

Barriers to Patients Seeking Emergency Care for Acute Coronary Heart Disease

To the Editor: It should come as no surprise that the community educational intervention described by Dr Luepker and colleagues¹ had no impact on the average time interval from onset of symptoms suggestive of myocardial infarction to arrival at the emergency department. There have been other studies with similar interventions and similar results.^{2,3} One set of studies, conducted in Sweden, did show a statistically significant improvement in delay time.⁴ This difference from the US experience may have been due to the difference in health care–related financial barriers between the United States and Sweden. Even the Swedish study, however, showed no improvement in mortality rates.

A fundamentally different approach must be taken to realize the benefits that rapid initiation of reperfusion therapy can offer to persons experiencing myocardial infarction or stroke. The educational message must be more intensive than mass media announcements and public service messages and must deal with the barriers that keep people from responding, even when they correctly recognize the symptoms. Such barriers include denial, dislike of the emergency department, fear of being asked to wait for hours while more severely ill patients are treated, and concern that health insurance will not cover the cost if their symptoms do not indicate a myocardial infarction.⁵

In addition, physicians, administrators, and clerical staff must be trained and authorized to direct such patients to immediate emergency care with the assurance that, once in the emergency department, such care will be promptly provided and that the visit will be fully covered by the health insurance carrier. Accomplishing all this will require active participation by each of the medical facilities and insurance carriers—a difficult, but not impossible, proposition.

Finally, most myocardial infarctions occur in persons already receiving medical care for predisposing conditions.⁵ It would probably be best to educate these high-risk patients in their usual medical settings and to make sure the educational program is running smoothly before initiating a mass media campaign.

Joel L. Nitzkin, MD, MPH
Engineering Management & Economics, Inc
New Orleans, La

1. Luepker RV, Raczynski JM, Osganian S, et al. Effect of a community intervention on patient delay and emergency medical service use in acute coronary heart disease: the Rapid Early Action for Coronary Treatment (REACT) Trial. *JAMA*. 2000; 284:60-67.
2. Herlitz J, Hartford M, Blohm M, et al. Effect of a media campaign on delay times and ambulance use in suspected acute myocardial infarction. *Am J Cardiol*. 1989; 64:90-93.
3. Moses H, Engelking N, Taylor G, et al. Effect of a two-year public education campaign on reducing response time of patients with symptoms of acute myocardial infarction. *Am J Cardiol*. 1991;68:249-251.
4. Blohm M, Hartford M, Karlsson B, Karlsson T, Herlitz J. A media campaign aiming at reducing delay times and increasing the use of ambulance in AMI. *Am J Emerg Med*. 1994;12:315-318.

5. National Heart, Lung, and Blood Institute. *Educational Strategies to Prevent Prehospital Delay in Patients at High Risk for Acute Myocardial Infarction*. Bethesda, Md: National Institutes of Health; 1997. NIH publication 97-3787.

In Reply: In constructing the Rapid Early Action for Coronary Treatment (REACT) intervention, we did take into account most of the factors that Dr Nitzkin rightly lists as underlying patient delay.¹ Indeed, our description of the REACT intervention included education of patients at high risk, health professional education, and community organization in addition to a media component. These intervention planning efforts have already been described in greater detail.²⁻⁵ In our formative data-gathering efforts, we also asked respondents whether cost was a barrier to seeking care and found that it was not commonly mentioned as such, although it likely does play a role in preventing patients from seeking care.⁶

Russell V. Luepker, MD, MS
Division of Epidemiology, School of Public Health
University of Minnesota
Minneapolis
for the REACT Investigators

1. Luepker RV, Raczynski JM, Osganian S, et al. Effect of a community intervention on patient delay and emergency medical service use in acute coronary heart disease: the Rapid Early Action for Coronary Treatment (REACT) Trial. *JAMA*. 2000; 284:60-67.
2. Raczynski JM, Finnegan JR, Zapka JG, et al. REACT theory-based intervention to reduce treatment-seeking delay for acute MI. *Am J Prev Med*. 1999;16:325-334.
3. Zapka JG, Estabrook B, Gilliland J, et al. Health care providers' perspectives on patient delay for seeking care for symptoms of acute myocardial infarction. *Health Behav Health Educ*. 1999;26:714-733.
4. Finnegan JR, Meischke H, Zapka JG, et al. Patient delay in seeking care for heart attack symptoms: findings from focus groups conducted in five US regions. *Prev Med*. In press.
5. Simons-Morton DG, Goff DC, Osganian S, et al. Rapid early action for coronary treatment: rationale, design, and baseline characteristics. *Acad Emerg Med*. 1998;5:726-738.
6. Siepmann DB, Mann NC, Hedges JR, Daya M. Association between prepayment systems and emergency medical services use among patients with acute chest discomfort syndrome. *Ann Emerg Med*. 2000;35:573-578.

