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Case 34-2010: A 65-Year-Old Woman with an Incorrect Operation on the Left Hand

David C. Ring, M.D., Ph.D., James H. Herndon, M.D., M.B.A.,
 and Gregg S. Meyer, M.D.

PRESENTATION OF CASE

From the Departments of Orthopedics (D.C.R., J.H.H.) and Medicine (G.S.M.) and the Massachusetts General Physicians Organization (G.S.M.), Massachusetts General Hospital; and the Departments of Orthopaedic Surgery (D.C.R., J.H.H.) and Medicine (G.S.M.), Harvard Medical School — both in Boston.

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A 65-year-old woman was admitted to the day-surgery unit at this hospital for release of a trigger finger of the left ring finger.

Approximately 3 months earlier, the patient was seen in the orthopedic clinic at this hospital because of pain and stiffness in the ring finger of the left hand. She reported that the finger intermittently “got stuck” in flexion. She had a history of coronary-artery and carotid-artery atherosclerosis, hypertension, diabetes mellitus, hyperlipidemia, and hypothyroidism. She had had a cholecystectomy in the past. Medications included nitroglycerin and nitrate preparations, metformin, levothyroxine, simvastatin, acetylsalicylic acid, and vitamins. She had no known allergies. She had been born in a Caribbean country and spoke only Spanish. She lived with her son. She did not smoke, drink alcohol, or use illicit drugs.

On examination, there was tenderness in the palm at the base of the left ring finger over the A1 pulley of the flexor tendon sheath and a slight flexion contracture of the proximal interphalangeal joint of the left ring finger. There was snapping of the left ring finger with flexion and extension. Motor and sensory function and tendon balance were normal, and there was no angular or rotational deformity. A diagnosis of idiopathic trigger finger (stenosing tenosynovitis) was made. The patient elected a trial of dexamethasone, which was injected locally. At follow-up 8 weeks later, she reported no improvement in the joint symptoms. The examination was unchanged. The risks, benefits, limitations, and alternatives of operative and non-operative treatment were discussed. The patient decided to proceed with surgery.

Ten days later, the patient was admitted to the day-surgery unit, and carpal-tunnel-release surgery was performed without complications. Immediately after completing the procedure, the surgeon realized that he had performed the incorrect operation.

DISCUSSION

Dr. Harry E. Rubash (Orthopedic Surgery): Dr. Ring asked that this case be presented at our departmental conference and published in the Case Records of the Massachusetts General Hospital, in hopes of stimulating discussions and encouraging the development and following of procedures that would minimize the risk for such events in the future.

THE SURGEON'S ACCOUNT

Dr. David C. Ring: This 65-year-old woman with a trigger finger that did not respond to glucocorticoid injection elected operative treatment under local anesthesia. She was my last patient scheduled for surgery that day and was one of three patients who were having hand surgery under local anesthesia, following three other patients who were having larger procedures performed while they were under general or regional anesthesia. My mind-set at the start of the day was, "I have three big procedures that I have specifically planned and prepared for and a few 'carpal tunnels' to perform today."

The first minor hand surgery was a carpal-tunnel release, with the patient under local anesthesia. The patient was quite nervous about the injection of the anesthetic agent. The surgery went well, but as we applied the dressing, she again became upset about the injection of the anesthetic, and I had to help console her.

Shortly thereafter and approximately 1 hour before the operation on the patient who is the subject of this conference, I was asked to translate during her preoperative preparation, since I speak Spanish and no interpreter was available. According to hospital protocol, the correct arm had been marked at the wrist by the nurse but the planned incision site on the hand was not marked. I went through my usual preprocedure routine with the patient, verifying the symptoms, the abnormal findings on physical examination, and the informed consent. I confirmed a persistent trigger finger of the left ring finger and reviewed the risks and benefits of the procedure with the patient.

Next I went to another operating room and performed a carpal-tunnel release on the second patient, without incident. Stress on the day-surgery unit was high because several other surgeons were behind schedule. The decision was made to move my last patient to another operating room. In addition to the change in venue, this resulted in a change in personnel; in particular, the nurse who had performed the preoperative assessment would not be in the room with us during the procedure.

