

COMMENTS AND RESPONSES

Physician–Industry Relations

TO THE EDITOR: The American College of Physicians (ACP) continues to evaluate issues related to relationships between physicians and industry and between physician organizations and industry and to work to emphasize relationships that maximize the interests of the patient. Recently, the College approved a revision to position 1 (Industry Gifts, Hospitality, Services, and Subsidies) of our position paper (part 1 of 2) on physician–industry relations (1). The revision was developed by the ACP Ethics and Human Rights Committee to help clarify the statement, including moving some language from the rationale directly into the position.

The revised position is as follows:

The acceptance by a physician of gifts, hospitality, trips, and subsidies of all types from the health care industry that might diminish, or appear to others to diminish, the objectivity of professional judgment is strongly discouraged. As documented by some studies, the acceptance of even small gifts can affect clinical judgment and heighten the perception and/or reality of a conflict of interest. Accordingly, physicians need to gauge regularly whether any gift relationship is ethically appropriate and evaluate any potential for influence on clinical judgment. In making such evaluations, it is recommended that physicians consider such questions as 1) What would the public or my patients think of this arrangement? 2) What is the purpose of the industry offer? 3) What would my colleagues think about this arrangement? 4) What would I think if my own physician accepted this offer? In all instances, it is the individual responsibility of each physician to assess any potential relationship with industry to assure that it enhances patient care and medical knowledge and does not compromise clinical judgment.

We hope that physicians will find this revision and the rest of the content of the 2002 position paper helpful and will continually evaluate their relationships with industry as well.

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Potential Financial Conflicts of Interest: None disclosed.

Reference

1. Coyle SL, for the American College of Physicians–American Society of Internal Medicine Ethics and Human Rights Committee. Physician–industry relations. Part 1: individual physicians. *Ann Intern Med.* 2002;136:396–402. [PMID: 11874314]

Missed and Delayed Diagnoses in the Ambulatory Setting

TO THE EDITOR: The article by Gandhi and colleagues (1) on malpractice cases is an interesting read, but it fails to help the primary care physician in his or her quest to maximize patient safety while preventing a suit for not doing so. While the authors lament the absence of a “silver bullet,” I believe there is a simple one.

I propose full disclosure of every malpractice case to every physician in his county or state on a regular basis with information from

the claim file—a repository of information accumulated by the insurer during the life of the claim. This claim file would include an executive summary with the 6-point confidence scale and an attached expert opinion about how the claim might have been prevented.

We learn from case studies. When it comes to malpractice cases, they are often sealed and we learn nothing. This is why history repeats itself in the form of 24% missed or delayed diagnoses of breast cancer.

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Potential Financial Conflicts of Interest: None disclosed.

Reference

1. Gandhi TK, Kachalia A, Thomas EJ, Puopolo AL, Yoon C, Brennan TA, et al. Missed and delayed diagnoses in the ambulatory setting: a study of closed malpractice claims. *Ann Intern Med.* 2006;145:488–96. [PMID: 17015866]

TO THE EDITOR: Although Gandhi and colleagues’ report (1) is an interesting and important descriptive study of a large series of malpractice cases, its conclusions about “errors” are tempered by methodological flaws. In addition to failing to blind reviewers to the outcome of the cases and other potentially prejudicial material in the legal files, the study used medical trainees to review cases, make gold standard determinations of error, and project the probable consequences of those errors—this method is difficult to understand. Because malpractice actions generally involve competing expert interpretations of critical medical evidence, it would seem reasonable to use experts in that particular field to review those cases to arrive at an independent conclusion.

For example, in 2 vignettes presented in Gandhi and colleagues’ Appendix Table 1, alleged error in interpretation of an electrocardiogram was a key component of each case. Misinterpretation of electrocardiograms is not a rare event (2, 3), even with board-certified attending physicians, and is probably related to the degree of experience with and training in electrocardiography.

These issues raise the larger questions, which hamper the science of error reduction: How can we define the term “error” in a way most health care providers can agree on, and how can we apply that definition meaningfully to individual cases?

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References

- Gandhi TK, Kachalia A, Thomas EJ, Puopolo AL, Yoon C, Brennan TA, et al. Missed and delayed diagnoses in the ambulatory setting: a study of closed malpractice claims. *Ann Intern Med.* 2006;145:488–96. [PMID: 17015866]
- Bogun F, Anh D, Kalahasty G, Wissner E, Bou Serhal C, Bazzi R, et al. Misdiagnosis of atrial fibrillation and its clinical consequences. *Am J Med.* 2004;117:636–42. [PMID: 15501200]
- Knight BP, Pelosi F, Michaud GF, Strickberger SA, Morady F. Clinical consequences of electrocardiographic artifact mimicking ventricular tachycardia. *N Engl J Med.* 1999;341:1270–4. [PMID: 10528037]

TO THE EDITOR: We applaud Gandhi and colleagues (1) for highlighting the problem of outpatient diagnostic errors. However, malpractice claims are a biased data source. Primary identification of diagnostic errors in ambulatory settings remains problematic.

