

CASE AND COMMENTARY: PEER-REVIEWED ARTICLE

What Should Patients Be Told About Device Representatives' Roles at the Point of Surgical Care?

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Abstract

Recent research has highlighted device representatives' roles in surgical cases. Additional review of cases based on actual events suggests that lack of training on the part of a surgeon and surgical team and lack of knowledge and training on the part of a representative can adversely affect a patient's clinical outcomes. While the necessity of surgical team training is acknowledged by health care organizations, organizations' policies about how to respond when surgeons or trainees refuse representatives' preoperative training remains unclear. Such a case is considered here with commentary that discusses a new model for technical support prior to, during, and after a patient's surgery.

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Case

Rep, a medical device representative for an orthopedic company, received a call from Dr N asking Rep to bring a specialized primary hip system and instrumentation for a patient with congenital dysplasia of the hip. Rep knew that Dr N had not previously worked with this implant, scheduled a time to meet Dr N and other resident physicians, and planned to perform a practice case using plastic foam pelvis and femur replicas. Upon arriving for the practice case, Dr N informed Rep that he did not need to perform the practice case. When Rep approached resident physicians working with Dr N and asked whether they would like to perform a practice case, they declined. Rep then tried to share with Dr N a training video illustrating the surgical technique, suggesting that Dr N review it over the weekend. Dr N declined and Rep agreed to be present for the case.

On the day of the case, Rep arrived in the operating room suite to find that the resident physicians had started the case. Dr N arrived and took over. Due to the unique shape of the acetabular cup Dr N wished to use, a specially designed reamer was needed for the cup. Dr N struggled with this reamer's assembly and use and the seating of the cup; Dr N requested fluoroscopy to visualize the cup's placement. After reviewing the fluoroscopy images, Dr N secured the cup. Dr N also encountered difficulty seating the

liner and asked Rep to verify that the liner was properly seated. Positioned beyond the sterile field, Rep was unable to see the liner. After struggling for 15 minutes to properly secure the acetabular liner, Dr N started the process of implanting the femoral prosthesis. The femoral component's unique design required Dr N to use special instruments to prepare the proximal femur for the prosthesis. Dr N struggled with the specialized instrumentation; to complete implantation of the femoral component, Rep held an illustration of the surgical technique and talked Dr N through each step. A trial reduction was completed, and the trial component was then replaced with the permanent femoral prosthesis.

Commentary

Interactions among device representatives and surgical care team members are often routine. Representatives are **regularly present during surgery** and often asked to respond to technical questions and facilitate smooth progress of a case. However, recent research suggests that there are times when device representatives' role exceeds the scope of their training or substitutes for surgeons' training or proficiency,¹ both of which pose significant risks for a surgical patient. The case above illuminates some questions about a device representative's role at the point of care.

A Device Representative's Role

Providing training resources and opportunities to a surgeon and surgical team members is a key responsibility of a device representative. Both the American College of Surgeons (ACS) and the American Medical Association (AMA) recognize the need for surgeons' assistance with devices and technologies^{2,3} and have developed guidelines for optimal patient outcomes. The ACS' "Revised Statement on Health Care Industry Representatives in the Operating Room" states: "The presence of the HCIR in the OR cannot substitute for preoperative training of the surgical team. The surgical team should have received training and demonstrated competence in the application of surgical devices and technologies used in the OR before the procedure."² And the AMA *Code of Medical Ethics* Opinion 10.6, "Industry Representatives in Clinical Settings," states: "Participation by industry representatives should not be allowed to substitute for training physicians to use devices and equipment safely themselves."³ It is reasonable to expect that a device representative, as a de facto surgical team member, should demonstrate the same ethical duty of care for the patient as everyone on a surgical team. However, that duty is realized through the representative's technical expertise in training the surgeon preparing for a procedure. Also ethically important is a representative's dependence on a surgeon for compensation; when this dependence compromises a representative's comfort with raising or capacity to **raise questions or concerns**—especially about a clinician's lack of training—manufacturer and institutional support can be key to keeping a patient safe.