Deficiencies in US Medical Care

To the Editor: In asking whether US health care is the best in the world, Dr Starfield¹ overlooks a much more fundamental

GUIDELINES FOR LETTERS. Letters discussing a recent *JAMA* article should be received within 4 weeks of the article's publication and should not exceed 400 words of text and 5 references. Letters reporting original research should not exceed 500 words and 6 references. All letters should include a word count. Letters must not duplicate other material published or submitted for publication. Letters will be published at the discretion of the editors as space permits and are subject to editing and abridgment. A signed statement for authorship criteria and responsibility, financial disclosure, copyright transfer, and acknowledgment is required for publication. Letters not meeting these specifications are generally not considered. Letters will not be returned unless specifically requested. Also see Instructions for Authors (July 5, 2000). Letters may be submitted by surface mail: Letters Editor, *JAMA*, 515 N State St, Chicago, IL 60610; e-mail: JAMA-letters@ama-assn.org; or fax (please also send a hard copy via surface mail): (312) 464-5824.

Letters Section Editors: Stephen J. Lurie, MD, PhD, Senior Editor; Phil B. Fontanarosa, MD, Executive Deputy Editor.

issue: the absence of nationally agreed-on goals and directions for promoting the good health of our citizens and the absence of a nationwide system for implementing health goals.

Without clear health policy goals and clearly developed ways of directing the health care effort in a goal-directed manner, US health care will be determined by “the invisible hand” of a relatively unregulated health care market that values efficiency, economy, cost-saving, and the most diluted, adulterated product that the public will tolerate. These de facto health care goals tend to promote the financial interests of an industry (health care financing) in preference to the public’s health interest. The false assumption behind the current adulation of market forces is that an informed “consumer” will make “rational” decisions and choices about health care coverage and that bad service will be competitively driven out by good service. However, for the most part “consumers” do not directly purchase health care for themselves. It is bought for them by their employers, whose managers are seeking the best deal, not necessarily the best or most comprehensive coverage.

If one looks at the current Darwinian competitive struggles playing themselves out on a daily basis in the US health care scene, it is no wonder that US health statistics fare badly when compared with those of other countries. The current US market-based system tends to promote and offer incentives for undertreatment, nontreatment, delayed treatment, and a radical underuse of hospitalization. These market-driven approaches lead to brief, fragmented treatments and to errors of treatment that are the result of inadequate time spent with patients. The United States currently has a system that encourages quick diagnosis and quick disposition of patients based on rapidly arrived at clinical probabilities. What is desperately needed is a well-designed, well-balanced national commission that would set national goals, develop policy proposals, and come up with a blueprint for health that would be in the interests of all US citizens.

Jerome A. Collins, MD
Private Practice, Psychiatry
Kennebunkport, Me

1. Starfield B. Is US health really the best in the world? *JAMA*. 2000;284:483-485.

To the Editor: Dr Starfield¹ mentions that Japanese citizens have the highest rate of longevity in the world, but I have found that the quality of care in Japan is questionable. True, Japan may have more magnetic resonance imaging scanners than any other country, but there is no convincing evidence this high-tech “toy” is used in a cost-effective manner.

Japan also has the fewest nurses per bed of any industrialized nation, thanks to the Ministry of Health and Welfare’s unrealistic fund allocation.² Many hidden expenses are borne by private citizens, and these are not reflected or included in Japan’s “lowest” level of health expenditure.

Japan has “universal” health care that promises access, but it is plagued with bureaucratic inflexibility and inefficiency. The Japanese system encourages abuses such as unnecessary prescription writing and patients visiting multiple medical facilities

for the same complaints. The ideas of accountability and locally controlled hospital accreditation systems do not appear to exist.

Family practitioners do exist in Japan, but patients tend to avoid physicians in private practice and congregate at university hospitals where young and inexperienced physicians are often poorly supervised. The Japanese system of specialist training leaves much to be desired. In comparison, the United States probably has the best medical education and training system in the world, but the delivery system and financial management suffer from the insurance industry producing wealth for its investors. Theoretically, Japan has better financial arrangements, but if I ever get sick or need surgery, I would prefer a medium-sized Catholic hospital in a midwestern city.

Yasuo Ishida, MD
St Louis, Mo

1. Starfield B. Is US health really the best in the world? *JAMA*. 2000;284:483-485.
2. *The Blue Book*. 30th ed. Tokyo, Japan: Institute of Social Insurance; 2000:779-780.

