

LETTERS

We welcome your responses to papers that appear in *Health Affairs*. We ask you to keep your comments brief (250–300 words, including any endnotes) and sharply focused. *Health Affairs* reserves the right to edit all letters for clarity and length and to publish them in the bound copy or on our Web site. *Health Affairs* will not acknowledge receiving unsolicited letters that are not published. Letters can be submitted by e-mail, letters@healthaffairs.org, or the *Health Affairs* Web site, <http://www.healthaffairs.org>.

‘Bundled’ Medications And The Underserved

In discussing advances in preventing and treating cardiovascular disease (Jan/Feb 07), Myron Weisfeldt and Susan Ziemann write that “combining several generic drugs...would be particularly useful in underserved populations with limited resources.” Indeed, the stark similarities in the pattern of cardiovascular disease (CVD) in developing countries—and among racial and ethnic minorities in the United States—remind us of the sobering realities of a health care system defined by populations of separate fates. Even in the face of evidence suggesting that preventive drug therapy can avoid thousands of needless deaths, the U.S. health care system fails to provide optimal preventive care for everyone, which is compounded by a disproportionate effect on the poor and minorities.

Kaiser Permanente strives to place all of its members over age fifty-five who have diabetes or documented CVD on a fixed-dose “bundle” of three pills: aspirin, lovastatin, and lisinopril (A-L-L). More than 73,000 new prescriptions for statins and angiotensin-converting enzyme (ACE) inhibitors have been written since the program started in 2003. Using the prediction of a 15 percent recurrence rate by Thomas Gaziano in the same issue of *Health Affairs* and the Steno-2 study (diabetes) savings of about 50 percent from a similar bundle of medications, we predict that members on this protocol will suffer 5,400 fewer heart attacks,

strokes, and other CVD events. At our overall cost of \$225 per member per year, Kaiser Permanente projects savings of more than \$300 a year for each member.

As part of Kaiser Permanente’s commitment to broad community benefit, in 2006 we launched a similar campaign among patients with diabetes in two community health centers in San Diego County. Together we provide A-L-L combination therapy for an uninsured, largely minority patient population at CVD risk, simplifying medication delivery while capitalizing on the centers’ strengths in community outreach and cultural competence. The centers have enrolled more than 171 previously untreated diabetic patients to begin the A-L-L therapy. We think that such an approach, if implemented aggressively, could well eradicate disparities in cardiovascular disease outcomes.

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‘Bundled’ Medications: The Authors Respond

We applaud Kaiser Permanente’s aggressive initiative to promote pharmaceutical prevention of primary and secondary cardiovascular disease (CVD) in a cost-effective manner by offering a universal “bundle” of aspirin, lovastatin, and lisinopril to their high-risk members. This underscores the concept we raised of a “polypill,” a single tablet that contains several evidence-based medications to decrease incident cardiovascular events as a method to reduce the burden of CVD in high-risk populations, especially those with limited resources. We emphasize that the potential ability of such a polypill to reduce cardiovascular events is based on projections from meta-analyses of studies focusing on primary prevention. A robust clinical trial is needed to demonstrate the efficacy of such an intervention, while paying particular attention to pos-

sible side effects. As we have learned, the efficacy of certain pharmacotherapy might also differ in people of certain ethnicities, which should be studied.

Additionally, we endorse Kaiser Permanente's appreciation that increasing age is the most potent risk factor for CVD by focusing these prevention efforts on members who are older than age fifty-five. Particular caution must be taken, however, when employing homogeneous strategies to the most heterogeneous and vulnerable cohort of our population: older adults. As the pharmacokinetics and pharmacodynamics change dramatically with increasing age, preventive and therapeutic strategies should take this into account. Accordingly, dosages and interactions of many of the commonly used prescribed, over-the-counter, and herbal medications must be judiciously monitored and ad-

justed to accommodate these constantly changing alterations to avoid untoward side effects, toxicities causing adverse events, and subtle diminutions in quality of life. Thus, one size might not fit all. Implementing cost-effective, efficacious, and evidence-supported interventions is critical to reduce the burden of CVD, as is appreciating the challenges of delivering care that emphasizes appropriate and individualized therapy to vulnerable populations.

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Role Of Smoking In U.S. CVD

I applaud *Health Affairs'* attempts to bridge the chasm between the worlds of medical science and health policy. The recent thematic issue on cardiovascular disease (CVD) (Jan/Feb 07) was a logical place to start that effort. I hope, however, that the journal maintains a broad interpretation of both medical science

and health policy and does not become overly focused on medical technologies. For example, the paper by Myron Weisfeldt and Susan Ziemann on advances in preventing and treating CVD fails to mention the most important and cost-effective step that clinicians can take: identifying smokers and helping them quit.

