

Psychiatric Consequences of September 11

To the Editor: In their article about Americans' reactions to the events of September 11, 2001, Dr Schlenger and colleagues¹ report that their survey used "stratified random-digit-dialing telephone sampling techniques, which make it possible to reach every US household with a telephone (95% of US households)." The survey was administered 1 to 2 months after the attacks and the results were stratified according to the proximity to the crash sites.

I live in close proximity to the World Trade Center. Neither I nor thousands of others living below Canal Street (ie, in South Manhattan) had phone service for weeks and months after September 11. Therefore, it seems unlikely that the sampling was as accurate as the authors claim.

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1. Schlenger WE, Caddell JM, Ebert L, et al. Psychological reactions to terrorist attacks: findings from the National Study of Americans' reactions to September 11. *JAMA*. 2002;288:581-588.

To the Editor: Dr Schlenger and colleagues¹ found that 2 months after September 11, 2001, overall distress levels in the United States were within normal ranges, including in New York City and Washington, DC. However, the authors did not measure demoralization, which is another expression of the after-effects of trauma in adults.² The advantage of measuring demoralization is that it can be reliably ascertained with the use of simple scales that are brief, easy to use, and do not require a health professional to administer them.³ The practical use of this measure is that it aids primary caregivers to identify those population groups in need of psychological support whether or not they eventually will develop psychiatric disorders.

This is why we used a demoralization scale to identify individuals who were reacting unduly to the effect of war in a Jerusalem neighborhood that had been under fire during several weeks. The most salient results we obtained in our modest study⁴ agreed in part with those of Schlenger et al. We administered a demoralization instrument to 125 patients who visited a general practitioner during a 10-week period. The physician added independent information on the prescription of sedatives. The patients resided in either Gilo (n=84; a neighborhood that was under gun fire in the autumn of 2001) or in gunfire-free Jerusalem neighborhoods (n=41). After controlling for confounder variables, the mean distress score was significantly higher among the Gilo residents than among those residing in other city areas. In the study of Schlenger et al, there were differences in emotional distress between residents of New York City and other areas of the country, but these were not statistically significant. In our study, demoralization was higher during periods of intensive gunfire exposure, as

was the prescription of sedative drugs. Higher demoralization scores do not necessarily indicate psychopathology, but normative "reactions."⁵ We suggest that simple scales can be used to monitor the psychological status of populations at risk for adverse effects.

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- Schlenger WE, Caddell JM, Ebert L, et al. Psychological reactions to terrorist attacks: findings from the National Study of Americans' reactions to September 11. *JAMA*. 2002;288:581-588.
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To the Editor: Dr Schlenger and colleagues¹ report an association between television viewing of the September 11, 2001, terrorist attacks and symptoms of posttraumatic stress disorder (PTSD) 1 to 2 months later. It is significant that a large number of individuals exposed only through the media appear to meet criteria for PTSD. To diagnose PTSD, the current edition of the *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)* requires that a person "experienced, witnessed, or was confronted with an event or events that involved actual or threatened death or serious injury, or a threat to the physical integrity of self or others."² On September 11 and during the days afterward, many television viewers may have feared that their personal safety and that of others was under threat. Insofar as such an event may provoke a subjective experience of "fear, helplessness, or horror," it fulfills the spirit of the *DSM-IV* definition.

The *DSM* definition of PTSD has changed dramatically in form and content since it first appeared in 1980. Thus, September 11 research may provide an opportunity to refine future *DSM* definitions. The *DSM-IV* relies on a syndromal model as the

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Letters Section Editor: Stephen J. Lurie, MD, PhD, Senior Editor.

initial step toward the study of etiology and treatment. However, emerging evidence supports a multidimensional model of posttraumatic symptomatology and impairment. In a screening survey of approximately 9000 individuals, we found associations between subthreshold PTSD symptoms and suicidal thoughts, major depression, and functional impairment.³ Although published studies to date about PTSD following September 11^{1,4} do not address this issue, analysis of the role of subthreshold symptoms may provide further insight into the scope of long-term public health need in New York City.

