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An Unnecessary Distraction: Vendors in the Operating Room

As part of the Office of Health Care Quality's continuing efforts to improve the safety of patient care in Maryland, we present the following two cases where vendors in the Operating Room (OR) directly contributed to adverse events.

Adverse Event: A patient was undergoing bilateral knee replacement. The vendor handed the right knee prosthesis to the surgeon, who implanted it into the left leg.

Root Causes: Over reliance on skill of vendor. Poor communication between surgeon and vendor.

Result: Patient had to have larger prosthesis implanted due to damage to the bone ends caused in trying to remove the cemented prosthesis.

Adverse Event: A patient was having a gynecological procedure in the OR. A warning light appeared on the machine in use. The vendor took over control of the machine to over-ride the alarm and pumped the foot pedal five or six times, each time giving the patient a blast of heat.

Root Causes: Over reliance on the skill of the vendor; vendors operating without supervision or controls.

Result: The patient suffered a thermal burn to the bowel and had to have emergency surgery two days later.

In the gynecological case above, the hospital identified several very troubling practices by their surgeons. We have to ask "could this happen in your facility?"

The hospital interviewed its surgeons and determined that the physicians often had private contacts with vendors, of which the hospital was unaware. The physicians were using the vendors for just-in-time training on new equipment that the hospital had not purchased. The physicians felt that the purchasing process was cumbersome and actively circumvented policy when they felt like it. Surgeons may not have the requisite training to operate new equipment and used the vendors for consultation. While the vendors were supposed to register with the Purchasing department, this department was not open as early as the vendors were arriving for the first OR cases. And, in especially complex cases, there may be multiple vendors in the OR.

While we congratulate the hospital on uncovering some latent system issues and sharing them with us with such candor, we find it extremely disturbing that people with no formal relationship with either the hospital or the patient are taking such a direct role in the treatment.

Discussion:

In researching the issue of vendors in the OR, we found a few articles extolling the virtues of using vendors as a resource for new methods and equipment. While vendors can help surgical staff stay current, make no mistake -- they are in your hospital to sell their company's products and services. They are not there to help you. And they represent an unsafe and potentially fatal distraction in the OR.

Most companies require that their vendors have a college degree in one of the biological sciences, but there are no standards for education or training. Some companies offer intensive, hands-on training on their equipment, while others may just give the vendors the equipment specifications and recommendations. Some companies mandate training in OR protocols, like sterile fields, OR garb, and patient privacy; others leave it up to each hospital. There are no credentialing or licensing bodies. The vendors are not licensed or regulated by the State.

Based on RCAs submitted to this office as well as a literature search, we have the following recommendations:

1. The vendors need to be formally credentialed by the hospital to verify education, training, and communicable disease status. The credentialing process should include the vendor's confirmation that he or she will abide by certain basic hospital policies regarding patient safety and privacy.
2. The role of vendors, and their allowable tasks, must be precisely defined in hospital policy.
3. Hands-on contact and access to protected health information should be prohibited.

Continued

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4. Each vendor should be sponsored by a member of the medical staff who will be responsible for policy infractions.
5. The presence of vendors during any procedure must be disclosed to the patient, who should be able to refuse to have the vendor present.
6. Private agreements between the vendors and physicians should be prohibited.
7. The circulating nurse needs to have ultimate control of the personnel in the OR, and vendors should be made aware that they may be asked to leave at any time, with or without cause.
8. No one should be allowed in the OR suite without an ID badge.

It should go without saying that the surgeons do not get to

substitute vendor assistance for training. The hospital in the GYN case noted above now requires that if the surgeons want the extra training on new equipment, that they have to have it in their offices or someplace not in the OR, prior to the actual day the equipment will be used on a patient.

Of course, these adverse events were not just a surgeon problem. One must ask where the nursing leadership was when these vendors were overstepping their bounds? Why would no one question the presence of multiple vendors in one OR? Why did anesthesia not say anything about this dangerous practice? Just because adverse events had not happened prior to this case, does not mean the practice is inherently safe.

If the Office of Health Care Quality had received the above GYN case as a patient complaint, it would have

triggered a survey for the Federal Conditions of Participation (COPs). The hospital would most likely have been found out of compliance with the COPs for Surgical Services and Patient Rights, and would also have deficiencies in Quality Assurance/Performance Improvement and Medical Staff.

The Office of Health Care Quality does not mean to imply that vendors are incompetent or that surgeons are lazy, but the presence of vendors in the OR is an often unnecessary distraction to the staff and risk for the patient. The OR exists for the treatment of patients, not for the selling of products. All activities in the OR need to pass through the filter of what's best for the patient. Besides being the right thing to do, hospitals also need to consider their liability.