and that the true improvement was in the high-risk donors from the brain-dead group. If this is true, a new trial is warranted to compare EVLP with standard preservation in marginal donors (similar to the brain-dead donor group in this trial), since the present study does not really answer the question of whether EVLP is beneficial in marginal donors.

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The Authors Reply: Our study included both brain-dead donors and cardiac-death donors. To be precise in our analysis of outcomes, we provided tables that clearly show the results of the EVLP group separated into these two donor categories. Statistical analysis showed no difference in outcomes between each of these subgroups and the controls. Although the lungs from the 11 brain-dead donors had undergone greater injury than those from the cardiac-death donors and would not have been used without EVLP, excellent outcomes were nevertheless achieved. On the basis of experience at our lung-transplant center, we believe that lungs from cardiac-death donors are less predictable organs owing to lung injuries that can occur after extubation and the withdrawal of life support.1 As such, we decided to include such donors for EVLP. Finally, this study was designed as a feasibility trial, the most important message being that EVLP is a safe procedure and that lungs will function well after transplantation if they perform well during the 4-hour EVLP procedure. Indeed, to determine whether EVLP truly provides superior results, as compared with controls, a randomized trial is required.

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Since publication of their article, the authors report no further potential conflict of interest.


Quality of Care and Negligence Litigation in Nursing Homes

To the Editor: Studdert and colleagues (March 31 issue)1 report a weak relationship between nursing home deficiencies and incidence of tort claims, finding that the low-performing facilities (bottom 10% in their sample) are sued just slightly more often than the high-performing ones (top 10%). Such results, the authors conclude, cast doubt on two of the central propositions of tort law: that “litigation induces defendants to be more careful and that superior performance will be rewarded with substantially lower risks of being sued.” I would argue that their data speak to neither proposition. First, actions are required to deter negligent care. If, as we might expect, the residents in the worst-performing homes had far fewer resources — economic, social, and familial — than their counterparts in the best-performing ones, they also would have been less likely to sue. Controlling for the percentage of patients on Medicaid does not sufficiently capture the extreme vulnerability of resident populations in the worst-performing institutions. Second, the authors do not present any data to suggest that the residents of the superior-performing facilities were filing frivolous claims.

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To the Editor: Studdert and colleagues found only a marginal relationship between the quality of care in nursing homes and the risk of being cited in a lawsuit. Is it possible, however, that any such relationship is obscured by their failure to examine the impact of the nursing homes’ policies and practices with regard to disclosure of harmful adverse events? Perhaps the worst-performing nursing homes were more open about these events and were therefore “forgiven” by patients and families. Or perhaps the best-performing nursing homes were more transparent and were still
sued, in contrast to the findings in other studies. In any case, institutional attitudes toward the disclosure of harmful incidents seem an important variable to consider when examining the relationship between quality of care and its implications for medicolegal actions.

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THE AUTHORS REPLY: Harris and Hébert point to two factors not considered in our study. First, previous studies of hospital care suggest that patients’ socioeconomic status is positively correlated with their propensity to sue. We controlled for the Medicaid mix among residents but not for socioeconomic status or vulnerability directly. If wealthy residents tended to choose high-quality nursing homes and poor residents tended to choose low-quality homes, such “sorting” may have contributed to the similarities we observed in the incidence of lawsuits across facilities. Second, there is considerable interest in whether openness about adverse events protects against litigation, and emerging signs suggest that it may. Systematically different approaches to disclosure — specifically, claim-inducing practices in higher-quality facilities and claim-reducing practices in lower-quality facilities — may also have narrowed the gap between the litigation-risk profiles of facilities at each end of the quality spectrum, although this seems unlikely.

Both theories focus on residents’ claiming behavior and both are interesting, but neither one seriously challenges the main study findings. One reason for this is that the theories fit best in relation to differences between nursing homes. However, reanalyses of the study data set with the use of a random-effects approach show that the estimates reported were due in larger part to variation in litigation risk within facilities over time.

More important, these theories may help to explain why the relationship between litigation risk and nursing-home quality is surprisingly weak, but they do not negate the finding that it is weak, nor do they change the fundamental question that this finding raises about litigation’s deterrent value. In other words, systematic differences in claiming behavior among residents in high-performing and low-performing facilities are best understood as a causal explanation for the relationship we observed, not as a potential confounder of that relationship.

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Case 9-2011: A Man with Flushing and Hypotension

TO THE EDITOR: In the Case Record regarding a patient with flushing and hypotension (March 24 issue), the discussants considered several alternatives, including anaphylaxis, before arriving at the correct diagnosis of mastocytosis. We believe a distinct clinical entity termed “food-dependent exercise-induced anaphylaxis” (FDEIA) warrants explicit mention.

Initially described in 1979, FDEIA is an important and underrecognized cause of seemingly unprovoked anaphylaxis. Ingestion of particular food antigens (typically wheat), followed by exercise, triggers anaphylaxis within hours in specific FDEIA. In the nonspecific form, however, plain physical exertion on a full stomach suffices. A putative mechanism is exercise-related mesenteric ischemia, leading to increased absorption of food antigens. Acetylsalicylic acid is known to aggravate symptoms.

The symptoms of the patient in this case were usually provoked by physical activity, developed after lunch (at least on the day of admission),