These results raise important issues about the nature of PTSD in the postdisaster period, and we look forward to further insights from clinical research. We hope these and future studies will spur discussion in the field both about the evolving nosology of PTSD, and about funding mechanisms for postdisaster research that will permit rapid deployment of epidemiologic and clinical assessments in the immediate postdisaster period.

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- Schlenger WE, Caddell JM, Ebert L, et al. Psychological reactions to terrorist attacks: findings from the national study of Americans' reactions to September 11. *JAMA*. 2002;288:581-588.
- American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*. Washington, DC: American Psychiatric Association; 1994:427.
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- Galea S, Ahern J, Resnick H, et al. Psychological sequelae of the September 11 terrorist attacks in New York City. *N Engl J Med*. 2002;346:982-987.

To the Editor: Dr Schlenger and colleagues¹ found an increased rate of "probable PTSD" associated with the September 11 attacks in the New York metropolitan area compared with rates in the rest of the country. We are concerned, however, that despite the authors' cautions, their data concerning "probable PTSD" may be misinterpreted as actual PTSD diagnoses. Although these data are based on a well-validated instrument, the PTSD Checklist–Civilian (PCL-C),² its validity in the face of ongoing events rather than a past trauma is questionable. Furthermore, the assessments may have occurred too soon after the event to draw definitive conclusions about enduring psychiatric morbidities and their implications for public health.

The PCL-C provides estimates of distress resulting from a past trauma, on the assumption that prolonged posttrauma distress reflects psychiatric morbidity. It assesses symptom domains including disturbing thoughts about the stressful event

and feeling very upset when reminded of the experience. The validation samples cited to support the accuracy of the PCL-C in screening for PTSD consist primarily of combat veterans³ and survivors of automobile crashes and sexual assaults.⁴ Those groups have experienced a discrete past stressor in which prolonged concern and difficulty with adjustment may indicate psychiatric morbidity.

Residents of New York City, however, continued to experience ongoing daily stress associated with consequences of the attacks. Residents' reports of intrusive thoughts may reflect ubiquitous reminders and stressors in the environment rather than classic symptoms of PTSD and are thus unreliable indicators of a PTSD diagnosis. In this context, responses to the PCL-C may reflect not only distress about the event, but also issues surrounding present difficulties and reasonable safety concerns. These reactions are likely to encompass a range of responses, including adaptive coping as well as psychiatric morbidity. Indeed, the finding that psychological distress in New York City was within normal limits, despite an increased rate of "probable PTSD," supports this interpretation.

Data collection within 2 months of September 11 also raises questions about whether the reported rate of probable PTSD should be interpreted as posing a "public health problem." Normal reactions to traumatic events can take longer to resolve, and early symptoms such as intrusive memories are not predictive of later adjustment.⁵ Based on these data, prevalence estimates of current PTSD are premature.

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- Schlenger WE, Caddell JM, Ebert L, et al. Psychological reactions to terrorist attacks: findings from the national study of Americans' reactions to September 11. *JAMA*. 2002;288:581-588.
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In Reply: Dr Henzlova raises the issue of potential sampling bias following events that involve substantial infrastructure damage. The impact of such damage on sampling in our study was minimal, as participants in our study were selected from a panel that was recruited before the attacks. Nevertheless, infrastructure damage could have kept sample members who lived in the areas most affected from responding. Although we cannot tell from our data whether nonresponse in our New York City sample is related to distance from the World Trade Center, it is reassuring that the response rate for the New York City sample (70%) was identical to that in our oversample of other major metro-

politan areas. This suggests that infrastructure damage was probably not an important source of response bias in our study.

Drs Levav and Ponizovsky describe some findings from Israel concerning the use of screening instruments that can help primary care providers identify patients who may need, but not ask for, special attention as a result of trauma exposure. We concur with their views on the need for such screening and applaud their efforts and those of the family physician in whose practice the study was conducted.

Dr Marshall and colleagues raise 3 important points. First, they note that a growing body of evidence documents a significant association between the amount of time spent watching television coverage of the September 11 events and subsequent psychological symptoms. In their Editorial that accompanied our article, North and Pfefferbaum¹ noted that the *DSM-IV* criteria for PTSD make “no provision . . . for classification of indirect witnessing through media images of the event.” Our research team includes members of the subcommittees that recommended the PTSD criteria for the 2 most recent revisions of the *DSM*,^{2,3} and we can recall no discussion of situations like September 11, in which millions of Americans viewed on television events that they had reason to believe may have involved death or injury to a family member, close friend, or other significant person in their lives.

