardiology, this linkage in hospital medicine has been seen in only one single-site, two-hospitalist study,² and studies of pneumonia and chronic obstructive pulmonary disease suggest that any association that may exist runs counter to that which would be predicted.^{3,4}

Our comment regarding community-based, or nonteaching, hospitals was made because previous studies examined large academic medical centers almost exclusively. Among other factors, we adjusted for the effects of hospital size, teaching status, region, and population served (urban or rural) in our multivariable models and also explored potential interactions between physician specialty and hospital teaching status. However, there was very little variation in the effects of physician specialty in these analyses. Figure 2 of our article shows the relative consistency of our findings across all 45 hospitals. We believe these analyses address Wei's concern about the need for subgroup analysis.

Although our analysis was limited to the outcomes of care in the hospital, van Amerongen is correct in noting that the wishes of primary care physicians may be as potent a catalyst for the continued growth of the hospitalist model of care as is interest in improving hospital efficiency and quality.⁵

Peter K. Lindenauer, M.D.

Michael B. Rothberg, M.D., M.P.H.

Baystate Medical Center
Springfield, MA 01199
peter.lindenauer@bhs.org

Andrew D. Auerbach, M.D., M.P.H.

University of California, San Francisco
San Francisco, CA 94143

1. 2005-2006 SHM survey, the authoritative source on the state of hospital medicine: highlights/executive summary. (Accessed March 28, 2008, at <http://www.hospitalmedicine.org/AM/Template.cfm?Section=Survey&Template=/CM/ContentDisplay.cfm&ContentID=14352>.)

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cian experience on costs and outcomes on an academic general medicine service: results of a trial of hospitalists. *Ann Intern Med* 2002;137:866-74.

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of the hospitalist in California. Oakland: California Healthcare Foundation, July 2007. (Accessed March 28, 2008, 2008, at <http://www.chcf.org/topics/hospitals/index.cfm?itemID=133365>.)

A Pivotal Medical-Device Case

TO THE EDITOR: Three cheers for the *Journal* for recognizing the importance of the Supreme Court's upcoming rulings on "FDA [Food and Drug Administration] preemption" cases: whether the fact that a drug or medical device is in compliance with FDA regulations ought to shield its manufacturer from product-liability claims. In your editorial on this topic (Jan. 3 issue),¹ you rightfully describe these cases as having "major, even momentous, implications" for patients' rights and manufacturers' accountability.

There is one point in the editorial that needs clarification. *Warner-Lambert v. Kent* — which concerns drugs rather than devices — turns on a Michigan law that allows liability claims if plaintiffs can show that the FDA was defrauded. Defendants argue that only the FDA can find fraud against itself, not state courts, and thus Michigan's "fraud exception" is preempted.

The *Kent* case explicitly does not address the wider issue of FDA preemption in the drug arena. However, that latter question — the big one — is the heart of another case the Supreme Court recently accepted, *Wyeth v. Levine*. Stay tuned.

Henry Greenspan, Ph.D.

University of Michigan
Ann Arbor, MI 48109
hgreesp@umich.edu

1. Curfman GD, Morrissey S, Drazen JM. A pivotal medical-device case. *N Engl J Med* 2008;358:76-7.

TO THE EDITOR: The editorial concerning the Medtronic medical-device case now before the Supreme Court concludes, "Ultimately, we believe that the pivotal question for the justices in *Riegel v. Medtronic* resides in what is in the best interest of American society." This is a commonly made er-

ror. The pivotal question for the justices is actually to decide whether FDA approval preempts liability claims in the state courts. It is the justices' job to decide on this issue based on their understanding of the law in question and the Constitution, not on what they perceive to be the best interest of American society. They are supposed to be interpreting the laws as written, not advocating for any individual vision of what they conclude is best for protecting patients.

If the American people deem that the justices' conclusions are not in their best interest, then they have the privilege of changing the law through Congress.

Stephen M. Picca, M.D.

57 Kenwood Dr.
Massapequa, NY 11758
eesp@aol.com

TO THE EDITOR: In the case of *Riegel v. Medtronic*, it would seem logical to state that premarketing approval by the FDA addresses solely the functional and medical adequacy of the device and that faultless quality of the marketed devices is assumed to be inherent. It would seem unreasonable to maintain that FDA approval would protect the manufacturer of an approved device against litigation based on faulty product quality (i.e., the defective balloon in *Riegel v. Medtronic*).

The approval process and subsequent approval do not and cannot ensure product quality or provide surveillance of manufacturing processes and quality control. The *Lohr* case proves this point.

Gerhard Sonder, B.M.E.

671 Shermantown Rd.
Saunderstown, RI 02874-2008

Central Venous Catheterization — Subclavian Vein

TO THE EDITOR: In their video and accompanying article, Braner et al. (Dec. 13 issue)¹ omit an important and common complication of subclavian

central-venous-catheter placement — misplacement of the catheter tip in the internal jugular vein. This occurs in approximately 5% of patients,