To the Editor: Dr Starfield’s Commentary¹ exploring the needless deaths from US medical care is perfect until it reaches the moment of needed epiphany. What does the United States have that Japan or other countries don’t? Forget about the money savings, tort reform would save untold numbers of lives. Trial lawyers separate us from the rest of the world, because only the United States can afford the excess of defensive medicine. Sadly, death is a side effect of this excess, and fear of litigation also keeps critical health care system failings from being discussed.

James Long, MD
Clysis Corporation of Minnesota
Andover

1. Starfield B. Is US health really the best in the world? *JAMA*. 2000;284:483-485.

To the Editor: The Commentary by Dr Starfield¹ raises a few questions about the efficiency and effectiveness of US health care spending. It would be helpful to know how much of the overall cost is used for direct patient services and how much is used to cover administrative costs, paperwork, corporate profits, advertising, liability, and other entities that are not directly related to patient care.

J. Louis Pecora, MD
Private Practice, Ophthalmology
Endicott, NY

1. Starfield B. Is US health really the best in the world? *JAMA*. 2000;284:483-485.

To the Editor: Dr Starfield¹ fails to mention the prevalence of obesity in the US population. I suspect that this is significantly higher than that of the comparison countries and might well account for the differences in health care indices that she cites.

I must also comment on the statistics on iatrogenic morbidity and mortality. In virtually all of the countries mentioned, a specialty board (such as the Royal College of Surgeons) con-

trols who is allowed to practice a specialty. Specialists generally cannot practice unless they complete a residency approved by the College and pass a certification examination given by the College. In the United States, specialists are allowed to practice when “board-eligible” and never need to take a certifying examination. Is it surprising, then, that the United States has a high level of poor outcomes?

Bradley L. White, MD, FRCSC
Nassau Orthopedic Surgeons
Levittown, NY

1. Starfield B. Is US health really the best in the world? *JAMA*. 2000;284:483-485.

To the Editor: Dr Starfield¹ relates the poor quality of US public health to often-quoted statistics about medication errors and other iatrogenic causes of death. The statistics on iatrogenic deaths are extrapolations based on limited reviews of adverse drug reaction forms, and their accuracy is questionable.² More important, these statistics are used without any reference to the type of patients experiencing these adverse events.

It is misleading to state that “. . . (medication errors and nosocomial infections) constitute the third leading cause of death . . . after heart disease and cancer.” People who die of iatrogenic causes are, by definition, already sick. Since heart disease and cancer are the most common causes of death, many of the patients who died of iatrogenic causes actually died of heart disease and cancer and are thus listed twice.

Similarly, it appears that no one has made an effort to find out who is dying as a result of medical errors. I contend that the sicker patients are the more medications they are receiving, the more likely they are to be in the hospital, and the more procedures they undergo. Therefore, they are most likely to die an “iatrogenic” death. To make sense of the numbers of iatrogenic deaths, the number must be converted to patient-years lost. I am skeptical of the reported numbers because in 9 years of practicing pediatrics I have seen many iatrogenic medication errors but only 1 death and 1 cardiac arrest and both of these children were already in intensive care units. My feeling is that children seldom die from these errors because they are generally healthy. Terminally ill patients frequently encounter heroic procedures, multiple potentially interactive medications, and higher-than-standard doses of medications including sedation. Reviewing charts or paperwork may not reveal the true cause of a patient's death.

The conjecture that public health statistics are better in other countries because we have too many iatrogenic deaths is to assume that other countries have systems of preventing medication errors and regulating procedures that do not exist in the United States. I have practiced medicine in and spoken to many practitioners from other countries, and I am not aware of such systems. If there are no additional safeguards in other countries, then US physicians are either incompetent or taking care of sicker patients. While there is no evidence to support the first contention, there certainly is evidence to support the latter. The United States spends more resources on critical care and terminal care than any nation on earth.³

One could argue that any iatrogenic death is a tragedy no matter how sick the patient, and I agree to a point. The problem is that public policy is being discussed based on statistics that do not define the problem. It is a much different situation if healthy children are dying from amoxicillin overdoses than if patients with terminal cancer are dying from compassionate morphine use.

One could also argue that the United States could reduce both its iatrogenic death rate and health care expenditures by curtailing terminal and critical care. Once again I agree to a point. It is just that treating the sick and preventing death were the reasons I went to medical school in the first place.

Jonathan D. Reich, MD, MSc
Pediatric Cardiology
Lakeland, Fla

1. Starfield B. Is US health really the best in the world? *JAMA*. 2000;284:483-485.
2. Lazarou J, Pomeranz B, Corey P. Incidence of adverse drug reactions in hospitalized patients. *JAMA*. 1998;279:1200-1205.
3. Angus DC, Sirio CA, Clemons G, Bion J. International comparisons of critical care outcome and resource consumption. *Crit Care Clin*. 1997;13:389-407.