Second, we concur with Marshall et al that progressively more accurate diagnostic taxonomy requires incorporation of valid, empirical information and that therefore the process needs always to be open to new data. It already seems clear that the exposure criterion for PTSD will be an important focus of attention in the upcoming deliberations about the *DSM-V*. As we noted in our article, however, it is also clear that much more research is needed “in designs that support more definitive causal inference.”

Third, Marshall et al also note that the *DSM* is based on a syndromal (ie, categorical) model of disorder, which has many strengths but which may cause clinicians to “miss” subsyndromal cases that nevertheless involve clinically significant impairment. We are also concerned about this problem, the importance of which became clear to us in the context of our earlier work with Vietnam veterans.⁴ Based on that work, Weiss et al⁵ reported that, in addition to the 15.2% of male and 8.5% of female Vietnam veterans who met criteria for current PTSD in 1987, another 11.1% of males and 7.8% of females were classified as having “partial PTSD,” defined as a pattern of clinically significant PTSD symptomatology that did not fully meet the diagnostic criteria. As an example, a common pattern among the “partial PTSD” cases involved symptom presentations that fully met all diagnostic criteria for PTSD except for being one symptom short of meeting the avoidance/numbing criterion, but the person also drank heavily and/or used illicit drugs. We believe that taking account of clinically significant subsyndromal presentations is also an important issue for the *DSM-V* that affects not only the PTSD diagnosis but also the full range of other psychiatric disorders.

Dr Sullivan and colleagues raise 2 additional points. First, they note that many of those exposed to the events of Septem-

ber 11 may have had additional, ongoing stress exposures at the time of our assessment. This is likely to be true of anyone who is exposed to trauma, and we know of no empirical evidence that ongoing exposure biases the assessment of PTSD symptoms.

Second, they question whether assessment of PTSD symptoms in the second month following exposure is too soon, presumably because in many instances the PTSD may prove to be self-limiting. Clearly, not enough is currently known about the course of PTSD. Based on work with Vietnam veterans, however, Weiss et al⁵ reported that 49.2% of male and 31.6% of female Vietnam veterans who had ever met criteria for PTSD remained current cases 15 or more years after their war experience. Even if the chronicity rates for September 11 survivors ultimately are much lower than those documented for Vietnam veterans, the current prevalence estimates we reported for the New York metropolitan area surely represent an important public health problem, both now and for the future.

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1. North CS, Pfefferbaum B. Research on the mental health effects of terrorism. *JAMA*. 2002;288:633-636.

2. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders, Revised Third Edition*. Washington, DC: American Psychiatric Association; 1987.

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5. Weiss DS, Marmar CR, Schlenger WE, et al. The prevalence of lifetime and partial post-traumatic stress disorder in Vietnam theater veterans. *J Trauma Stress*. 1992;5:365-376.

Bioterrorism and Public Health Law

To the Editor: In their article promoting the Model State Emergency Health Powers Act (MSEHPA) that they drafted, Mr Gostin and colleagues¹ cite only 1 published criticism of it, which I wrote.² This use of a single citation is misleading in 2 important ways: it implies that their act has wider support than it does, and it misstates the range of criticisms about it. As to the first, the authors themselves stated on the first page of the MSEHPA that it was intended simply as a “draft for discussion.”³ They further wrote that it does “not represent the official policy, endorsement, or views” of anyone, including the US Centers for Disease Control and Prevention (CDC), or any of the organizations listed in the acknowledgments.

