Antimicrobial Prophylaxis to Prevent Surgical Site Infection

By Joseph Bernstein, MD, and Menachem M. Meller, MD, PhD

Antimicrobial prophylaxis reduces the incidence of surgical site infection for many procedures[1]. Nonetheless, these medications are not always given appropriately[2]. This failure may stem from a diffusion of responsibility[3]: both the surgeon and the anesthesiologist may assume that the other has attended to this issue. The root cause, we believe, is the reliance on human action, which invites avoidable error and demands fail-safe routines.

To that end, we have incorporated a check on antimicrobial prophylaxis into the "time-out" mandated by the United States Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in the "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery."[4] Our time-out comprises four questions, the first three of which are part of the JCAHO standard:

1. Who is the patient?
2. What procedure is being done?
3. Which is the correct operative side?
4. Have antibiotics been administered?

These four questions are summarized by the mnemonic "The 4 Ps," which stand for patient, procedure, position (operative side), and prophylactic antibiotics.

A Fail-Safe—Not a Front-Line Defense

The "4P" method is a fail-safe, a compensatory process, to prevent undetected error. It is not intended to be the primary means of ensuring that antimicrobial prophylaxis is administered. This is a practical distinction. Consider the following situation: a patient is allergic to penicillin, and the drug of choice may be vancomycin, which must be infused slowly. If the fact the patient did not receive prophylaxis is discovered only at the last minute—when asking the fourth question—then there may be long delay, during which time the patient remains under anesthesia. (What is worse is that the patient may have received a spinal anesthetic with a duration of action that is not long enough to account for both the delay and procedure itself. Thus, the delay in starting the procedure may create a need for general anesthesia as well.)

Although it is preferable to detect an error even at the last minute than not to detect it at all ("better late than never"), it is incumbent on the surgical team to ensure that antibiotics are given in a timely manner. Written orders accompanying the documentation for admission (even at an outpatient center) can be helpful in that regard. At the suggestion of a process action team convened at the Philadelphia Veterans Affairs Medical Center to optimize the administration of prophylactic antibiotics, we have further refined our process of administering prophylactic antibiotics by reiterating a verbal order at the time of signing the surgical site—i.e., when verifying with the patient the correct limb and the proposed procedure. This verification is done outside the operating room, which usually gives ample time for infusing the antibiotic, even if vancomycin is used.

Joint and Several Responsibility

The primary responsibility for determining whether an antibiotic is indicated, and choosing which one to administer, rests with the surgeon, we believe. Our training, knowledge, and experience make us the best arbiter of this issue. Nonetheless, the anesthesiologist will be the doctor who actually administers the drug, and therefore he or she should actively participate in the process of ensuring that correct prophylaxis is applied. Just as surgeons ask, "Does this patient have adequate anesthesia for surgery to begin?" the anesthesiologist should be responsible for asking, "Does this patient have adequate antibiotic prophylaxis for surgery to begin?" The 4P method is an explicit means for all operating-room staff to engage this question.

Error prevention increases with redundancy. That is, it is far better that both the surgeon and the anesthesiologist consider themselves individually responsible than for neither to do so. The choice of antibiotic and the need for it for a specific procedure can be defined by surgeons in guidelines shared with the anesthesia staff, obviating the need for the anesthesiologist to wrestle with questions that he or she may not feel trained to consider.

Validity of the Method

We introduce the 4P approach without any explicit studies proving its validity. Nonetheless, we assert that this method has inherent face validity and content validity. The face validity refers to the (perhaps obvious) fact that asking about the administration of antibiotics is an apt means to detect instances of a failure to administer them. Content validity describes the sense that the experts—authors, peer reviewers, readers, etc.—agree that this is reasonable.