In Reply: The points made by Dr Collins are well taken. My concern is that, in the current political climate, any appointed commission would fail to question the underlying reasons for our health system being the way it is.

Dr Ishida's observations are consistent with my suspicions. I have been to Japan and encouraged officials there to take a more introspective look at their health care delivery. It may be that the resistance of the Japanese people to undergo invasive interventions sets them apart from their US counterparts, who have been taught to believe that more intervention is better.

With regard to Dr Long's comments, although I have not found any published studies of the relative frequency of lawsuits for errors of omission and errors of commission, my look at malpractice claims data suggests that the latter may be more frequent. Perhaps if physicians recognized this, they would do less rather than more. A good analysis of this phenomenon is sorely needed.

Dr Pecora asks about costs of health care. Previous studies have shown that administrative costs alone in the United States constitute 24% of health care costs—far greater, for example, than in the Canadian health care system (11%).¹ Profits and other nonpatient costs would further add to the percentage of costs that are unrelated to patient care.

In response to Dr White, studies have shown that board certification (as distinguished from board eligibility) has little if any relationship to higher-quality practice; it is the length of postgraduate education and the organizational arrangements of practice that are related to higher-quality practice.² The problems that countries face with health care are largely with the system of delivery, not with the individual practitioners.

With regard to obesity, although it plays a role at the individual level, it clearly does not account for the poor health of the population. It plays no role in infant mortality. The “health disadvantage” of the US population is greater in infancy and childhood than it is later in life, which is inconsistent with Dr White's proposition that obesity accounts for poorer health in the population.

Dr Reich seems to argue that treating the sick and preventing death requires higher costs and incurs higher risk of adverse effects. In every country, physicians have the same aspirations as his, and sicker patients command more resources; the United States is not unique in this. The question is: why is the US unique in spending so much more with little to show for it in better health status? The fact is that we do not know either the magnitude of benefit or harm done by higher rates of intervention. Other countries are instituting systems to assess the magnitude of adverse effects. Japan, for example, is in the process of mandating post-marketing surveillance.³ The aim of treating the sick and preventing death need not imply increasing use of technologically innovative interventions that are not only costly but relatively inefficient, if not ineffective. Physicians in the United States ought to be in the forefront of efforts to critically examine the benefits and harms resulting from what they do.

Barbara Starfield, MD, MPH
Department of Health Policy Management
Johns Hopkins School of Hygiene and Public Health
Baltimore, Md

1. Woolhandler S, Himmelstein DU. The deteriorating efficiency of the US health care system. *N Engl J Med*. 1991;324:1253-1258.
2. Starfield B. *Primary Care: Balancing Health Needs, Services, and Technology*. New York, NY: Oxford University Press; 1998:chap 12.
3. Lamar J. Japan plans improved monitoring of new drugs [news]. *BMJ*. 2000;320:1560.

How Many Deaths Are Due to Medical Errors?

To the Editor: Dr McDonald and colleagues¹ and Dr Leape² discussed the recent Institute of Medicine (IOM) report about medical errors.³ I am concerned, however, that deaths due to errors may mean different things to different people.

Specifically, I question some of the scenarios that Leape notes as examples of errors leading to death. He cites 3 examples: a stroke in a patient with atrial flutter, a patient with a ruptured bowel who was not taken to surgery, and a patient with hypoxicemic brain damage due to hemorrhagic shock from splenic rupture. These are not what I think of when I think of errors in the hospital. All of these examples strike me as evidence that medicine is still an art. These are examples of medical judgments that were, in retrospect, wrong. Physicians make dozens or hundreds of such judgments every day, and some of these are sometimes incorrect. Without knowing the details of the cases, I can only speculate about why the patient with atrial flutter did not receive anticoagulants, why the patient with intestinal obstruction was observed rather than immediately taken to the operating room, and why the splenic rupture was not recognized. It is not difficult for me to suggest reasons why these things happened. They may indeed represent cases of gross negligence, but they also may represent cases of quite appropriate judgment made on the basis of what was then known about the individual patients. I hope that these are not the errors that we think we can correct by simply improving the "processes" of care.

When I think of medical errors, I think of errors that are due to the environment of care and to processes of care. These are

errors such as ordering or administering the wrong medication or the wrong dosage, inappropriate care due to inability to access the medical record, laboratory errors leading to incorrect treatment, and similar occurrences. These are the errors that society must resolve not to accept. However, we must then be willing to pay for this resolution. Society cannot expect physicians in private practice and hospitals operating in the red to invest large sums of money to computerize their medical record systems, engage in massive quality improvement projects, or increase their staffing without helping them recover the cost.

