Germs and the Pseudoscience of Quality Improvement

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No one wants a hospital-acquired infection—a wound infection, a central line infection, or any other kind. But today, the level of concern in American hospitals about infection rates has reached a new peak—better termed paranoia than legitimate concern.

The fear of infection is leading to the arbitrary institution of brand new rules. These aren't based on scientific research involving controlled studies. As far as I can tell, these new rules are made up by people who are under pressure to create the appearance that action is being taken.

Here's an example. An edict just came down in one big-city hospital that all scrub tops must be tucked into scrub pants. The "Association of periOperative Registered Nurses" (AORN) apparently thinks that this is more hygienic because stray skin cells may be less likely to escape, though there is no data proving that surgical infection rates will decrease as a result. Surgeons, anesthesiologists, and OR nurses are confused, amused, and annoyed in varying degrees. Some are paying attention to the new rule, and many others are ignoring it. One OR supervisor stopped an experienced nurse and told to tuck in her scrub top while she was running to get supplies for an emergency aortic repair, raising (in my mind at least) a question of misplaced priorities.

The Joint Commission, of course, loves nothing more than to make up new rules, based sometimes on real data and other times on data about as substantial as fairy dust.

A year or two ago, another new rule surfaced, mandating that physicians' personal items such as briefcases must be placed in containers or plastic trash bags if they are brought into the operating room. Apparently someone thinks trash bags are cleaner.

Now one anesthesiology department chairman has taken this concept a step further, decreeing that no personal items at all are to be brought into the operating room—except for cell phones and iPods. That's right, iPods, not iPads. This policy (of course) probably won't be applied uniformly to high-ranking

surgeons or to people like the pacemaker technicians who routinely bring entire suitcases of equipment into the OR with them.

What's particularly irrational about this rule is that cell phones likely are *more* contaminated with bacteria than briefcases or purses, even if they're wiped off frequently. And I have to ask how an iPhone 6+ meets eligibility criteria while the barely-larger iPad mini doesn't. Again, please show me the data demonstrating that this will reduce infection rates, unless someone is making it a habit to toss briefcases and iPads onto the sterile surgical field.

Show me the money

I wish I could say that the driving force behind hospitals' fear of infection is simply the wish for patients to get well. Unfortunately, it's probably driven as much by financial motives as benevolent ones. Today, Medicare won't pay for care related to surgical site infections, and it fines hospitals whenever too many patients need to be readmitted within 30 days of discharge. In 2014, a record 2610 hospitals–including 223 in California–were penalized, and will receive lower Medicare payments for *all* patients over the next year, not just those who were readmitted.

What does this mean at the grassroots level?

It means that the epidemiology department in your hospital is under a lot of pressure to do something. The epidemiology doctors and nurses are the people charged with preventing infections. Their mission is to kill germs in the hospital wherever they may be until the day when hospital-acquired infection rates reach zero.

Some progress has been made. The CDC reports that between 2008 and 2012, central line-associated bloodstream infections decreased by 44%. This can be credited chiefly to work headed by Dr. Peter Pronovost, a physician anesthesiologist who championed standard aseptic procedures for central line insertion in ICUs.

But other initiatives aren't based on this type of solid science, with sound methodology and careful tracking of results over time.

The Centers for Medicare and Medicaid Services recently released results of its "Partnership for Patients" (PPP) program, and boasted large improvements in several outcomes including pneumonia. In reply, Dr. Pronovost and Dr. Ashish Jha wrote an editorial in the New England Journal of Medicine, arguing that "weak study design and methods, combined with a lack of transparency and rigor in evaluation, make it difficult to determine whether the program improved care."

"Though the evaluation of many other CMS programs also lacks this basic level of rigor, given the large public investment in the PPP, estimated at $1 billion, and the strong public inferences about its impact, the lack of valid information about its effect is particularly troubling," they concluded. "Some patient-safety interventions appear to lead to improvements but are no more effective than controls."

Choosing action over evidence

The need to do something—anything—to improve healthcare quality often leads to action that isn't justified by evidence or subjected to controlled follow-up study. Writing in the New England Journal of Medicine, Dr. Andrew Auerbach and his colleagues analyzed "The Tension between Needing to Improve Care and Knowing How to Do It." They elegantly described arguments often used in favor of rapid quality improvement interventions, and then explained why scientific evaluation is critical. Among the key points:

1. *The need to treat disease is just as urgent as quality improvement, but we demand rigorous evidence that a therapy works before recommending it widely.*
2. *Emulation and collaboration can incorrectly promote or even overlook interventions that have not worked.*
3. *Given the complexity of quality and safety problems, the complexity of their causes, and how little we understand them, we should use rigorous study designs to evaluate them.*

Hospitals have little incentive to examine their quality improvement efforts critically, the authors concluded, since "if anecdotal reports or superficial analyses are positive, the organization will understandably focus on advertising these measures of success rather than pursuing more rigorous evaluation."