Harder to assess is the construct validity—that is, is the 4P approach effective at preventing errors of failure to administer antibiotics? In our brief ex-

perience using this method over a period of two months, there were at least three instances in which the failure to give preoperative prophylactic antibiotics was detected and corrected. This anecdotal experience, of course, does not prove the effectiveness of the method, as (in the extreme example) a universal ban on the performance of surgery would also prevent the occurrence of surgery without appropriate antibiotics. Effectiveness, then, refers to something more subtle—how many instances are prevented, and at what cost? This is yet unknown.

Cost-Benefit Analysis

The precise number of instances in which doctors would fail to give necessary antibiotics without the 4P method is unknown. (From our experience, this would be far more common than operating on the wrong patient or the wrong limb; although, admittedly, the cost of this antibiotic error is far smaller too.) Still, if it is assumed that 98% of patients who should receive antibiotics currently do so and that the 4P method would increase this rate to 99%, that the risk of surgical site infection is 1% with prophylaxis and 2% without, and that there are five million orthopaedic surgical procedures performed annually in which prophylaxis is indicated, a case can be made that the adoption of the 4P method would prevent 500 surgical site infections annually.

The prevention of 500 infections is not the only benefit. We assert that adding a question regarding antibiotics to the time-out can make the entire time-out more effective. The reason for this is that screening tests that are truly positive only rarely (if ever) may lose their power. It is well known from the experience of baggage examiners at the airport that it is difficult to remain attentive when a scant minority of test results (if that) are truly positive. Likewise, one could imagine that, after a few years of following the JCAHO Universal Protocol without a single instance of wrong-site surgery explicitly prevented, the operating-room staff may be lulled into complacency. Operating by rote, the participants over time may not even listen to the answers. By incorporating a question regarding prophylactic antibiotics—a question that is not uniformly answered in the affirmative, even in the absence of error, as prophylaxis is not always indicated—we can invigorate the entire JCAHO Universal Protocol and promote vigilance.

The costs of the method are small, but they are not zero. It is certainly possible to overwhelm the time-out with so many extraneous but seemingly reasonable questions, including those that are important but just not timely (such as questions regarding allergies), that it ceases to be a time-out but rather a procedure unto itself. It is also possible that an effective fail-safe method may detract from efforts to ensure a priori that antibiotics were ordered, in the same way that automobile air-bags are thought to decrease the use of seat belts.

Recommendations

Our personal cost-benefit estimation strongly favors including a question regarding antibiotics into the JCAHO time-out, and we have done so. The Philadelphia Veterans Affairs Medical Center has officially included this question in its policies. The JCAHO may wish to conduct its own assessment of validity before making this a national standard. Because the issue of antibiotic prophylaxis is particularly germane to orthopaedic surgery, our orthopaedic organizations may wish to consider this issue independently. Individual surgeons, of course, are free to adopt this approach on their own without an official mandate, and we recommend that they do.

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Commentary

Medicine is attempting to undergo a transformation in improving quality and reducing error. The list of organizations (both government and private) vying to lead the way grows each year. In particular, two organizations, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Centers for Medicare and Medicaid Services (CMS), have shown remarkable initiative by setting concrete standards and expectations.

The practice of surgery has been a focus of these efforts. In particular, two parallel initiatives are having an impact

on surgeons before their scalpel touches the skin:

1. JCAHO: Surgical time-out for wrong-site surgery. (Effective July 1, 2004, compliance with the "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery" is required of all Joint Commission-accredited organizations[1].)

2. CMS: Measures for the prevention of surgical infection recommending that prophylactic antibiotics be received within one hour prior to surgical incision[2].

Both organizations specifically outline the intended goal and/or outcome, but both are careful to avoid specific recommendations regarding implementation. JCAHO "recognizes the need for flexibility to accommodate the logistical and procedural realities of the full range of surgical facilities."[3]

Dr. Bernstein and Dr. Meller present their method of addressing these two initiatives. They should be commended for their proactive approach in addressing two related issues. Their general recommendation to include "a question regarding antibiotics into the JCAHO time-out" is useful. The authors' specific recommendations are problematic in two regards: timing and their use of a mnemonic.