In a recent article on medical errors, Kizer⁴ stated that the electronic medical record "is an absolute must for where we need to go, not just for medical error prevention, but for collecting data on quality. The government needs to take a man-on-the-moon approach to this and say, by a certain year, we will do this. It's a public good that needs to happen." I could not agree more strongly. All of the lip-service, posturing, and rhetoric in the world will do no good unless we take action. We can be dismayed about the number of deaths due to medical errors (whether 1000 or 10000 or 100000), but if we do nothing to fix the problem, then we are doing nothing but being dismayed. This is hardly a noble role for physicians.

Christopher M. Hughes, MD
Monongahela Valley Hospital
Monongahela, Pa

1. McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in Institute of Medicine report. *JAMA*. 2000;284:93-95.
2. Leape LL. Institute of Medicine medical error figures are not exaggerated. *JAMA*. 2000;284:95-97.
3. Kohn LT, Corrigan JM, Donaldson M, eds. *To Err Is Human: Building a Safer Health System*. Washington, DC: Institute of Medicine; 1999.
4. Hallam K. Battling medical errors Star Wars style. *Modern Healthcare*. May 29, 2000:18-20.

To the Editor: Dr McDonald and colleagues¹ and Dr Leape² debated the validity of the data that formed the basis of the conclusions and recommendations of the IOM report on medical errors.³ McDonald et al appropriately highlight methodological flaws intrinsic to the prior studies by Leape and others.^{4,5} It would be unfortunate, however, to allow the assertion that the magnitude of the problem of medical errors (preventable or otherwise) is grossly exaggerated to cloud the message and blunt the impact of the IOM report. Whether annual mortality is 10000 or 100000, medical errors are a serious public health problem.

What message has the Center for Drug Evaluation and Research (CDER) at the US Food and Drug Administration (FDA) taken from the IOM report? First, although we may have concerns about the methods and results of the studies used to support the recommendations, we view this as a call to develop better data through which we can understand the root causes of errors in pharmacotherapy and, more importantly, measure the impact of any proposed interventions. Second, the FDA must do everything it can to eliminate the potential for drug errors due to name confusion, packaging mix-ups, and un-

clear, cumbersome, or uninformative labeling and directions for use.

Errors involving pharmaceutical use are influencing our benefit-risk assessments. The recent market withdrawals of terfenadine, astemizole, mebendazole, bromphenac, and cisapride resulted, in part, from the health care system's inability to manage the known and preventable risks associated with these products. These experiences have catalyzed an evolution in our thinking on risk management and the evaluation of new drugs for approval. The FDA's risk assessment must evaluate both a drug's intrinsic safety profile as well as the ability of the health care system to adequately manage known toxicities. Unless effective risk management strategies and methods are brought to bear, additional effective drugs are likely to be withdrawn, and some drugs may never become available in the first place. This would be an unfortunate but inevitable consequence of not moving forward to address the findings of the IOM report.

Peter Honig, MD, MPH
 Jerry Phillips, RPh
 Janet Woodcock, MD
 Center for Drug Evaluation and Research
 US Food and Drug Administration
 Rockville, Md

1. McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in the Institute of Medicine Report. *JAMA*. 2000;284:93-95.
2. Leape LL. Institute of Medicine medical error figures are not exaggerated. *JAMA*. 2000;284:95-97.
3. Kohn LT, Corrigan JM, Donaldson M, eds. *To Err Is Human: Building a Safer Health System*. Washington, DC: Institute of Medicine; 1999.
4. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. *N Engl J Med*. 1991;324:370-376.
5. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients: results of the Harvard Medical Practice Study II. *N Engl J Med*. 1991;324:377-384.

To the Editor: Dr McDonald and colleagues¹ provide an important critique of the IOM report² on medical errors and of the Harvard Medical Practice Study (MPS)³ that is integral to it. McDonald et al correctly argue that the basis of estimating death rates due to medical adverse events was inappropriate because a high-severity group was chosen for analysis without a control group to provide context and because a causal relationship was not established between the existence of adverse events and subsequent death.

In fact, the headline number of 98 000 deaths annually due to medical error does not represent actual deaths but is conflated from a flawed analysis of fewer than 200 actual deaths in the index 1984 study. (The lower number of 44 000 deaths was derived in the same manner from a 1992 study of data from Colorado and Utah). The original MPS authors noted that a blinded analysis by a second team of their own reviewers failed to identify the same set of adverse events as the first team, but they did find the same incidence of adverse and negligent adverse events. Nonetheless, the authors declared their data reliable.³ This is roughly equivalent to saying it does not matter whether we incarcerate the innocent or the guilty as long as the overall number of convictions matches the crime rate.⁴ Even more remark-

able, the MPS reviewers agreed only 10% of the time on the simple presence or absence of medical negligence.⁵ The study methods were sufficiently idiosyncratic that the authors themselves found no correlation whatsoever between their determinations of medical negligence and the outcome of malpractice verdicts.⁶

It is interesting that the IOM report calls for a national goal of a 50% reduction in medical error. Although this is indisputably a worthy target, if we were to take the MPS data at face value, this has already been achieved between 1984 and 1992 (55% decline in deaths due to medical error from 98 000 to 44 000).