Importance of Training Requirements

In the case, the rep provided training resources and opportunities to the surgical team: an opportunity to perform a practice case (or multiple cases, if so desired) using the implant instrumentation and training prosthesis on plastic bone replicas of the pelvis and femur, a video recording of a complete case, and a surgical technique illustration. The surgeon and surgical residents declined these resources. And Dr N's statement confirming that the rep would be present during the case certainly gives the impression that Dr N was planning to draw upon the rep's expertise, possibly as a substitute for Dr N's own training. While both the ACS and the AMA recognize that this kind of situation can occur, they offer no guidance about how to navigate it. To the best of my knowledge,

no health care organization provides guidance to representatives concerned about a surgeon's lack of training with a new technology. One health care industry representative's response to a survey conducted by me and my colleagues draws attention to this concern: "Our current medical environment does not allow for a 'sales rep' to question the ability of a surgeon regardless of patient outcome. There is no 'whistle blower law' in healthcare. The rep would lose their ability to call on the hospital and likely lose their job."¹

This case also suggests a possible disconnect between the device manufacturer's and the health care organization's **training requirements for new technology use**, especially at the point of care, and how those requirements are communicated. Collaboratively established training requirements could provide a mechanism by which device representatives could raise concerns about training adequacy and be supported by both the device's manufacturer and a health care organization, such that both could be held accountable for noncompliance. Training requirements should also clarify how someone might, even anonymously, report violations of training requirements, especially if someone feels that patient safety has been compromised.

Duty and Trust

Dr N's lack of preparation and training quickly became evident. His difficulty in assembling and using instrumentation and in recognizing when the acetabular cup was properly seated—which necessitated a fluoroscopy unit to visualize cup placement—added to the length of the patient's surgery. His difficulty seating the liner due to lack of familiarity with the components and how a properly seated liner should look also contributed to unnecessary delay of this patient's case and longer-than-necessary anesthesia. Finally, it should not have been necessary for the rep to hold up an illustration to talk Dr N through the femoral prosthesis implantation.

If the representative is not knowledgeable and well trained and a surgeon is untrained and lacking ability to implement critical steps safely, outcomes can be disastrous. In 2006, the Ohio Eighth District Court of Appeals upheld a \$1.75 million judgment against an Ohio neurosurgeon, a device representative, and the representative's employer.⁴ The representative had incorrectly informed the surgeon that the company's hydroxyapatite cement without mesh support was sufficient to cover a nearly 48 cm craniotomy cut when it was not. The representative also failed to inform the surgeon that drain placement would facilitate the patient's recovery. No drain was placed, the cement fractured, and, as a result, the patient endured 4 subsequent surgeries to repair the damage from fractured cement. The Ohio appeals court upheld the jury verdict finding both the representative and the manufacturer liable for negligence and negligent misrepresentation.

This case highlights a device or material manufacturer's duty to warn a learned intermediary. The representative noticed that the surgeon did not read the company's instructions about how to use hydroxyapatite cement without mesh support, failed to adequately guide the surgeon, and, as the manufacturer's agent, failed to execute a duty to adequately warn the surgeon about a prospective poor outcome for the patient. This case also decided that, though the intermediary, the neurosurgeon, was learned in surgery—presumably more so than the device representative—it does not follow that the device representative and manufacturer were not negligent.

The Ohio case sheds further light on the above case. Dr N's patients may rightfully assume that Dr N is well trained and owes patients a fiduciary duty to be technically competent. Placing a third party, such as a device representative, in a clinical decision-making role is a breach of Dr N's duty. Learning on the fly should be anathema for any physician, and a decision to postpone learning to the actual point of care damages patient-clinician relationships and violates trust.

Go Rep-less?

New models of providing support to those like the rep in the case above should also be considered. In 2014, a California academic health center (AHC) implemented a model of working with device innovators in which it acquired orthopedic implants directly from a manufacturer and trained one of its own surgical technicians to provide support.^{5,6} Although this AHC was looking to save on costs, other advantages to training its own surgical technicians include direct oversight of technicians as key members of a surgical care team who have a duty to the patient and are accountable, along with other team members, for providing a standard of care. Another benefit of a rep-less model is that an organization can establish its own rigorous training and continuing education programs to ensure all clinicians' technical proficiency, which could also improve clinical outcomes for patients undergoing implantation of new materials or devices.

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Editor's Note

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The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.