The change of rooms also introduced a delay, during which I went to an inpatient floor for a consultation. When I returned to the outpatient-surgery area, I was told that the patient who had been upset about the injection of the anesthetic for her carpal-tunnel release had become very agitated in the recovery area. Although I was able

to help put her at ease, the encounter was very emotional, producing in me both the cognitive and physiological aspects of anxiety, as well as a resolve to do everything possible to prevent such an unpleasant experience for future patients. Her emotions were very intense, and my sympathy for her was such that I recall privately counseling myself that the next operation would be "the best carpal tunnel release that I have ever performed."

When I entered the room, the patient was already there and preparations were under way. I noticed that we did not have a tourniquet. The circulating nurse had to leave the room to get one, which distracted her from the patient and made her fall behind on her documentation. The patient's arm was washed with soap, alcohol, and povidone-iodine according to hospital protocol. The alcohol caused the site marking to be wiped off the limb. I spoke with the patient in Spanish, which the circulating nurse mistook as a time-out, and as a consequence, no formal time-out took place before the procedure was begun. In addition, there was a change in the nursing team in the middle of the procedure.

I performed a carpal-tunnel release on this patient, rather than a trigger-finger release. About 15 minutes later, while I was in my office dictating the report of the operation, I realized that I had performed the wrong procedure. I immediately informed the staff and then went straight to the patient and personally informed her of the error. I apologized and explained that I could perform the correct procedure if she wanted me to do so. She agreed, and I reassembled the staff. During the preparations for the correct procedure, I filed a safety report and notified the hospital's risk manager of the error and the rectification. I then performed a trigger-finger release, without complication. The patient was discharged home that day after a brief recovery.

I spoke with the patient's son by phone several times after the operation to apologize, waive fees, and arrange follow-up care. Several days after the incident, he informed me that his mother had lost faith in me and would not return. I received a call from a community clinic associated with our hospital where the patient went to have sutures removed, and I instructed them in the postoperative management. All charges were waived, according to Massachusetts General Hospital policy. A financial settlement was negotiated shortly after the event.

WRONG-SITE SURGERY AND WRONG PROCEDURES

Dr. James H. Herndon: This case is an example of wrong-site surgery or a wrong procedure. Data pertaining to wrong-site surgery were first documented in the United Kingdom in 1988 by the Medical Defense Union and in Canada in 1993 by the Canadian Medical Protective Association.¹

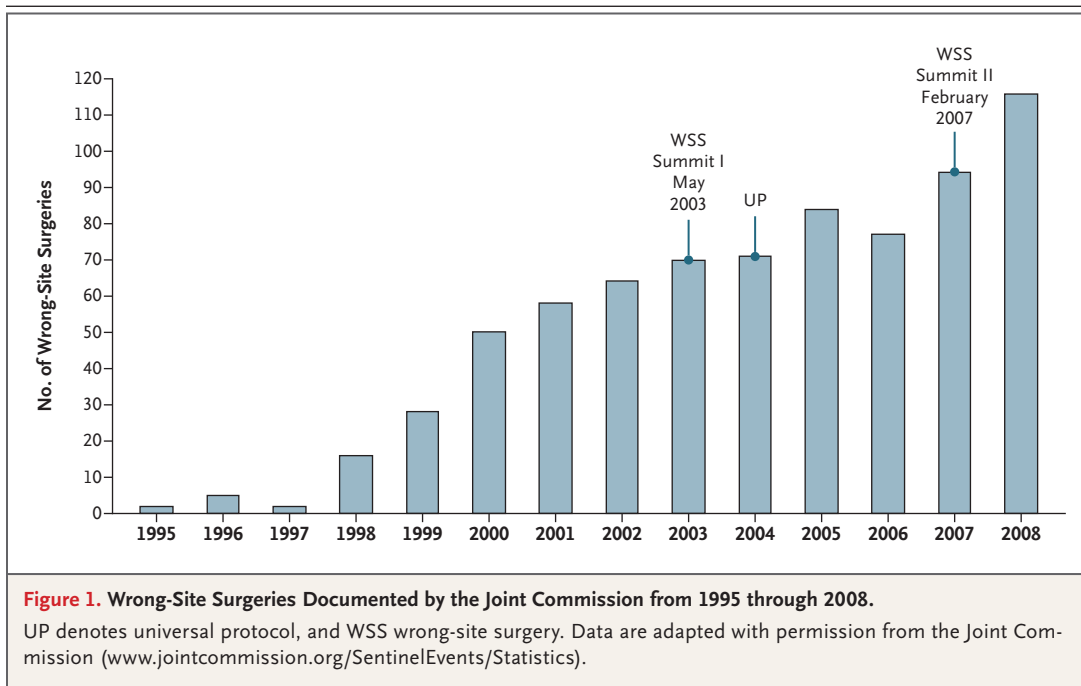
“Sign Your Site”