Second, the authors imply that my primary objection is that the act gives governors too much power. In fact, on this issue I stated simply, “State governors already have broad emergency powers; there is no compelling reason to expand them.”²

The 3 most important objections I have to the act are (1) bioterrorism is inherently a federal issue, and only secondarily a state issue; (2) the premise that Americans must trade freedom for security in the event of a bioterrorist attack is false; the public and physicians are not the enemy and are in fact eager to cooperate if properly informed; and (3) the arbitrary use of force by public officials with immunity from liability is incompatible with medical ethics, constitutional principles, and basic democratic values.²

It is not surprising that almost all of the states that have considered the act have either rejected it or made major modifications in it. Of these, the authors mention only Minnesota, stating that its new law makes quarantine and isolation “subject to modernized, significant personal safeguards including due process.” The Minnesota law provides that, even in a public health emergency, “individuals have a fundamental right to refuse medical treatment, testing, physical or mental examination, vaccination, participation in experimental procedures and protocols, collection of specimens, and preventive treatment programs.”⁴

What is surprising about the authors’ embrace of the Minnesota law is that it is so contrary to the provisions of their own MSEHPA. If the authors believe (as I do) that the Minnesota language is more modern and provides better safeguards, then it should replace the corresponding language in their draft act. Writing legislation is an exercise in democracy, and everyone gains by open debate in which their biases and assumptions can be challenged.

Gostin et al have provided a service by presenting their “draft for discussion.” But the MSEHPA is a seriously flawed proposal that should not be rigidly defended but rather should be regularly amended as better provisions are adopted by legislatures or proposed by commentators.

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1. Gostin LO, Sapsin JW, Teret SP, et al. The Model State Emergency Health Powers Act: planning for and response to bioterrorism and naturally occurring infectious diseases. *JAMA*. 2002;288:622-628.
2. Annas GJ. Bioterrorism, public health, and civil liberties. *N Engl J Med*. 2002;346:1337-1342.
3. Center for Law and the Public’s Health. The Model State Emergency Health Powers Act as of December 21, 2001. Available at: <http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf>. Accessibility verified October 23, 2002.
4. Minn Rev Stat Ann §144.419 (West 2002).

To the Editor: The vulnerability of the United States to a bioterrorist event causing many thousands, even millions, of casualties has been discussed for more than 10 years.¹ Since that time, the United States has done little to improve intelligence capabilities, to develop technological devices to provide early detection of an attack, to deploy defensive weapons systems, to stockpile decontaminants, medical supplies, and drugs, to provide civilian shelters or safe rooms, to enhance public health laboratories and add surge capability, or to train citizens in ways to protect themselves.

The MSEHPA, written and advocated by Mr Gostin and colleagues,² would do nothing to improve the actual ability of government agencies to mitigate a massive attack. Both the original proposal³ and the revised version cited by Gostin et al, which was apparently modified somewhat in response to criticism, give state governments tremendous unbridled power to seize property, commandeer resources, and force potentially misdirected treatment or quarantine on the population. To date most states have rejected or shelved the act, with good reason.

Under the act, a governor would have unlimited discretion to define an emergency, granting himself or herself enormous power in the event of, for example, a half dozen deaths from West Nile virus. In the meantime, citizens are actually forbidden to try to diminish their nearly total susceptibility to smallpox by choosing preemptive vaccination. Many suggestions have been made, including accelerated programs to test and stockpile potentially effective antiviral agents, use of high-efficiency particulate air filters in large buildings, and systems to monitor the air in public places for increased nitric oxide in exhaled breath.⁴

The MSEHPA does nothing to correct the “pervasive unpreparedness [that] well characterizes our present condition—near-term outlook—to several classes of neobarbarian threats.”⁵ Enacting the MSEHPA law would, at best, be another symptom of denial while creating a mechanism susceptible to massive governmental abuse.

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1. Orient JM. Chemical and biological warfare: should defenses be researched and deployed? *JAMA*. 1989;262:644-648.
2. Gostin LO, Sapsin JW, Teret SP, et al. The Model State Emergency Health Powers Act: planning for and response to bioterrorism and naturally occurring infectious diseases. *JAMA*. 2002;288:622-628.
3. Center for Law and the Public’s Health at Georgetown and Johns Hopkins Universities. *The Model State Emergency Health Powers Act as of October 23, 2001*. Available at: <http://www.aapsonline.org/legis/msehpa.pdf>. Accessed September 3, 2002.
4. Koonin SE. Biodefense: scenarios, science, and security. *Eng Sci*. 2001;LXIV(3/4):23-29.
5. Wood L. From terrorists to missiles: large-scale threats to the USA. Presented at: Doctors for Disaster Preparedness 20th annual meeting; July 28, 2002; Colorado Springs, Colo. Available at: <http://www.oism.org/ddp/wood02.pdf>. Accessed September 3, 2002.