It is unfortunate that the authors of the IOM report chose to use the headline-grabbing death numbers from 2 flawed studies. Use of the death numbers not only undermined the integrity of the IOM's otherwise strong report but has led health care policymakers to declare solutions based on faulty data.

Richard E. Anderson, MD
 The Doctors Company
 Napa, Calif

1. McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in Institute of Medicine report. *JAMA*. 2000;284:93-95.
2. Kohn LT, Corrigan JM, Donaldson M, eds. *To Err Is Human: Building a Safer Health System*. Washington, DC: Institute of Medicine; 1999.
3. Localio AR, Lawthers AG, Brennan TA, et al. Relation between malpractice claims and adverse events due to negligence. *N Engl J Med*. 1991;325:245-251.
4. Anderson RE. Billions for defense: the pervasive nature of defensive medicine. *Arch Intern Med*. 1999;159:2399-2402.
5. Localio AR, Weaver SL, Brennan TA, et al. Identifying adverse events caused by medical care: degree of physician agreement in a retrospective chart review. *Ann Intern Med*. 1996;125:457-464.
6. Brennan TA, Sox CM, Burstin HR. Relation between negligent adverse events and the outcomes of medical malpractice litigation. *N Engl J Med*. 1996;335:1963-1967.

In Reply: One of the important contributions of the MPS¹ is a practical measuring "instrument" for adverse events, both avoidable and unavoidable. We think that this is an important and useful instrument. However, underlying our article was the same question that Dr Hughes raises—to what degree does this method reflect what an average person or even a health professional would consider an error?

Three factors could lead to such miscalibration. First, there is the influence of practical rules for designating an adverse event as preventable. Brennan² described 1 example—all cases of patients who returned to surgery for postoperative bleeding were classified as preventable even though there is no way to prevent all such incidents. The number of such pragmatic rules and their potential contribution to the numbers has not been reported, so we can only speculate about their influence. The second—as Hughes also indicates—is hindsight bias. Chart reviewers make their judgments retrospectively with full knowledge of outcomes, which is not necessarily comparable with the best judgment a physician could make before the outcome is revealed. Furthermore, even with this extra knowledge, the reviewers in the MPS were relatively unreliable in their judgment.

The third potentially miscalibrating factor relates to the problem of assigning cause and assessing preventability in a severely ill patient with several life-threatening pathologic pro-

cesses. Dr Leape³ argues that the populations selected for adverse event reviews were not this sick. Yet, our calculations reveal that this sample had a death rate 4 times that of the unselected population and Table 1 in Leape's article affirms that the sample did include all of the in-hospital deaths. Furthermore, in a Veterans Affairs study that imitated the MPS, the physician chart reviewers estimated that, even in the absence of an adverse event, less than 1% of the patients who died in association with a preventable adverse event would have been alive and functional 1 year after their index hospitalization.⁴ We look forward to a careful analysis of the attributable cause of adverse events on patient outcomes to give a better sense of the usefulness of the MPS instrument.

Of course, errors do occur and we support the goal of eliminating every such error, especially the most blatant ones as cited by Hughes and Dr Honig and colleagues. We also applaud the Medical Errors and Patient Safety Research initiative of the Agency for Healthcare Research and Quality. This initiative will provide better information and methods for eliminating such errors.⁵ However, the size (and the precision) of the number of preventable adverse events do matter. First, the remedies and resources needed to implement them will differ depending on the size and the nature of the problem. Second, if the most precise estimate of the effects of errors ranges 10-fold from the highest to the lowest, as hinted by 2 letters here, we will not know whether the remedies we do implement have a useful effect.

Technology exists for eliminating most errors in prescribing, and we applaud the FDA's steps, especially those that are quick and easy to apply. One could imagine that aggressive and carefully planned computer feedback could lead to the safer use of potentially dangerous drugs that might otherwise have to be banned. Of course, we agree with Dr Anderson's statements about the IOM report.