Wachter (2) highlighted differences that make diagnostic error detection more difficult in ambulatory settings than in hospitals. Outpatient diagnosticians typically record their observations and conclusions incompletely and illegibly on paper charts, which contributes to the lack of knowledge about the extent of diagnostic errors. Paper-based outpatient records are expensive to collect and analyze for outcome studies. In outpatient settings, fewer diagnostic gold standard procedures occur and irregular follow-up facilitates missing sentinel events. Incorrect outpatient diagnoses may go unnoticed for self-limited disorders. For more serious conditions, patients may present to serial physicians for second opinions; earlier physicians in the chain may never learn of a definitive diagnosis made elsewhere. As a result, available estimates of rates of outpatient diagnostic errors may represent lower bounds for their true frequency. Malpractice claims make up an even smaller proportion of the total.

Gandhi and colleagues' suggestion to use diagnostic decision-support tools is a good one because these tools have been notoriously underused. Barriers to adopting them include the lack of impartial, nonproprietary, high-quality, and comprehensive diagnostic knowledge bases and the time required to use such systems as "stand-alone" consultants during busy clinical practice (3, 4). Data transfer from electronic health record systems may address the problem of time-consuming data entry for diagnostic systems, but a bigger problem is that outpatient clinicians may not recognize any need for diagnostic assistance. It is not surprising that, without consistent feedback on the accuracy of their outpatient diagnostic decisions, many clinicians may seem overconfident in their diagnostic skills and fail to adopt decision-support tools (5). We concur with Gandhi and colleagues that use of clinical decision-support systems should not depend on a physician's perception that a case may pose diagnostic challenges.

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References

- Gandhi TK, Kachalia A, Thomas EJ, Puopolo AL, Yoon C, Brennan TA, et al. Missed and delayed diagnoses in the ambulatory setting: a study of closed malpractice claims. *Ann Intern Med.* 2006;145:488-96. [PMID: 17015866]
- Wachter RM. Is ambulatory patient safety just like hospital safety, only without the "star"? [Editorial]. *Ann Intern Med.* 2006;145:547-9. [PMID: 17015874]
- Miller RA. Medical diagnostic decision support systems—past, present, and future: a threaded bibliography and brief commentary. *J Am Med Inform Assoc.* 1994;1:8-27.

[PMID: 7719792]

4. Miller RA, Giuse NB. Medical knowledge bases. *Acad Med.* 1991;66:15-7. [PMID: 1985669]

5. Graber M. Diagnostic errors in medicine: a case of neglect. *Jt Comm J Qual Patient Saf.* 2005;31:106-13. [PMID: 15791770]

IN RESPONSE: We agree with Dr. Clairmont's suggestion that greater transparency of errors in malpractice claims would advance patient safety. If appropriately identified, such information could help pull the liability system toward a broader culture of openness in which mistakes are seen as valuable opportunities to improve care, not as problems to be hidden. All errors, regardless of whether they prompted malpractice claims, should be construed and discussed in this light.

We are disappointed by Dr. Clairmont's view that our findings will not help primary care physicians. By highlighting several points in the diagnostic processes in which breakdowns frequently occur and proposing several relatively "low-tech" prevention strategies, we believe the research provides some practical guidance for clinicians.

Dr. Marine makes several reasonable methodological criticisms of our study. It was not possible within the available study resources to purge all references to the litigation outcomes from the numerous pages of documentation in the claim files, so reviewers may have been aware of the outcomes. The likely effect of this knowledge would be to make reviewers more likely to judge claims that attracted payments to be errors and vice versa. Senior residents or fellows reviewed approximately one quarter of the claims, and their detection rate did not differ from that of more senior reviewers. In previous large-scale studies of adverse events (1, 2), the quality of reviews by upper-level trainees and attending physicians were similar. Finally, better agreement over what constitutes an error is certainly needed (3). The World Health Organization's ongoing work in this area should be applauded (4). But more sophisticated definitions and classification tools cannot avoid the complex questions of causation and appropriateness that surround errors of omission, such as missed diagnoses—they will remain intrinsically difficult to identify reliably.

We agree with Drs. Berner, Miller, and Graber that malpractice claims are a biased source of data on medical errors, but it is important to consider what effect those biases may have on etiologic analyses. Many specific concerns mentioned are problems for a study aimed at estimating an error rate. However, we focused on causal factors. As we note in our paper, some factors, such as fatigue, may have been routinely undercounted because claim file documentation is not well-suited to record these. (This is a problem for any retrospective review of records.) Consequently, the prevalence estimates for some causal factors are likely to be lower bounds, and the multifactorial nature of diagnostic errors depicted by our findings is probably an understatement of their true complexity.

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Potential Financial Conflicts of Interest: None disclosed.

References

1. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med*. 1991;324:370-6. [PMID: 1987460]
2. Thomas EJ, Studdert DM, Burstin HR, Orav EJ, Zeena T, Williams EJ, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care*. 2000;38:261-71. [PMID: 10718351]
3. Thomas EJ, Petersen LA. Measuring errors and adverse events in health care. *J Gen Intern Med*. 2003;18:61-7. [PMID: 12534766]
4. World Health Organization. More than words: international patient safety event classification. Accessed at www.who.int/patientsafety/taxonomy/en/ on 4 December 2006.