Although much of the recent decline in U.S. deaths from CVD has been attributed to declines in smoking prevalence, there is still much more to be done for the nation's 44.5 mil-

lion smokers. For example, the Partnership for Prevention estimates that raising the current rate of tobacco-use screening and brief intervention from the current rate of 35 percent of all smokers to 90 percent would save 1.3 million quality-adjusted life-years (QALYs). No other preventive measure comes close to that potential gain. I hope that cardiologists understand those data and are prepared

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to act on them.

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Clinical Inertia And Organizational Change

In their paper on the value of antihypertensive drugs (Jan/Feb 07), David Cutler and colleagues address the treatment of the most important chronic disease in America, as hypertension is the common denominator that contributes to poor outcomes for patients with coronary heart disease, heart failure, stroke, renal disease, and diabetes. A number of factors cause poor blood pressure control, many of which Cutler and colleagues address. They opine that policies such as reduced cost sharing and pay-for-performance incentives for physicians are opportunities to advance blood pressure control. I do not disagree, but these policies alone will not solve the problem.

Many doctors treating patients with hyper-

tension (and other problems that often have no symptoms) don't initiate or intensify therapy when it is indicated. Lawrence Phillips and colleagues have termed this failure to properly manage this sort of chronic disease "clinical inertia," which they describe as "recognition of the problem but failure to act."¹ They write that this tendency toward inactivity has three underlying causes. Physicians often (1) overestimate the amount of care they are providing to their patients; (2) use "soft" reasons to avoid intensifying therapy (including believing that the situation is improving); and (3) lack the educational background, training, and practice structure needed to achieve the desired treatment goals.

To truly affect treatment of hypertension and other chronic diseases, we need organizational change, including creating an end to clinical inertia. Pay-for-performance and reduced cost sharing are simply pieces of a much broader solution.

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NOTE

1. L.S. Phillips et al., "Clinical Inertia," *Annals of Internal Medicine* 135, no. 9 (2001): 825-834.

Rates And Inpatient Nursing Care

In their paper addressing payment rates for inpatient cardiovascular services (Jan/Feb 07), Kevin Hayes and colleagues overlook an obvious source of variability in inpatient spending: nursing care. Overall, nursing contributes 44 percent of direct patient costs and makes up 42.9 percent of all hospital labor. Nursing care is subsumed within routine and intensive care cost centers, which make up nearly half of all costs in the revised inpatient prospective payment system (IPPS), and is billed using fixed daily "room and board" charges.

The problem with this approach is that per diem room rates hold all nursing care constant; thus, it does not influence the relative weights of the diagnosis-related group (DRG), despite known variability in nursing intensity by

DRG. This leads to a major payment system distortion that has gone unnoticed.

An alternative approach to inpatient billing and payment is one that separates nursing charges from room and board using the existing "023X Nursing Incremental Charge" revenue code. This would give hospitals the option to bill directly for nursing care (using data for actual nursing hours expended for each patient) or to use established nursing intensity weights for each DRG to calculate routine and intensive care nursing charges. This second method was initially proposed by John Devereaux Thompson and Robert Fetter in their original conceptualization of the DRG system in 1979 but never implemented. We estimate that a unique nursing cost center will make up approximately 20-25 percent of all inpatient costs and provide an independent source of information about the distribution of nursing resources at U.S. hospitals that will improve payment accuracy. The lack of any nursing input into the derivation of the DRG relative weights—in particular, the differences in nursing intensity and costs for each patient—threatens the validity of the payment system.

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Many Factors Drive Increased Use

Kevin Hayes and colleagues (Jan/Feb 07) argue that because Medicare's use of echocardiography (heart ultrasound) is growing more quickly than other physician services, echocardiography must be overpriced. The premise is incorrect. Many factors contribute to the use of echocardiography, including the increasing prevalence of heart disease, the increasing survival rate of patients with heart disease, and technological advances that have expanded echocardiography's clinical applications. Ironically, these factors are discussed in other articles in the same issue of *Health Affairs*.

The authors' analysis counts as "new growth" those expenditures that shifted from hospital to nonhospital settings. If site of ser-

vice is held constant, the use of echocardiography is growing at the same rate as other physician services covered by Medicare.