Clement J. McDonald, MD
Michael Weiner, MD
Siu L. Hui, PhD
Regenstrief Institute
Indiana University School of Medicine
Indianapolis

1. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. *N Engl J Med.* 1991;324:370-376.
2. Brennan TA. The Institute of Medicine Report on Medical Errors: could it do harm? *N Engl J Med.* 2000;342:1123-1125.
3. Leape LL. Institute of Medicine medical error figures are not exaggerated. *JAMA.* 2000;284:95-97.
4. Hofer TP, Hayward R. Have deaths due to medical errors been overestimated? *J Gen Intern Med.* 2000;15(S1):276.
5. Eisenberg JM, Meyer G, Foster N. Medical errors and patient safety: a growing research priority. *Health Serv Res.* 2000;35:3.

These letters were shown to Dr Leape, who declined to reply.—Ed.

Lead in Candle Wicks

To the Editor: In response to the Research Letter by Dr Sobel and colleagues¹ on lead in candles, consumers should know

©2000 American Medical Association. All rights reserved.

that candles made in the United States today are safe. Even though the US Consumer Product Safety Commission (CPSC) determined in 1974 that lead-core wicks do not present a health hazard, the members of the National Candle Association (NCA) voluntarily agreed to stop using lead wicks. Companies belonging to the NCA make about 95% of the candles now manufactured in the United States. The vast majority of wicks manufactured in the United States are made of 100% cotton with no metal core. Those few wicks with metal are typically zinc-core wicks. All of these wicks are safe. A small percentage of imported candles recently appearing on the market may contain lead-core wicks. However, the CPSC and the NCA have taken strong action to remove them from store shelves. The CPSC recently told retailers to stop selling candles with lead-core wicks, and the NCA supports a ban on all lead wicks.

One way to determine if a candle has a lead-core wick is by using this easy test: rub a piece of paper on the tip of an unused metal wick. A lead-core wick will leave a gray pencil-like mark, while a zinc- or tin-core wick will not.

The NCA is committed to making only safe candles. Detailed information is available at <http://www.candles.org/info.htm>.

Marianne McDermott, JD
National Candle Association
Washington, DC

1. Sobel HL, Lurie P, Wolfe SM. Lead exposure from candles [letter]. *JAMA.* 2000;284:180.

In Reply: Ms McDermott and the NCA suggest that consumers identify lead wicks by rubbing the wick on white paper. This is impractical if, as was the case in our survey, the candles are sealed in plastic. Moreover, we performed this unvalidated test on the 9 candles with lead wicks in our study, and 6 failed to produce the pencil-like mark.

The NCA's suggestion that most candles made in the United States are lead-free is irrelevant to consumers who do not know to check for country of origin. However, even this would not suffice; in our study, 1 of the 9 candles with a lead-containing wick was made by a US company.

The NCA trumpets the claim that their members "voluntarily agreed to stop using lead wicks" in 1974. They do not mention that in the late 1970s several NCA members resumed production of lead-wick candles.

McDermott's assertion that the CPSC "determined in 1974 that lead-core wicks do not represent a health hazard" is misleading. While the agency did conclude that the dangers of lead-core wicks were not an "imminent hazard," a category of dangerous products for which the CPSC can order an immediate ban, it stated that CPSC "should seek to replace lead-core wicks in candles in the future."¹ Moreover, lead poisoning in children is now recognized to occur at blood levels far less than those thought to be hazardous in 1974.²

All of the NCA's suggestions shift the burden of responsibility away from its members and the CPSC and instead place the burden inappropriately on consumers in ways that may be unnecessarily dangerous. That is why we have petitioned the

(Reprinted) *JAMA*, November 1, 2000—Vol 284, No. 17 2189

CPSC for a permanent ban and recall on candles with lead wicks.

Howard L. Sobel, MD, MPH, MS
Department of Preventive Medicine
Johns Hopkins School of Hygiene and Public Health
Baltimore, Md

Peter Lurie, MD, MPH
Sidney M. Wolfe, MD
Public Citizen's Health Research Group
Washington, DC

1. Hehir RM. Memorandum to Commissioners: candles with lead core wicks. Consumer Product Safety Commission, December 26, 1973.
2. Centers for Disease Control and Prevention. Update: blood lead levels—United States, 1991-1994. *MMWR Morb Mortal Wkly Rep.* 1997;46:141-146.

RESEARCH LETTER

Chemical Analysis of Ecstasy Pills

To the Editor: 3,4-Methylenedioxyamphetamine (MDMA) has achieved notoriety as the drug “ecstasy” and has been associated with dance events called “raves.” Few reports of the content of ecstasy pills from the United States are available,¹ but European reports suggest that ecstasy commonly contains substances other than MDMA.² We sought to describe the range of drugs found in ecstasy pills in the United States.

Methods. Samples were solicited by DanceSafe, a national organization active at dance events, using a Web site (<http://www.dancesafe.org>) and informational tables at dance events. Individuals were informed they could anonymously mail pills to the analyzing laboratory along with a money order for the cost of the assay (\$100) for each sample.