Correction: Plasma Exchange When Myeloma Presents as Acute Renal Failure

TO THE EDITOR: We are submitting a new Table 2 to replace the original Table 2 that appeared in our article (1). We discovered an error in the order of data entry in the original table. The control group (no plasma exchange group) was compared with the plasma exchange group instead of the plasma exchange group being compared with the control group. This error has no effect on the interpretation or conclusions of the paper. In the original Table 2, the

primary composite outcome occurred more frequently in the control group than in the plasma exchange group. Thus, when comparing the control group with the plasma exchange group, the odds ratio is greater than 1.0. In our corrected Table 2, the plasma exchange group is compared with the control group and the odds ratio is less than 1.0. However, the relationship between the event rates of the primary composite outcome in the plasma exchange and control groups does not change, since the 95% CIs nearly always included 1.0. We apologize for this error but reiterate that the error does not affect our conclusion about treatment of acute renal failure at the onset of multiple myeloma: Plasma exchange and conventional treatment (i.e., no plasma exchange) had the same composite outcome rate.

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Potential Financial Conflicts of Interest: None disclosed.

Reference

1. Clark WF, Stewart AK, Rock GA, Sternbach M, Sutton DM, Barrett BJ, et al. Plasma exchange when myeloma presents as acute renal failure: a randomized, controlled trial. *Ann Intern Med*. 2005;143:777-84. [PMID: 16330788]

Table 2. Unadjusted and Adjusted Odds Ratios for Primary Outcomes in Patients Treated with Plasma Exchange versus No Plasma Exchange (Control)*

Potential Determinants of Specified Outcome	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio (95% CI)
Death by 6 mo		
Received plasma exchange	0.975 (0.411–2.309)	1.130 (0.402–3.175)
Received VAD chemotherapy	0.658 (0.277–1.563)	1.276 (0.369–4.405)
Receiving dialysis at baseline	1.100 (0.439–2.755)	0.923 (0.291–2.933)
Durie–Salmon stage IIIB	2.857 (1.193–6.849)	2.114 (0.694–6.452)
Age at entry	1.042 (0.999–1.086)	1.060 (0.995–1.129)
Baseline urine protein level	0.980 (0.927–1.037)	0.998 (0.940–1.060)
Baseline serum albumin level	0.965 (0.910–1.024)	0.960 (0.894–1.031)
Death by 6 mo or receiving dialysis at 6 mo		
Received plasma exchange	0.671 (0.296–1.517)	0.885 (0.323–2.427)
Received VAD chemotherapy	1.087 (0.486–2.427)	3.003 (0.845–10.638)
Receiving dialysis at baseline	2.646 (1.080–6.452)	2.849 (0.907–8.929)
Durie–Salmon stage IIIB	3.040 (1.318–7.042)	2.646 (0.872–8.065)
Age at entry	1.029 (0.992–1.067)	1.092 (1.024–1.164)
Baseline urine protein level	1.027 (0.977–1.080)	1.050 (0.978–1.129)
Baseline serum albumin level	1.016 (0.962–1.073)	1.019 (0.950–1.093)
Death, receiving dialysis, or GFR <30 mL/min per 1.73 m² at 6 mo†		
Received plasma exchange	0.587 (0.249–1.381)	0.831 (0.291–2.375)
Received VAD chemotherapy	0.899 (0.395–2.049)	2.045 (0.557–7.519)
Receiving dialysis at baseline	1.555 (0.618–3.922)	1.692 (0.482–5.952)
Durie–Salmon stage IIIB	1.949 (0.829–4.587)	1.799 (0.563–5.747)
Age at entry	1.031 (0.993–1.070)	1.079 (1.016–1.145)
Baseline urine protein level	1.021 (0.965–1.080)	1.037 (0.963–1.117)
Baseline serum albumin level	1.063 (1.002–1.126)	1.075 (0.995–1.161)
Receiving dialysis or GFR <30 mL/min per 1.73 m² at 6 mo‡		
Received plasma exchange	0.480 (0.175–1.319)	1.124 (0.279–4.525)
Received VAD chemotherapy	1.176 (0.440–3.145)	2.110 (0.415–10.753)
Receiving dialysis at baseline	1.727 (0.588–5.076)	3.333 (0.648–17.241)
Durie–Salmon stage IIIB	1.157 (0.411–3.257)	1.033 (0.243–4.386)
Age at entry	1.013 (0.972–1.057)	1.064 (0.992–1.142)
Baseline urine protein level	1.034 (0.971–1.101)	1.064 (0.965–1.174)
Baseline serum albumin level	1.117 (1.036–1.205)	1.145 (1.033–1.272)

* Exp (B) by logistic regression. All independent variables are categorical except age, baseline urine protein level, and baseline albumin level. GFR = glomerular filtration rate; VAD = vincristine–adriamycin–dexamethasone.

† GFR calculated with the Modified Diet in Renal Disease formula 2.

‡ GFR calculated with the Modified Diet in Renal Disease formula 2. This primary outcome excludes patients who died during follow-up.