A committee of the Canadian Orthopaedic Association issued a report in 1994 that recommended a program entitled Operate through Your Initials,² whereby surgeons were advised to write their initials over the planned incision site with a permanent marker before the patient entered the operating room. The rates of wrong-site surgery in Canada have been declining ever since.³

Wrong-site surgery occurs in all surgical specialties but is most common among orthopedic surgeons and neurosurgeons,⁴ with 68% of claims in the United States related to orthopedic surgery.⁵ In order to avoid the problem, a task force of the American Academy of Orthopaedic Surgeons (AAOS) developed the Sign Your Site initiative in 1998, advising surgeons to mark the surgical site with their initials.⁵ In a 2003 survey of hand surgeons, 21% of the surgeons reported having operated on the wrong site at least once

in their career, and 2% more than once; 45% reported having changed their practices as a result of the Sign Your Site campaign.⁶

The AAOS expected that the incidence of wrong-site surgery would decrease with the Sign Your Site program, as it had in Canada, but instead, the number of cases documented by the Joint Commission (TJC) has been increasing (Fig. 1) (www.jointcommission.org/SentinelEvents/Statistics). There are no national estimates on the true incidence of wrong-site surgery, but it is probably not decreasing. A recent survey of AAOS members revealed that 5.6% of reported medical errors were wrong-site procedures or wrong procedures⁷: of these, approximately 59% involved the wrong side, 23% another wrong site (e.g., the wrong finger on the correct hand), 14% the wrong procedure, and 5% the wrong patient. The most common sites were the knee, the finger or hand, and the foot or ankle. Commonly reported factors that can result in a wrong-site surgery include the absence of a surgeon's mark or a marking near the site but not on the site.⁴ Since more than one third of the patients in one survey were not helpful when asked to identify the surgical site, it is crucial that there be a systematic and consistent approach to identifying the correct patient, correct operation, and correct site before each operation is started.⁸



The Universal Protocol

Because of the continued reports of wrong-site surgeries, TJC, along with the AAOS, the American College of Surgeons, and other professional organizations, held a summit on wrong-site surgery in 2003, and another in 2007. The resulting guidelines recommended a universal protocol involving preoperative verification of the patient and the

procedure, marking of the surgical site, and a time-out before the start of the operation (Table 1). Although there has been concern about infection from the ink used to mark the site, one study showed that preoperative signing of the surgical site did not compromise sterility.⁹ The guidelines recommend that the time-out include the surgeon, anesthesiologist, nurse, and patient and that just

Table 1. Universal Protocol.***Conduct a preprocedure verification process.**

Address missing information or discrepancies before starting the procedure.

Verify the correct procedure, for the correct patient, at the correct site.

Involve the patient in the verification process when possible.

Identify the items that must be available for the procedure. These should include at least:

Relevant documentation

Properly displayed and labeled results of diagnostic and radiologic tests

Any required blood products, implants, devices, or special equipment

Use a standardized list to verify the availability of the items for the procedure.

Ensure that the items that must be available for the procedure pertain to the proper patient.

Mark the procedure site before the procedure is performed.

Mark the site when more than one possible site for the procedure exists and when performing the procedure in a different site could harm the patient.

Involve the patient in the site-marking process, if possible.

Have the site marked by a licensed independent practitioner who is ultimately accountable for the procedure and will be present when the procedure is performed.†

Make a mark that is unambiguous and that is used consistently throughout the organization.

Make the mark at or near the procedure site.

Make the mark sufficiently permanent to be visible after skin preparation and draping.

Adhesive markers are not the only way of marking the site.

Perform a time-out.

Resolve all questions and concerns before the procedure is begun.

Conduct a time-out immediately before starting the invasive procedure or making the incision.

Designate a member of the team to start the time-out.

Standardize the time-out.

Involve the immediate members of the procedure team in the time-out: the person performing the procedure, anesthesia providers, circulating nurse, operating room technician, and other active participants who will be participating in the procedure from the beginning.

All relevant members of the procedure team should actively communicate during the time-out.