Pills were dissolved in methanol and assayed by gas chromatography–mass spectroscopy in full-scan electron impact mode (70 eV). Compounds were identified with a computerized reference library and confirmed with analytical standards. Complete methods are available from the authors.

Results. Between February 1999 and March 2000, 107 pills were received and assayed. By region, 48 pills (45%) were from California and southwestern states, 18 (17%) from the South, 17 (16%) from New England states, 17 (16%) from Mid-Atlantic states, 3 (3%) from the Pacific Northwest, 3 (3%) from the Midwest, and 1 (1%) from Hawaii.

Sixty-seven pills (63%) contained some MDMA or an analogue (either 3,4-methylenedioxy-ethyl-amphetamine or 3,4-methylenedioxyamphetamine). Thirty-one pills (29%) contained identifiable drugs but no MDMA or analogue. The most common drugs identified other than MDMA was the antitussive dextromethorphan (DXM), found in 23 pills (21%). Other drugs included caffeine, ephedrine, pseudoephedrine, and salicylates. Nine pills (8%) contained no identifiable drug.

Because of the prevalence of DXM in this sample, quantitative analyses were carried out on the first 8 DXM-containing pills received; these contained an average (SD) of 136 (33) mg DXM (range, 103-211 mg).

Comment. Most pills contained MDMA (or an analogue) or 1 or more unscheduled drugs. The most common unsched-

uled drug was DXM, present in amounts considerably higher than the usual therapeutic dose of 15 to 30 mg (taken up to 4 times daily). Because DXM is apparently common in ecstasy pills but not detected by standard drug abuse toxicology screening tests, it may have an unrecognized role in adverse reactions attributed to MDMA. None of the other unscheduled drugs identified appear likely to produce significant toxicity.

High doses of DXM (>300 mg) can cause lethargy or hyperexcitability, tachycardia, ataxia, and nystagmus, as well as a phencyclidine-like psychosis^{3,4} caused by the *N*-methyl-D-aspartate–blocking effects of its metabolite, dextrophan. Dextromethorphan intoxication should be considered for patients reporting ecstasy use and presenting with these symptoms, particularly if toxicology screens are negative for MDMA and amphetamines.

Since many ecstasy users ingest multiple pills, DXM and MDMA may be coadministered, leading to adverse interactions. Both drugs are substrates for cytochrome P450 isozyme 2D6 (CYP2D6), and MDMA and its metabolites inhibit the activity of CYP2D6.⁵ Coadministration of a CYP2D6 inhibitor increases the incidence and severity of adverse reactions to DXM.⁶

The distribution of drugs in this sample series may not accurately reflect the appearance of these drugs in all illicit ecstasy markets. Because individuals who submitted pills paid the assay costs, they may have been disproportionately older, wealthier ecstasy users. Those pills associated with unexpected drug effects may be overrepresented in this series. Nonetheless, our results appear to describe the range, if not the precise distribution, of drugs in illicit ecstasy pills.

Matthew Baggott, BS
Boris Heifets, BS
Reese T. Jones, MD
John Mendelson, MD
Drug Dependence Research Center
University of California
San Francisco
Emanuel Sferios, BA
DanceSafe
Berkeley, Calif
Jeff Zehnder, BS
Drug Detection Laboratories
Sacramento, Calif

Funding/Support: This research was supported in part by grants DA00053, DA01696, and DA12393 from the National Institute on Drug Abuse, National Institutes of Health.

Acknowledgment: Kaye Welch provided editorial assistance. David Nichols, PhD, of Purdue University, West Lafayette, Ind, kindly donated analytical standards.

1. Renfroe CL. MDMA on the street. *J Psychoactive Drugs.* 1986;18:363-369.
2. Sherlock K, Wolff K, Hay AW, Conner M. Analysis of illicit ecstasy tablets. *J Accid Emerg Med.* 1999;16:194-197.
3. Olson K, ed. *Poisoning and Drug Overdose.* 3rd ed. Stamford, Conn: Appleton & Lange; 1999:155-156.
4. Dodds A, Revai E. Toxic psychosis due to dextromethorphan. *Med J Aust.* 1967;2:231.
5. Delaforge M, Jaousen M, Bouille G. Inhibitory metabolite complex formation of methylenedioxyamphetamine with rat and human cytochrome P450: particular involvement of CYP2D. *Environ Toxicol Pharmacol.* 1999;7:153-158.
6. Zhang Y, Britto MR, Valderhaug KL, Wedlund PJ, Smith RA. Dextromethorphan: enhancing its systemic availability by way of low-dose quinidine-mediated inhibition of cytochrome P4502D6. *Clin Pharmacol Ther.* 1992;51:647-655.