While no one is suggesting a randomized study of parachute use, or of sterile vs. non-sterile glove use for surgeons and scrub techs, other issues aren't as straightforward, Dr. Auerbach noted. "Many apparently obvious quality-improvement interventions have more in common with calls for world peace than with parachutes—the goal is not in question, but the path for achieving it is."

"Squames" vs. long sleeves

Some rules seem to mutate over time. A while back, nurses were told not to wear long-sleeved scrub jackets in the OR because the sleeves could accidentally contaminate sterile surfaces. Now, the AORN says that everyone *should* wear long sleeves to reduce the risk that those pesky "squames"—dead skin cells which everyone routinely sheds—will cause contamination of the OR.

Of course, no one knows if squames or sleeves have any relation to surgical infection rates because the research hasn't been done. This controversy reminds me of the argument in years past over the wearing of shoe covers in the OR. That rule seems to have faded into oblivion, whether because it had no beneficial effect or because the shoe covers cost too much money, I'm not sure.

Even hand-washing isn't as obvious a solution as it seems. A much-quoted study in the American Journal of Infection Control reported that anesthesiologists and nurse anesthetists were poorly compliant with World Health Organization (WHO) guidelines for hand hygiene (HH). However, full compliance with the guidelines is impossible. An average of 149 "HH opportunities" were identified by observers during each hour of anesthesia care.

"Complete compliance with HH practice as recommended by WHO guidelines would have consumed more than the 60 minutes available in each hour of anesthesia time," the authors concluded. "HH compliance is especially difficult during the complex and rapidly evolving induction and emergence phases of anesthesia, a situation that is not easy to improve."

The hand-washing study ignored the fact that the anesthesia practitioner who is directly administering anesthesia is caring for only one patient at a time, not going from patient to patient without appropriate hand hygiene. The study involved observation of only 10 surgical cases, and did not report whether or not any of the patients developed a surgical site infection or any other postoperative infectious complication. Most important, it did not address the fundamental question of whether bacterial counts in the anesthesia work area, which is physically separated by sterile drapes from the surgical field, have any bearing on the real issue of patient wellbeing.

What are we to do?

Certainly sleeves can be contaminated. Skin, shoes, cell phones—all harbor bacteria. Yet most patients don't develop infections after surgery.

Everyone knows that the patient whose thyroid gland is removed is at less risk for surgical site infection than the patient whose large intestine is removed, because the large intestine is contaminated with fecal bacteria.

Everyone knows that patients who are diabetic or immunocompromised are more susceptible to surgical site infections.

So perhaps we're asking the wrong questions and setting in place new rules that don't address the roots of the infection problem.

Instead of creating more and more rules governing the care of *all* patients, perhaps we need to focus on the subsets of patients and case types that we already know are at higher risk, and examine what additional steps we need to take on their behalf.

As an example, we already know that the bacterial count found on surgical scrubs increases as the day wears on, and OR staff members stop by the preoperative and recovery care areas, the cafeteria, and (inevitably) the bathroom. No one yet, to my knowledge, has done a rigorous, controlled, prospective study to see if there is any correlation between the bacterial counts on surgical scrubs and surgical infection rates when cases are done in the morning compared to later in the day.

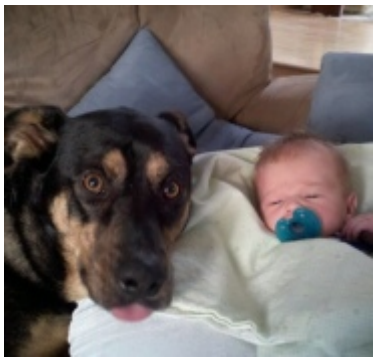
Should the American healthcare system pay for fresh disposable scrubs to be worn for cases at high infection risk? Could the system conserve resources by allowing staff the option to select, purchase, and launder their own scrubs for routine use, just as they select, purchase, and launder the socks that they

wear to the OR every day?

No one really knows the answer to this basic question: Do higher bacterial counts on scrubs, cell phones, or nonsterile surfaces, assuming that these are carefully kept apart from the sterile surgical field, actually correlate with a higher risk of surgical site infection? Right now, rule-makers simply assume that they do. We urgently need good science, with prospective, controlled studies, to answer this question. If the answer is no, then we need to look elsewhere for ways to lower infection rates.

Finally, it's fair to ask if the quest to eliminate all bacteria from the operating room is creating an environment in which the truly dangerous bacteria flourish since they have no competition from the relatively harmless ones. This is the process that takes place when antibiotics and antibacterial cleansers are overused, killing off weak bacteria and allowing the resistant ones to multiply and thrive.

You may have heard of the "hygiene hypothesis", which argues that lack of exposure to normal bacteria, and overexposure to antibacterial chemicals, makes children more prone to a wide range of food and environmental allergies.



Early childhood exposure to common pathogens appears to be essential in building healthy immune responses. A child who isn't exposed to normal bacteria may develop an overactive immune system that misfires against food proteins, pollen, or pet dander.

The three-week-old baby in the photo? He just celebrated his fourth birthday. He's never had an ear infection, has never needed a prescription for antibiotics, and requests peanut butter every day for lunch.

Maybe we should schedule a "take your dog to the OR" day.

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