During the time-out, obtain agreement among the team members on at least the following:

Correct identity of the patient

Correct site

Procedure to be performed

If the same patient will have two or more procedures and if the procedures will not be performed by the same person, conduct a time-out before each procedure is begun.

Document the completion of the time-out. The organization determines the amount and type of documentation.

* Data are adapted from the Universal Protocol of the Joint Commission (www.jointcommission.org/NR/rdonlyres/F8046F2C-A8A2-412F-88D4-E1762BCC5C26/0/UP_Poster.pdf) with permission.

† The mark is a communication tool about the patient for members of the team. Therefore, the team member who knows the most about the patient should mark the site. In most cases, that will be the person performing the procedure. In limited circumstances, site marking may be delegated to some medical residents, physician assistants, or advanced-practice registered nurses, but ultimately, the licensed independent practitioner is accountable for the procedure.

before induction of anesthesia, all participants agree on the patient's identification, the operation type, and the correct surgical site (Table 1).

A Medicare "Never Event"

Wrong-site surgery is included in the list of adverse events, also known as never events (i.e., hospital-acquired conditions), originally described by the National Quality Forum and later adopted by Medicare. Some adverse events are included in the National Quality Forum's list of never events (events that should never happen) and others are included in Medicare's list of never events (adverse events that are not reimbursable by Medicare). A third list of never events (events that should not happen and that are potentially non-reimbursable) overlaps the National Quality Forum list and the Medicare list (www.pssjournal.com/content/3/1/26). Wrong-site surgery is on this third list. In the future, hospitals and physicians may not be reimbursed for a never event such as wrong-site surgery.

INVESTIGATION OF WRONG-SITE SURGERY BY THE CENTER FOR QUALITY AND SAFETY

Dr. Gregg S. Meyer: Dr. Ring has described an event that was devastating for both a patient and a physician: a wrong-site surgery or a wrong procedure. Although wrong-site surgery and other patient-safety challenges have most recently been interpreted in the context of the 1999 Institute of Medicine's report *To Err Is Human*,¹⁰ this problem is far from new. There is evidence, based on trephinations at multiple sites of the skull, that surgeons in the Stone Age sometimes operated on the wrong site.¹¹ Ironically, wrong-site craniotomies still occur, many centuries later.¹²

Increased Awareness and Reporting of Wrong-Site Surgeries

The increased number of reports to TJC in recent years about wrong-site surgeries is most likely a reflection of increased awareness and more consistent reporting of these events, marking a positive cultural change in attitudes toward patient safety and part of an important transformation of health care organizations into true learning organizations.¹³ As disclosure and transparency become standard practice, the proportion of dramatic cases (e.g., the removal of the wrong limb at surgery) will probably decrease, and the number of more subtle cases (e.g., the placement of a central catheter in an artery instead of a vein)

and cases from outside the operating room (e.g., bedside insertion of a chest tube on the wrong side) will probably increase. This inverse relationship between the number of events reported and the severity of the events is a well-described tenet of the science of safety.¹⁴

Causes of Human Error

How could this have happened to Dr. Ring and his patient? The question is more complex than it initially appears. Breakdowns can occur in skill-based behavior, rule-based behavior, and knowledge-based behavior.¹⁵ In many cases, such as the wrong procedure described here, all three occur. A failure of skill-based behavior is an error in performing a routine task, usually a result of distraction. An example is texting while operating a motor vehicle, which leads to a failure to recognize hazards. Failures of rule-based behaviors are typically driven by familiarity with the task at hand, leading to stretching the rules. For example, a stop sign is a clear signal to stop a motor vehicle completely and look in both directions before proceeding. Stretching those rules, such as through a rolling stop, is a classic deviation from rule-based behavior. Knowledge-based behaviors involve conscious problem solving to deal with new situations, such as deciding how to proceed through an intersection when the traffic light is broken.

In this case, distractions that interfered with the surgeon's performance of routine tasks included personnel changes, an inpatient consult, and a previous patient's needs. There was deviation from rule-based behavior in the failure to follow the universal protocol for a full time-out. There was also a problem involving knowledge-based behavior: the ability of the surgeon to speak the patient's language (and the inability of the other team members to do so) allowed for a nonstandard solution (surgeon acting as interpreter) that effectively shut out other team members from full participation in the informed-consent process. Since the replacement staff members were unable to verify communication between the physician and their patient, a misunderstanding resulted, in which the nurse thought that a conversation between the patient and the surgeon represented a time-out.