The fourth P (for prophylactic antibiotic) illustrates a problem with mnemonics. Often the available letter does not represent the best possible description of the issue at hand. The phrase "prophylactic antibiotic" does not readily translate into the authors' question, "Have the antibiotics been administered?"

A more important problem with the fourth P is that it does not address the issue of timing. To fully address this issue, any preoperative checklist should include the familiar who (patient name), what (operation), where (which extremity or body part), and *when* (time that the antibiotic was infused). According to the CMS measures for the prevention of surgical infection, "*When* was the antibiotic given?" is as important as "*Has* the antibiotic been given?"[4] The CMS recommendations stipulate that it is not enough to *give* the antibiotic; it must be infused within one hour prior to surgery. Delivery of the antibiotic one minute outside this window is considered a compliance failure and is reported as such by the online database "Hospital Compare."[4]

The use of a preoperative checklist has been called a "preoperative verification process," "universal protocol," and, most recently, "time-out." The medical use of the phrase "time-out" is not consistent with the dictionary definition of "time-out." Regardless of what this process is ultimately called, some form of preincision checklist is now a mandated function.

The danger in medicine is that we make the checklist more than it is. While it is clearly here to stay, it is not clearly defined how such checklists should be categorized from a "systems" standpoint. In other industries, the use of a checklist is a means of monitoring the effectiveness of the "system." We believe it is important to use a checklist to monitor the system rather than to have the checklist serve as the system. Any variances picked up by a checklist should be viewed as a failure of the delivery system rather than as a success of the checklist.

Shigeo Shingo, one of the industrial engineers who revolutionized Toyota, has said that a checklist wouldn't be necessary if people never forgot things[5]. Shingo introduced the concept of Poka-Yoke (Japanese slang for avoiding inadvertent errors and translated as mistake-proofing). This has led to terms such as "error management," "forcing-function,"[6] and "foolproofization."[7] Error management is facilitated by forcing-function devices, which have three attributes: inspection, setting function, and regulatory function. To illustrate these concepts, consider the example of an airplane passenger who enters a bathroom. Inspection is used to determine that there is no light, and a switch (the setting function) is used to turn the light on, which automatically locks the door and sets the outside signage to read "occupied" (the regulatory function). As an added precaution, many passengers might *check* to make sure the door is locked. If by chance the door is not locked, most likely the "system" is broken. Rather than view this as a success of the final door check, it should be viewed as a failure of the locking mechanism.

Dr. Bernstein and Dr. Meller state that "there were at least three instances in which the failure to give preoperative prophylactic antibiotics was detected and corrected." In the airline industry, this would be viewed as an identification of three near misses rather than as a success of the mnemonic. While near misses are preferred to the actual occurrence of harmful events, use of a checklist as a weak, human-attention-dependent barrier to error is only a starting place. As the authors note, it is "not intended to be the primary means of ensuring that antimicrobial prophylaxis is administered."

Improved inspection techniques, setting functions, and regulatory functions should be sought. Error detection should be moved as close to the actual time and place of the error as possible, and should prevent the error in ways that depend less on human attention and action. There are examples of forcing functions in medicine[8], but these responses to error are not routine. In this respect, health care lags behind other safety-critical industries. Ideally, responses to error will be improved as a "systems approach" to error reduction leads to the development of forcing function devices. For example, incorporating "a regulatory function" (an alarm) into an anesthesia software program has a greater potential to reduce human error than does a human-dependent "time-out."

Specific recommendations, once universally adopted, are difficult to amend. The readership would best use this contribution to the Orthopaedic Forum as a starting place to stimulate thought rather than as an endorsement of the method proposed by Dr. Bernstein and Dr. Meller. Their recommendations fall short of the timing

guidelines recommended by the CMS. The introduction of the recommendations may have a paradoxical effect by adding another human-dependent element. That is why JCAHO correctly recognizes the danger of making specific recommendations.

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