In Reply: We have responded in detail elsewhere to the relatively few vocal critics of the Act.^{1,2} The claim that the MSEHPA,³ drafted at the CDC’s request, does not have wide support is untrue. During the single legislative session since its release in December, 2001, 36 of 50 states introduced legislation based in whole or in part on the MSEHPA. Of these, 20 states and the District of Columbia have passed bills.

There are, of course, valid disagreements about any legislation designed to ensure active surveillance for and effective response to bioterrorism. The most important issue is the appropriate balance between civil liberties and the public good. The MSEHPA provides carefully crafted safeguards of personal rights; indeed the standards and procedures in the

MSEHPA are more rigorous than those in many current public health statutes.

The particular objections of Mr Annas and Dr Orient are not telling. Certainly, the federal government has an important role to play in bioterrorism, but the states are critically important constitutionally, historically, and practically.⁴ States and localities would be the first to detect an outbreak and would be centrally involved in containment. The assertion that there are never tradeoffs between civil liberties and public health has no support, even in liberal philosophy. Although most people will comply with public health advice, common sense suggests that public health officials also may need adequate authority to avert a significant risk. Arbitrary or unnecessary use of force is egregious. This is precisely why it is essential to have a modern set of laws at the state level. Our model law is intended to provide a flexible checklist for the states to adapt to their unique structures.

Both Annas and Orient mischaracterize the MSEHPA to make a general argument against the exercise of public health authority. The MSEHPA does not provide "unbridled power," but uses careful checks and balances as we discussed in our article. A governor would not have unlimited discretion but would be required to follow explicit criteria defined by the state legislature. Furthermore, a governor's decision could be overturned by the legislature or the courts.

We believe that the MSEHPA has galvanized public debate in public health law and ethics. The debate is healthy and we welcome continuous improvement of public health laws to safeguard the common good while promoting respect for human rights.

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1. Gostin LO. Public health law in an age of terrorism: rethinking individual rights and common goods. *Health Aff (Millwood)*. In press.
2. Mair JS, Sapsin JW, Teret SP. The Model State Emergency Health Powers Act and beyond. *Biodefense Q*. 2002;3:1-11.
3. Center for Law and the Public's Health. The Model State Emergency Health Powers Act as of December 21, 2001. Available at: <http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf>. Accessibility verified October 23, 2002.
4. Gostin LO. *Public Health Law: Power, Duty, Restraint*. Berkeley: University of California Press; 2000.

Police Detainment of a Patient Following Treatment With Radioactive Iodine

To the Editor: We recently treated a 34-year-old man for Graves disease with 20 mCi of iodine 131. Twenty-four hours after treatment, his radioactive iodine uptake was 63%. Three weeks af-

ter treatment, he returned to our clinic complaining that he had been strip-searched twice at Manhattan subway stations. Police had identified him as emitting radiation and had detained him for further questioning. He returned to the clinic and requested a letter stating that he had recently been treated with radioactive iodine.

This patient's experience indicates that radiation detection devices are being installed in public places in New York City and perhaps elsewhere. Patients who have been treated with radioactive iodine or other isotopes may be identified and interrogated by the police because of the radiation they emit.

We called the Terrorism Task Force of the New York City Police Department to determine how to prevent detainment of this group of patients. They recommended that treating physicians provide such patients with letters describing the isotope used and its dose, its biological half-life, and the date and time of treatment. The letters should also provide the physician's 24-hour telephone numbers to allow the police to verify the content of the letters. If a person who has been detected as emitting radiation provides such a letter, the police would then verify the letter's authenticity. Even in the best-case scenario, however, the patient would have to wait during this verification process. Patients should be informed about this potential problem after treatment with radioactive isotopes; they may choose not to use public transportation to avoid this inconvenience.