Further, the authors attribute the growth in echocardiography to its Medicare payment rate, implying that cardiologists provide these services more frequently because they are financially lucrative. Yet approximately 70 percent of echocardiography services are ordered by noncardiologists, who do not perform them and have no financial incentive to order them.

Finally, having assumed unjustifiable growth of echocardiography services, the authors recommend Medicare payment reductions as the solution. The current allowances result from processes whose legitimacy depends on their being applied even-handedly to all services, without reference to rate of growth. Altering this formula on the basis of growth rate would undermine the legitimacy of these well-established processes.

Although we support studies to better understand the appropriate use of cardiovascular services, the studies should be based on accurate data analysis, especially if they are to be the basis for broad policy recommendations.

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Don't Target The Tools

Health Affairs' recent theme issue, "Cardiovascular Disease and Society" (Jan/Feb 07), provides valuable insights into the current state of cardiovascular care and the challenges of improving prevention and determining the most beneficial care. Unfortunately, the paper by Kevin Hayes and colleagues offers an incomplete analysis of trends in the frequency with which some cardiovascular services are provided to Medicare patients.

The paper offers no data to support the assertion that the potential for profit has driven volume growth for office-based diagnostic imaging services. Changes in the prevalence of heart disease, as well as advances in medical knowledge and technology and consequent changes in standards of care, all influence

practice patterns. It is essential to fully evaluate all reasons for growth, rather than to assume that it results primarily because inappropriate financial incentives for providers.

The American College of Cardiology (ACC) is committed to ensuring access to appropriate, high-quality cardiovascular care. We agree with Hayes and colleagues that Medicare must use its resources wisely and price services accurately. The authors' recommended approach of targeting certain services for arbitrary payment cuts, however, promotes neither rational resource use nor accurate pricing. Moreover, such an approach does nothing to promote access and quality.

The ACC believes, instead, that efforts should be focused on strengthening the understanding of what services should be provided to beneficiaries. We are committed to developing tools to help physicians, payers, and policy-makers ensure that patients receive timely, appropriate, high-quality cardiovascular care.

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Inpatient CVD Services: The Authors Respond

To begin with the letter from John Welton, we are aware of the problem that he discusses with the way nursing care costs are accounted for in the IPPS. Analyses of Medicare's hospital payment rates, including ours, are constrained by the limited information available on nursing intensity differences for Medicare patients among the diagnosis-related groups (DRGs). It is unclear, however, whether this refinement, if we could make it, would have a substantial effect on our results. As Welton points out, these data limitations reflect hospitals' traditional practices in setting charges for routine and intensive care on the basis of uniform per diem rates without regard to actual nursing resource use. But they also reflect the lack of widely used methods of accounting for and reporting nursing intensity differences among patients. Others have suggested that this could be addressed, perhaps by developing national

nursing intensity differentials, or hospitals could begin to set these charges to recognize differences in nursing resources used by different patients. This latter solution might be less effective, however, because it would depend on hospitals' voluntary changes in charge setting, which might occur slowly and need not be consistent among hospitals.

Turning now to the letters from Michael Picard and Steven Nissen, we believe that they overstate our conclusions about the prices for cardiovascular services in Medicare's physician fee schedule. We are only saying that rapid volume growth raises questions about whether services are overvalued. To address these questions, the Centers for Medicare and Medicaid Services (CMS) should consult an expert panel and review the accuracy of the prices for these services. By law, the CMS must review the relative value

units (RVUs) in the physician fee schedule at least every five years. On the basis of the three reviews of RVUs for physician work that have occurred so far, experience shows that only selected services are considered. Selecting services is difficult, however, because there are about 6,700 services billable under the fee schedule. To assist with this effort, we suggest that certain cardiovascular diagnostic services might be good candidates for the next review. The use of a number of these services is growing rapidly, and physicians are choosing increasingly to furnish the services in their offices instead of facility settings, such as a hospital outpatient department. For many of the services, work RVUs have not changed during the fifteen-year history of the fee schedule.

Medicare claims data do not support Picard's assertion that the growth rate for echocardiography is the same as that for other physician services. As shown in the March 2006 *Report to the Congress: Medicare Payment Policy* by the Medicare Payment Advisory Commission (MedPAC), use of echocardi-

ography grew one-and-a-half to two times as fast as all services payable under the fee schedule. We see growth differentials in two measures of service use: units of service and volume. The number of units is simply the number of times a service is billed. This measure is the same for all settings and does not go up unless the number of services used by Medicare beneficiaries goes up. The second measure—volume—is units of service multiplied by RVUs. Consequently, volume is influ-

enced both by the number of services used and by the higher RVUs per unit of service for the office setting. But either way, we see more rapid growth in use of echocardiography than use of physician services overall.

