Editorial

Making Surgical Care Better: Hard Work, Small Gains

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Three papers in this issue of the journal illustrate areas of active concern and academic inquiry for surgeons and their colleagues from epidemiology who are committed to the complex task of designing incremental reductions of surgical-wound infection risks. After reading the articles, one has an opportunity to ponder some difficulties that can complicate or derail searches for clinically useful truths that support practices of benefit to patients.

In "The Evolution of the Surgical Mask: Filtering Efficiency Versus Effectiveness," Belkin[1] provides a detailed review of the 100-year history that underpins current surgical-mask–design features. At issue in the essay is the difference between constructions that feature maximal filtering effect and those that assure minimal droplet spread from the wearer, as measured in actual provocative testing. Obviously, the availability of modern synthetic materials has led to newer designs, compositions, and product choices. In the operating room area of my hospital, no fewer than four kinds of masks are available above each of the 50 scrub sinks. Thankfully, the old cloth mask used by early 20th-century surgeons can be regarded as a museum item. Reconfirming the old principle "there is no free lunch" is the finding in Belkin's review that attempts over the years to make masks ever more restrictive to passage of bacteria-laden moisture or air expired by the wearer ultimately yielded mask prototypes that effectively channel exhaled air or spittle (and presumably pathogens) to the sides of the mask, challenging there the skin-mask interface. Wearing two masks—a not uncommon practice in some modern operating rooms—will give a similar paradoxical result. Once again, the laws of physics are immutable! Although the author is not a surgeon, he clearly has been in touch with operating room workers, because he retells a familiar anecdote concerning what to do in the operating room if you are scrubbed in and suddenly feel that you are about to sneeze. Predictably, most of us instinctively turn away from the sterile field, probably assuring that, ironically, leakage of our "sneeze blast" will be straight out the mask-skin interface and aimed directly at the open incision. Victorian manners are hard habits to break.

In the modern operating room, of course, everybody wears a mask, beginning before the outset of procedures in which sterile equipment and the patient's sterile tissues will be open to the room environment. In addition to scrub nurses and surgeons who actually are working in the sterile field and handling instruments and anatomic structures, anesthesia personnel, circulating nurses, and any visitors to the room are masked continuously. The period of this faithfully practiced ritual ends when the incision is closed and dressed, just before patient transport to the recovery area. I agree with the author that there is a widespread, and probably random, assortment of ways in which I and my surgical coworkers do not uniformly observe rigid protocols for assuring mask fit and function. I strongly disagree that we should question mask use as a ritual element of operating room behavior.

It will surprise some who do not work in operating rooms that only a very long tradition in surgery—and not hard science—says that "wearing a mask reduces the chance of wound infection in the patient." When I say "hard science," I specifically mean clinical trials in which the wound infection surveillance was blinded, the surveillance assuredly checked every sin-

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gle patient in both arms over a 30-day period, and uniformly recognized definitions for infection diagnosis were used. I assert that a properly performed, definitive, randomized, prospective clinical trial will never take place to test the null hypothesis, "operations performed by workers wearing surgical masks are complicated by wound infection no less frequently than operations performed by workers wearing no masks." The Society for Healthcare Epidemiology of America (SHEA) readership is epidemiologically sophisticated and will visualize all the impediments to such a grand experiment, as well as immediately imagine numerous other highly regarded (and equally untestable) behavior practices currently held in high esteem by those of us who carry the major responsibilities of operating on fellow humans. That same readership easily can do power calculations to estimate population sizes needed to confirm the absence of a beneficial "mask effect" for clean-category operations if it were proposed that an infection rate of approximately 1% to 2% in the masked group would be observed. Notwithstanding the fact that risk managers, lawyers, and most human studies committees in United States' hospitals would frown on such an experiment, it also would be absolutely necessary to form case groups that were virtually identical in regard to all other conceivable risk factors. *Such an experiment in humans simply is not going to take place.* What then are we to think about mask use—or, for that matter, any of the other behavioral rituals enforced in the modern operating room suite, but unlikely ever to be amenable to certification by the sanctity of a full–court-press clinical experiment? How do we make our nonoperating colleagues more comfortable with a harsh reality: some things that are probably clinically good in taking care of surgical patients cannot necessarily be subjected to scientific testing? How do we squelch the naive stance that nothing in a healthcare process step should be done that has not been proven (at $P<.05$) to be good?