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Health Literacy and Diabetic Control

To the Editor: Dr Schillinger and colleagues¹ found a relationship between health literacy and glycosylated hemoglobin (HbA_{1c}) levels in low-income urban patients in San Francisco. Unlike Schillinger et al, however, we² did not identify a relationship between health literacy and HbA_{1c} levels among patients in North Carolina with poor diabetic control (HbA_{1c} ≥8.0%). The lack of a significant relationship between literacy and HbA_{1c} remained whether we treated literacy scores as a categorical variable or as a continuous measure, and did not change after adjustment for potential confounding variables. Similar to a previous study,³ we did find that patients with low literacy had significantly poorer knowledge about the treatment of diabetes. For example, patients with low literacy were less likely to know the treatment of low blood sugar or the normal range of blood glucose levels.

Several factors may explain our discordant findings. We examined only a subgroup of patients with poor control, as opposed to all patients with type 2 diabetes. In this subpopulation, other factors may be more important than literacy in determining glycemic control. Similarly, we did not include His-

panic patients in our study, and perhaps literacy is a more important factor for this population. We did find a direct relationship between health literacy and knowledge of diabetes self-management, and this may be a partial explanation for findings of Schillinger et al that health literacy was associated with HbA_{1c} levels.

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1. Schillinger D, Grumbach K, Piette J, et al. Association of health literacy with diabetes outcomes. *JAMA*. 2002;288:475-482.
2. Rothman R, Pignone M, Malone R, Bryant B, Horlen C, Padgett P. The relationship between health literacy and diabetes related measures for patients with type 2 diabetes. *J Gen Intern Med*. 2002;17(suppl 1):167.
3. Williams MV, Baker DW, Parker RM, Nurss JR. Relationship of functional health literacy to patients' knowledge of their chronic disease: a study of patients with hypertension and diabetes. *Arch Intern Med*. 1998;158:166-172.

To the Editor: Dr Schillinger and colleagues¹ found a correlation between poor health literacy and uncontrolled type 2 diabetes. However, we suspect that the correlation is even greater than this study suggests.

Several aspects of the study could falsely underestimate the effect of poor health literacy on diabetic control. First, individuals with the constellation of factors that are often associated with poor health literacy (eg, less education, ethnic minority background, low socioeconomic status) may be less likely to seek medical care and thus to have less access to adequate longitudinal care. We assume that poor access to medical care can further increase the likelihood of uncontrolled diabetes. If this is the case, then the 261 patients not included in this study because they did not visit their physicians during study enrollment probably represent a significant number of patients with "poor health literacy," who are at a higher risk for poorly controlled type 2 diabetes than their counterparts who were included in the study (because they made a primary care visit).

Second, of the potential diabetic complications, Schillinger et al found only retinopathy and cerebrovascular disease to have significantly increased incidence in patients with poor health literacy. But 2 systematic factors could result in falsely low incidences of these and some other diabetic complications. One is the reduced opportunity for physicians to evaluate and diagnose these complications. The other is that these patients are probably more likely to be unaware of asymptomatic complications.

Finally, the authors excluded 28 potential subjects because they spoke neither English nor Spanish; these patients may also

have greater difficulty seeking medical care and their disease could theoretically be more poorly controlled.

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1. Schillinger D, Grumbach K, Piette J, et al. Association of health literacy with diabetes outcomes. *JAMA*. 2002;288:475-482.

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

Preoperative Hand-Rubbing vs Hand-Scrubbing

To the Editor: Dr Parienti and colleagues¹ found that hand-rubbing with an aqueous alcoholic solution was as effective as traditional surgical hand-scrubbing in preventing surgical site infections (SSI).

This type of study is difficult to perform because SSI rates are low and therefore a very large number of patients would be required to find a difference in infection rates. In this randomized but nonblinded study, 4387 patients were studied based on a power analysis assuming an SSI rate of 4%. However, the results showed an SSI rate of only 2.46%, a result similar to other studies cited by the authors. Indeed, the authors could not cite any studies with an SSI rate of 4% for routine surgery. Therefore, their power analysis was incorrect and the result showing no statistically significant difference may simply be a type 2 error due to an insufficient number of patients studied.

The group using the hand-rubbing with an aqueous alcoholic solution was supposed to do a 1-minute skin wash including subungual space cleaning with a brush before the first case of the day; however, in 6% of the cases, this was not done and an SSI rate of 5.9% occurred. This suggests that when a traditional scrub is not required, surgical personnel may fail to perform an adequate hand cleansing before their first case.