We do not agree that site of service is unimportant, however. Many factors affect site of service, including the patient's medical conditions, type of procedure, and pa-

tients' and physicians' preferences, but also the relationship between payments and costs. When growth is occurring more rapidly in the office setting than elsewhere, physicians are likely comparing payments and costs and are concluding that payments are at least adequate. A CMS review would show whether payments are more than adequate.

We agree with Picard that the process for pricing services should be even-handed. The concern is that existing processes do not appear so even. Previous reviews of prices in the fee schedule have led to many more price increases than decreases. For instance, during the review just completed (and to be in effect for 2007), the RVUs for 251 services were revised upward, with the RVUs for only 27 services revised downward. We believe that analyses of service use are one way among others to bring more balance to the process.

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“We agree with Picard that the process for pricing services should be even-handed. The concern is that existing processes do not appear so even.”

Bad Modeling?

In science, a mathematical model is intended to replicate the behavior of the modeled process in the real world and make testable predictions. In their paper on disclosing medical injury to patients (Jan/Feb 07), David Studdert and colleagues construct a mathematical model to predict the financial outcome if disclosures of medical errors became widespread. They conclude a high likelihood of increased cost.

The model, however, is based on a large group of anonymous “experts” making judgments on the basis of their own disclosure experiences. Whether they have any and how much is undisclosed. Then a Monte Carlo procedure is used to attempt to correct for uncertainty. This is problematic at best. What’s more, although the authors acknowledge that our 1999 paper is the only study to examine the disclosure-claim relationship, they still draw their conclusions entirely from their questionably expert-based model.¹

Our report of seven years’ experience using a full disclosure and voluntary compensation system (which is now in its twentieth year) supported a conclusion of more claims but no more direct cost. This was the case despite disclosure (without exception) and compensation for all sizes of errors and injuries, not only the ones large enough to attract an attorney. Studdert and colleagues state that “disclosure is the right thing to do; so is compensating patients who sustain injury as a result of substandard care.” Yet they seem sanguine in publishing a flawed study that is apt to encourage risk managers to stay the deny-and-defend course because of the (unfounded) fear of doubling or tripling their liability exposure. We see this as both irresponsible and bad science.

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NOTE

1. S.S. Kraman and G. Hamm, “Risk Management: Extreme Honesty May Be the Best Policy,” *Annals of Internal Medicine* 131, no. 12 (1999): 963–967.

Open Disclosure: Details Matter

The paper by David Studdert and colleagues (Jan/Feb 07) has gained some attention in Australia, for which we must express regret, as the conclusion that “the spread of disclosure through health care systems is likely to amplify malpractice litigation” cannot be sustained.

The relationship between harm and litigation in health care is obscure. “Open disclosure” is a new variable, although the authors opine that “to infer...that changes to any one factor, such as disclosure, would alone alter the claim decision is questionable” and dismiss research demonstrating that litigation is reduced where open disclosure is practiced.

A study using a convenience sample of experts giving opinions on cases lacking detail is of doubtful value. Opinions are founded in the detail—the personalities of patients and families, the presence or absence of grief, whether the overall care had been perceived as expert and nurturing, and the nature of the harm. Details of disclosure are essential—whether apology or compensation was offered and the level of communication skills in making the disclosure will all determine patient responses.

Nor was there any calibration to prove that the experts were good at estimating patient decision making. Humans are generally poor at estimating proportions. These flaws mean that the sophisticated mathematical analysis that was then performed becomes irrelevant.

It is not proven that patients’ ignorance about their injuries is an “important [factor] in explaining why they do not seek legal redress.” Patients are, however, known to instigate litigation because of perceived suspicion of cover-up of errors and lack of communication. The choice to study new knowledge as the only factor potentially altering the decision to sue ignores the substantial evidence that communication and relationships between staff, patients, and family are critical. Trust underpins

relationships, and appropriate disclosure can only build that trust. It would be unfortunate if open disclosure work in Australia, and other countries, was impeded on the basis of speculative claims.

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Disclosure: The Authors Respond

The reactions to our disclosure study are forceful in their dismissal of it but short on specific concerns with the analysis. Apart from skepticism about the survey data embedded in our model, no methodological issue is mentioned.