The "Swiss Cheese" Model of Harm

The case presented here illustrates that hazards will always exist in medicine. In his "Swiss cheese"

model, James Reason notes that hazards will result in harm when each of our defensive barriers is incomplete and contains random holes like the holes in slices of Swiss cheese; occasionally, these holes line up, allowing those hazards to create harm.¹⁶ In this case, the holes included a busy operating room with delays and changes in the room and personnel before the procedure, a language barrier, a break from the preprocedural routine, a change in key personnel during the procedure, and — as we learned during our later investigation — inattention by the nurses that was fostered by placement of clinical computer monitors in a way that diverted the nurses' gaze away from the patient.

Active versus Latent Errors

This case illustrates the importance of considering both active and latent errors. Active errors are those that are committed by front-line caregivers. Latent errors are those that are delayed consequences of technological and organizational decisions.¹⁷ In this case, the active errors included the failure to complete a full universal protocol and the marking of the side but not the actual operative site.¹⁸ The latent errors, however, were just as important. These included the problems in the scheduling and deployment of personnel that delayed and then interrupted the procedure and distracted the surgeon, the use of the surgeon as an interpreter instead of the use of a professional interpreter during the procedure, the poor placement of computer monitors and the consequent diversion of the operating room nurses from the task at hand, and most important, a culture that allowed nurses who were not directly involved in the procedure to perform tasks such as marking the surgical site. Consideration of all these factors is essential in the effort to reduce risk in the future. Focusing exclusively on the active errors and not addressing the latent factors will preclude the prevention of harm.

The assessment of safety requires a disciplined approach, as illustrated by this case. It begins with an analysis of contributing factors, which requires careful attention to three critical questions. What happened? Why did it happen? What can we do to prevent it from happening again?¹⁹ It is important to note that the question "Who was involved?" is not pertinent to future risk unless it is evidence of reckless behavior by the operator, which is rare and would require

disciplinary action.²⁰ In most cases, the appropriate response to the persons (in this case, Dr. Ring and the others in the operating room) who are associated with an event involving the safety of patients is to coach, not discipline. Such an approach may lead to a more forthcoming culture, in which persons are likely to report events that compromise patient safety, and thus provide an opportunity for learning and improvement within an organization.²¹

Disclosure of Errors

One important aspect of this case was the prompt disclosure of the event to the patient and her family. Although the disclosure of deficient practice has been a part of the American Medical Association's code of medical ethics for more than 50 years,²² it had been interpreted as the need to report such events to hospital and professional organizations. More recent experience has shown the value of direct disclosure to patients and their families in terms of salvaging trust, decreasing the likelihood of litigation, and facilitating the healing of both the patient and the provider.^{23,24} Disclosure and, when appropriate (as in this case), apology and the waiving of fees are now accepted, and patients have come to expect them. Properly disclosing an error requires training and experience. In each department at our hospital, certain physicians who are chairpersons responsible for quality of care are trained to coach colleagues through disclosure; we have also created an intranet site with supporting documentation, including a disclosure checklist.

In this case, it is remarkable that despite the wrong procedure, the patient had sufficient trust in Dr. Ring to allow him to perform the planned procedure. The disclosure and apology facilitated both the maintenance of a trusting relationship and counteraction of harm, both physical and psychological, and allowed the intended procedure to take place with minimal delay. In more complex scenarios (e.g., amputation of the wrong limb), disclosure and apology can help initiate psychological healing for the patient. In this case, despite Dr. Ring's apology and follow-up, the patient ultimately transferred her care elsewhere.

Caring for the Caregivers

In the aftermath of an event that seriously compromises safety, it is important not only to counteract the harm to the patient but also to care for

the caregivers. Shortly after this event, Dr. Ring met with the quality-of-care representatives for the operating rooms, anesthesiology, and orthopedic surgery. In addition, senior leadership, including the senior vice president of quality and safety and designated representatives of the chief medical officer and the chief nursing officer were present. This allowed us to provide institutional support for the surgeon at a time when he, too, was hurting. Such interventions have been shown to be an important component of the disclosure program.²⁵

Summary

In 1852, the Massachusetts General Hospital was featured in a *New York Times* article detailing a series of events that led to the death of a young patient. Under the care of the surgeon, Dr. John Collins Warren, the patient had received chloroform instead of the usual chloric ether anesthesia.²⁶ The event that we describe here, more than 150 years later, is a sad reminder that despite expert and well-intentioned providers, our patients continue to face risks caused by human fallibility and systems that do not fully support our efforts to provide safe care. By publishing this case, we hope to encourage health care practitioners to discuss such events, investigate them fully, disclose them quickly and clearly to patients and their families, care for the providers involved, and use these learning opportunities to reduce the risk for future patients.