This study advocates shortcuts in hand washing that are unwarranted, unproven, and may be dangerous. The need for traditional hand-scrubbing before surgery should not be abandoned on the basis of this study.

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1. Parienti JJ, Thibon P, Heller R, et al. Hand-rubbing with an aqueous alcoholic solution vs traditional surgical hand-scrubbing and 30-day surgical site infection rates: a randomized equivalence study. *JAMA*. 2002;288:722-727.

In Reply: Dr Sosis underscores the pitfalls of equivalence trials and raises an important issue that could have seriously flawed our conclusion, namely a lack of statistical power due to the incorrect assumption of the rate of SSI in the control group. In addition, Sosis reminds us that absence of evidence is not evidence of absence (of difference). Our trial, however, was designed to demonstrate the equivalence of hand-rubbing and traditional hand-scrubbing protocols in terms of the SSI rate. Relative to a conventional superiority trial, this choice im-

plied an average of 10% larger sample size with specific methods of calculation.¹

Regarding our estimate of the likely SSI rate in the control group (required to calculate the number of patients to be included), we used our previous routine SSI surveillance obtained with traditional hand-scrubbing (cited in the article as reference 13).² In fact, we assumed that our SSI rate would be lower, as we chose to study only clean and clean-contaminated procedures. However, when we simulated a lower prevalence of SSI in the control group, we found no reduction of statistical power. For example, with an SSI rate of 2.48% (which was actually observed in the control group), only 2618 patients would have been required.¹ In any event, we included 4387 patients, yielding a power higher than 99%.¹

Type II error is the risk of wrongly accepting the null hypothesis when the alternative hypothesis is true. We rejected the null hypothesis by showing that the 2 protocols were equivalent (alternative hypothesis in an equivalence trial). This is a positive outcome ($\chi^2=19.5$; $P<.001$) as shown in Table 2 of our article. Consequently, regardless of the power of the study, it cannot be a type II error as Sosis suggests.

The weakness of equivalence trials lies elsewhere. Because it is impossible to prove an exact equality, the calculation of statistical power in even the best designed study contains an irreducibly subjective element, namely the clinically significant difference that the study was designed to exclude. A value of 10% is usually chosen for bioequivalence studies. However, after discussions with the study group surgeons, epidemiologists, and clinical investigators, we set the maximal limit at 2%, which is particularly low for an equivalence trial. Moreover, the 95% confidence interval of the SSI rate difference between the 2 protocols we observed was less than 1%.

In response to the second point, the decision to omit simple hand-washing including subungual space cleaning was made by choice rather than by chance. Thus, as discussed in our article, it is difficult to compare the SSI rate we observed in these cases. On the other hand, we observed no omission of the an-

tiseptic alcohol-based hand rub in the hand-rubbing protocol, which is quite reassuring.

Finally, our study contributes to the scientific evidence base for hand-hygiene guidelines in surgery. Because improving the surgical team's compliance and tolerance are both desirable, we believe that the hand-rubbing protocol for presurgical hand disinfection should be considered as a good alternative to traditional hand-scrubbing.

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1. Makuch R, Simon R. Sample size requirements for evaluating a conservative therapy. *Cancer Treat Rep.* 1978;62:1037-1040.

2. Lefrançois C, Deshayes JP, Mayo P, et al. Surveillance of surgical site infections in abdominal surgery 1997-2000. *Ann Fr Anesth Réanim.* 2001;20(suppl 1):2325.

CORRECTION

Incorrect Author First Name: In the Original Contribution entitled "Hand-Rubbing With an Aqueous Alcoholic Solution vs Traditional Surgical Hand-Scrubbing and 30-Day Surgical Site Infection Rates: A Randomized Equivalence Study" published in the August 14, 2002, issue of THE JOURNAL (2002;288:722-727), there was an incorrect author first name. On page 722, the sixth author, Hervé Bensadoun, MD, DCh, should be Henri Bensadoun, MD, DCh.

CME ANNOUNCEMENT

Online CME to Begin in Mid-2003

In mid-2003, *online* CME will be available for JAMA/Archives journals and will offer many enhancements:

- Article-specific questions
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We apologize for the interruption in CME and hope that you will enjoy the improved online features that will be available in mid-2003.