The critiques appear to have no quarrel with the basic epidemiology of medical injuries and claims, which, contrary to the assertion by John Wakefield and colleagues, is reasonably well understood. (At least a half-million patients sustain severe medical injuries in the United States annually, one-quarter of them due to negligent care, and these injuries give rise to approximately 50,000 malpractice claims.) Also uncontested is the foundation of our analytical model, disclosure's dual impact: While deterring some patients from suing, or encouraging them to settle more quickly and for less, disclosure will also prompt some proportion of patients who would not otherwise have sued to do so. The latter effect is particularly likely for patients whose injury is due to negligence and who would not have recognized this in the absence of the disclosure.

To the best of our knowledge, no published

research has formally evaluated the effect of disclosure on litigation. Previous writing on disclosure and litigation, including several reports from the field, has focused on the deterrent impact, bypassing any serious consideration of the claim-prompting impact. The letters in response to our article do the same.

Our analysis contemplated both types of "transition" behavior. Estimates came from a survey of doctors, lawyers, and risk managers familiar with experience in disclosure and its effects on patients. Survey respondents estimated that among patients with serious injury due to negligence, disclosure would eliminate lawsuits from 25 percent of patients who currently sue and would prompt 25 percent of those who would not have sued to do so (median values). Among patients with serious injury not due to negligence, it would deter 50 percent of those who currently sue and would prompt 15 percent to litigate.

Are these numbers implausible? Can disclosure really be expected to change the litigation decisions of more than one-quarter of patients who have sustained negligent injury and would, in the normal course, have sought recovery for it? Is it unreasonable to expect that it would prompt one in four negligently injured patients to seek compensation? (And if the answer to either question is "Yes," shouldn't we become deeply concerned about what disclosure is doing?) Sensitivity analyses suggested that the prompted claims could dip as low as one in twenty among negligent injuries and one in thirty among non-negligent injuries before the basic result—more litigation—would change.

We do not regard disclosure's litigation-inducing potential as a threat to its future in health policy or practice. Responsible health care institutions will not use our study findings as a reason to violate regulatory and professional ethical mandates to disclose injuries. Transparency around medical injury requires no instrumental justification and is ill served by a flimsy one. Among its many virtues, disclosure represents a valuable opportunity to correct a well-documented shortcoming of the medical malpractice system: Most patients

who sustain debilitating injury from negligent care obtain no compensation. To ignore this phenomenon and how it intersects with the disclosure movement is misguided.

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Errata

Exhibit 2 in the paper titled “Medicaid at the Ten-Year Anniversary of SCHIP: Looking Back and Moving Forward,” by Lisa Dubay and colleagues (Mar/Apr 07), contained several errors. All of the data for “children <125% FPL” and “children 125–200% FPL” were incorrectly reported. As a result of these errors, incorrect numbers appeared in the text in several places: (1) Page 370, Abstract: “nearly 60 percent” should be “more than 70 percent.” (2) page 374, first full paragraph, fourth line, “approximately 30 percent” should be “approximately 50 percent”; eleventh line, “58.8 percent” should be “73.8 percent.” (3) Page 380, Note 15, “1.6 million” should be “2.5 million,” and “35 percent” should be “47 percent.” (4) Page 380, Note 17, “1.4 million children” should be “1.8 million children,” and “51.4 percent” should be “72 percent.” Corrected Exhibit 2 is available online at <http://content.healthaffairs.org/cgi/content/abstract/26/2/370/T2>. A corrected copy of the paper, including Exhibit 2, is available online at <http://content.healthaffairs.org/cgi/content/abstract/26/2/370>. The authors and *Health Affairs* regret any inconvenience these errors might have caused.

Exhibit 1 in the paper titled “Estimates of Health Insurance Coverage: Comparing State Surveys with the Current Population Survey,” by Kathleen Thiede Call and colleagues (Jan/Feb 07), contained several errors. The data for Massachusetts in columns 1 and 2 were reversed; likewise for columns 4 and 5, and columns 7 and 8. This affected the line for “Average difference,” where the numbers should now read –20.9, –47.0, –20.6, and –45.6. In the paragraph below Exhibit 1, several numbers are affected: “21.9 percent” should be “20.9 percent,” and “21.7 percent” should be “20.6 percent.” Two paragraphs later, “45.4 percent” should be “47.0 percent,” and “43.8 percent” should be “45.6 percent.” A corrected copy of the article is online at <http://content.healthaffairs.org/cgi/content/full/26/1/269>. The authors and *Health Affairs* regret any confusion these errors might have caused.