Dr. Rubash: What has changed in operating rooms today as a result of this event?

Dr. Peter Dunn (Anesthesia, Critical Care, and Pain Medicine): We worked with Dr. Meyer and his team at the Center for Quality and Safety to implement TJC's updated universal protocol for 2009 (available at www.jointcommission.org/patientsafety/universalprotocol) (Table 1). The universal protocol stipulates that the patient, when possible, should participate in the verification process by reviewing the consent form, identifying himself or herself as the patient, and identifying the procedure. After that, the surgeon marks the surgical site, with input from the patient if possible; site marking is no longer the nurses' responsibility. The use of alcohol-based preparations that may erase the marking ink has been discontinued. The time-out is to occur once the patient is in the final position, prepped and draped, just before the incision is made. During the time-out, the patient's identi-

ty, the site, and the procedure are again verified. The surgical scrub nurses are instructed not to hand the knife to the surgeon until the time-out is finished. There was an intensive educational program at this hospital for surgeons and nurses when these policies were rolled out.

Dr. Meyer: To ensure that this education has an ongoing effect, we initiated a process whereby an auditor from the Center for Quality and Safety directly observes the performance of the universal protocol in all inpatient and outpatient procedural areas, which continues to this day. It is also crucial that if anyone in the room has a concern about any aspect of the verification at any time during the process, the steps should be repeated. Everyone on the team should feel empowered to say, "Wait, are we sure that what we are doing is correct?" I learned an important rule in the U.S. Air Force: "Never worry alone." If you think something doesn't look right, whether you are a scrub nurse, a technician, a medical assistant, a surgeon, or an internist, never worry alone. Stop and discuss it, because those stops result in close calls instead of real events.

Dr. Herndon: Surgeons need to take ownership of these policies. When the airline industry evaluates a crash, the pilot is not considered responsible except in two circumstances: the pilot was under the influence of drugs or alcohol, or the pilot did not follow protocol. All hospitals need to have a culture in which surgeons feel responsible for making sure the protocol is followed.

Dr. Joseph S. Barr, Jr. (Orthopaedic Surgery): Most of what I currently do is review medical legal cases. Mistakes must be documented in the medical record, and the medical record can never be altered. If you have written something in the record that you now believe is inaccurate, you do not cross it out or remove it. Also, your relationship with the patient and the family is critical. Your initial informed-consent process and description of the possible hazards are important in case complications develop. If a problem does arise, talk to the patient and the family and decide the best course of action for the patient. Finally, it is helpful to talk to the patient-safety officer, if your institution has one.

Dr. Rubash: I want to thank Dr. Ring for presenting this case, which teaches us some important lessons. One is that the entire team has responsibility for getting this right. Another is that preoperative verification needs to be done

according to TJC protocols, and surgeons need to take the lead on this.

Dr. Ring: I hope that none of you ever have to go through what my patient and I went through. I no longer see these protocols as a burden. That is the lesson.

FINAL DIAGNOSIS

Wrong-site surgery and wrong procedure (carpal-tunnel release instead of trigger-finger release).

This case was presented at the Orthopedics Morbidity and Mortality Conference, January 8, 2009.

Dr. Ring reports receiving consulting fees from Wright Medical, Biomet, Skeletal Dynamics, Acumed, and Tornier; payment for ex-

pert testimony from motor vehicle insurance companies, corporations, and legal firms regarding personal injury and malpractice lawsuits; grant support from Joint Active Systems, Stryker, and Biomet; lecture fees from AO North America and AO International; and royalties from Hand Innovations, Wright Medical, Skeletal Dynamics, and Biomet; and owning stock in Illuminos and Mimedex. Dr. Herndon reports receiving payment for serving on the board of trustees of the *Journal of Bone and Joint Surgery*. Dr. Meyer reports receiving consulting fees from Boston Consulting Group, honoraria from the Agency for Healthcare Research and Quality, and grant support to his institution from CRICO Risk Management Foundation. No other potential conflict of interest relevant to this article was reported.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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