From ongoing experience as a consultant to the Association of Operating Room Nurses (AORN), I have become familiar with a remarkable document that is revised continuously and published annually, the *AORN Standards and Recommended Practices.*[2] To my knowledge, this is the only repository in the world of detailed descriptions for every aspect of modern aseptic operating room practice. The various practices and standards are worded very carefully and submitted annually to critical, no-holds-barred review by surgeons and operating room nurses who participate actively in daily clinical practice. The obvious tripartite theme of the contents might be described alliteratively as conservative, cautious, and common-sense. Curious journal readers who do not perform surgery will benefit from perusing this document to read its recommendations regarding mask use by surgical workers. It is of no surprise to me that the AORN recommends masks for all of us in the operating room, but includes the qualifying comment, "further research is needed to determine the actual value of masks." The key word here is "value," and the underlying strategy seems clear (and applies to every other aspect of the operating room behavior ritual): *Until crystal-clear evidence is developed that a ritual element is hazardous or has no good effect whatsoever, let us maintain this element of behavior as a goal for every operation.* Nobody wants his or her mate, parent, or child to undergo any operation in which live oral or nasal bacteria from surgeons or nurses can enter a sterile field. None of our patients should get less consideration. If surgical masks or their offshoots (eg, full face shields) were expensive (they are not), if they impaired our surgical judgment or dexterity (they do not), or if they added any hazards to a patient's or employee's intraoperative experience (I cannot think of any), then intellectual honesty and ethical considerations would compel serious academic probes of their value/nonvalue. The fact that masks do not perform their function perfectly does not mean that they are worthless. Dr. Belkin, and others with his clear interest in seeking the truth, may not be aware of a curious fact: no known infection prevention adjunct used in surgery (or in any branch of medicine) has 100% determinance, including prophylactic antibiotics, gloves, drapes, and gowns. Surgeons and their nursing partners intentionally use adjuncts in combination to reduce to the smallest possible level the degree of bacterial contamination during an operation. It is nice if an adjunct's perceived benefit for a single patient is supported by prior controlled observations in groups of patients. It is nicer if the observations carry the approbation of "the authorities." Such luxuries are not always available or even attainable. As uncomfortable as it may seem to those in search of academic projects under the heady inspiration of the current quality-improvement excitement, certain hard-won core points within surgical skill and art simply must be left undisturbed absent overwhelming evidence that they are unsafe, totally useless, or outrageously expensive. The alternative is regression to a procedural anarchy that honors no tradition, discounts refined skills, and contradicts common sense.

Two other articles in this issue of the Journal come from the General Hospital de Jaen, a component of the Andalusian Health Service in southern Spain. The first is entitled "Total Cholesterol, HDL-Cholesterol, and Risk of Nosocomial Infection: A Prospective Study in Surgical Patients."[3] This study

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was carried out in a 680-bed tertiary-care hospital. Dr. Delgado-Rodríguez and his coauthors carefully noted admission values of serum lipids in preoperative patients, then sought correlations of the values with the presence or absence of postoperative nosocomial infections. Observers who determined presence or absence of infection were not aware of the laboratory data. The authors bent over backwards to explain why this study cannot be fairly given the label of "data-dredging," and I take them at their word. I was somewhat discomfited to note that postdischarge surveillance was accomplished simply by looking for medical record evidence of patient visits to the emergency room within the 30-day postdischarge surveillance window. This may work in Spain, but it surely is flawed in the United States. As a surgeon, I also was perplexed at having no information about the actual operations performed. The label "general surgery" is very broad, and we have no idea what diseases necessitated the elective operations performed. Were lipid levels somehow surrogates for particular kinds of operations that carried intrinsically different infection risk? Every SHEA reader will draw his or her own conclusions about the article's statistical flourishes, which lead to the finding of a significant correlation between the risk of wound infection and certain levels of serum lipids. The U-shaped relationship of infection risk and total cholesterol stimulated my parietal cells a bit. I have never been aware of any biologically plausible connection of lipid levels and surgical infection propensity, but I have been around long enough to suspend a hasty negative opinion about the article's modus operandi and findings. Who knows? We may have another useful and easily garnered risk-stratifying variable right under our noses! It should be easy enough to retest the article's findings in any large US hospital where an aggressive global wound surveillance effort is running at full tilt.

The third article, also from Dr. Delgado-Rodríguez's hospital in Spain, examines the same patient population used for the serum lipid-infection risk study mentioned above. The article is entitled "Nosocomial Infections in Surgical Patients: Comparison of Two Measures of Intrinsic Patient Risk."[4] The authors have applied two different wound infection risk-stratifying techniques (Study on the Efficacy of Nosocomial Infection Control [SENIC] index and the National Nosocomial Infection Surveillance [NNIS] System risk index) to 1,483 general surgery patients who suffered 155 postoperative infections. The article details various tests used to determine whether one of the two schemes is better. Again, every reader will have to dig through this article's statistical arguments and attempt to reach a conclusion about the meaning of the contrast. I was struck by the article's failure to mention an elegant and very large piece of work by Haley,[5] which essentially puts SENIC and NNIS schemes head-to-head and comes to a different conclusion than did the Spanish workers.

There are three conceivable reasons to construct and refine an infection risk index for surgical patients. The obvious one is to make possible fair inter-hospital comparisons of surgical performance—does hospital A have better, worse, or equivalent infection rates relative to hospital B? Getting rid of this apples-and-oranges problem is such an obvious need that it hardly merits further discussion. A second reason to have and apply a sophisticated risk-stratifying technique is to allow the design of sharper clinical trials of infection-reducing adjuncts. For example, many of us still believe that our criteria for antibiotic prophylaxis use are somewhat crude, to say the least. A third reason to calibrate intrinsic predicted infection risk—for indices that can be computed before a patient goes to the operating room—is to allow surgeons to alter infection prevention practices intelligently and in the direction of increased patient benefit, according to predicted infection risk. The NNIS scheme seems to fill the bill on all three counts, but, by now, everyone must be aware that it has not been prospectively tested with rigor. Further, I continue to be bothered by the fact that the NNIS index was derived using data that were flawed—nearly 70% of the hospitals contributing the original infection data had no procedures in place to capture late wound infections.[6] Regardless of one's opinion of the NNIS index, time spent reading the article by Delgado-Rodríguez will reveal evidence of a laudable effort motivated by good intentions. This surely is not the last attempt that will be made in a single hospital to clarify an important area of surveillance art, science, and lore.

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