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# Ground rules for vendors in the OR

Vendors bring many contributions to the OR, such as staff education and support to surgeons for new products. Like any external visitor to the OR, however, vendors must be managed appropriately to meet regulatory requirements. It takes collaboration to create a policy that works and to establish ongoing monitoring to ensure adherence.

Despite some challenges, vendors play a useful role in the OR.

"Vendors provide an excellent education service to us and our staff for products," says Amy Bethel, RN, MPA, CNA, executive director of surgical services for Iowa Health in Des Moines. "Orthopedic vendors, particularly, have a tremendous knowledge for troubleshooting products."

John Clarke, MD, FACS, clinical director of the Pennsylvania Patient Safety Authority, says it comes down to the perception of the vendor's purpose. "Today, there is a lot of complex technical equipment, so if vendors can supply technical support that contributes to the success of the procedure, they will be perceived as helpful. If they are perceived as just there to sell products, they will not." One example of a useful role is vendors who bring in equipment that they use to help surgeons set pacemakers and implantable defibrillators. It's important to remember, however, that vendors should never touch patients directly.

Here's how you can get the most from your vendor relationships while minimizing the risk of potential harm.

## Ground rules

Leaders of the OR and materials management departments must craft a policy that addresses several areas, including vendor health status and education requirements. Surgeon involvement is key, and input from the quality improvement department is helpful in addressing patient safety and privacy issues. In essence, vendors are being "credentialed" to enter the OR. Fortunately, many resources, including sample policies online, are available to keep you from reinventing the wheel.

Vendors should complete an educational course before they step into the OR. Some product companies and many hospitals offer their own courses. Another option is to refer the vendor to the AORN OR Protocol, an online, self-study education program developed by AORN and HealthStream (www.healthstream.com/Products/STS/RepDirect/orProtocol. htm#). Neither AORN nor the American College of Surgeons (ACS), which both have guidance statements on vendor relationships, makes any recommendation for ongoing education for vendors.

Most hospitals provide packets of information and ask vendors to sign a form indicating that they agree to abide by the rules.

Once the rules are set, Bethel says it's important to empower staff to hold vendors accountable. In her facility, vendors spend the most time with team leaders. "We tell them [team leaders] not to accept cold calls, to have an agenda for a meeting, and to escort them as needed." One challenge is the close working relationship that naturally arises between vendors and those who meet with them on a regular basis.

"Nurses get to know them well, so they might say, 'I know him so he doesn't wear a name badge,'" says Bethel. "It's important for staff to understand that everyone must be held to the same standards."

## Consent issues

Based on recommendations from professional organizations, patients should be told

that a vendor will be present during surgery. The AORN guidance statement says, "Patients have the right to be informed about the presence of a health care industry representative/invasive procedure setting during a surgical procedure according to local, state, and federal regulations." The ACS statement on vendors says the patient should give "written, informed consent."

Dr Clarke says this is no different from any other outside observer. "Patients need to know what the vendor will provide in terms of technical support so they can understand the benefit," he says. "If you can't explain the benefit to the patient, then maybe they shouldn't be there."

To address consent issues, Bethel's hospital includes a note on the patient's consent form saying vendors may be allowed per the physician's request. At one hospital, the vendor's name is included on the consent form, and the OR at another facility even introduces the vendor to the patient before surgery.

## Practical ideas

One of the biggest challenges with vendor management is proper identification. Some hospitals use name tags with photos to facilitate identification. Mary Johnston, RN, MSN, division director, surgical services, Highline Medical Center in Burien, Washington, says when vendors sign in, they receive a special badge. They leave a driver's license or credit card until the badge is returned.

Susan Nielsen, RN, MSA, CNOR, director of central processing at Beaumont Royal Oak Hospital in Royal Oak, Michigan, has an inexpensive solution for identification—a color-coded sticker with Beaumont's logo on it.

"We change the color daily so we know they're current," she says. She also requires vendors to purchase and wear yellow scrub tops with black pants. "It helps us identify them as vendors from a distance."

Bethel says it's most important to monitor traffic into the OR. At Iowa Health, the OR is designed so that vendors must don their jumpsuits in a room near the OR control desk, so it would be difficult for them to enter the OR without being seen.

## Automated credentialing

Some hospitals have turned to external companies for help with managing vendors. These companies, which include RepTrax, Vendormate, Vendor Check, Status Blue, PreCheck, and Vendor Credentialing Service (VCS), use software to provide hospitals with real-time credentialing information about vendors in the companies' databases. Usually the vendor companies pay a set fee per employee to be listed in the database, which hospitals access through a web-based system at little or no cost.

Some companies, such as VCS, offer badge scanners. The vendor scans the badge so the hospital receives a report verifying the vendor is credentialed. VCS provides 3 badge scanners at no cost. Hospitals can also purchase a label printer from VCS for about $200 to print out color paper badges for each vendor to wear in the OR.

VCS CEO Troy Kyle says hospitals list what they want to know about each vendor, and then VCS creates a profile for hospitals to access. He adds that OR managers should ask about how the database is updated.

"We don't allow the company to upload its own information," he says. "It goes through our customer service department so we can verify the primary source."

VCS also provides its vendor clients with access to education programs their employees can take to meet credentialing requirements and enables managers of the vendors to access detailed tracking reports of their employees' activities.

An option that will become more common in the future is a tracking system for all staff and external visitors to the OR, such as vendors. Personnel will wear or scan a badge each time they enter or leave an individual OR. If you do not have an automated tracking system, be sure to keep documentation such as vendor sign-in and sign-out sheets and entries in the intraoperative record.

## When rules are broken

What happens when vendors don't follow the rules? Bethel says common violations include lack of appropriate credentials, roaming around the OR, and talking with surgeons with whom vendors don't have appointments.

The correction process is one that managers know well. "First, we give them a verbal warning," she says. If the problem continues, a written warning is given, and the vendor's manager is notified. Next, the manager counsels the vendor in the presence of the vendor's supervisor. "If they still don't comply, they're banned from the OR," she says.

The presence of vendors in the OR is not likely to change any time soon.

"As technology advances, we're going to see more of vendors," says Bethel. "We'll need them from the education side." With a little work, the relationship between vendors and OR staff can be a positive one. ❖

*—Cynthia Saver, RN, MS*

*Cynthia Saver is a freelance writer in Columbia, Md.*

## References

American College of Surgeons. ST-33. Statement on health care industry representatives in the operating room. Revised September 2005. www.facs.org/fellows_info/statements/st-33.html.

Association of periOperative Registered Nurses. AORN guidance statement: The role of the health care industry representative in the perioperative setting. In *Standards, Recommended Prac-tices, and Guidelines.* Denver: AORN, Inc, 2007. 261-263.

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Healthcare industry representatives: maximizing benefits and reducing risks. Patient Safety Advisory. March 2006;3(1):13-19. www.psa.state.pa.us/psa/site/default.asp/. Look under Advisories and Related Resources.

## *Vendor packet*

A typical vendor packet includes:

- need for current TB test results
- identification requirements
- validation of education on HIPAA (patient privacy)
- release of liability
- confidentiality agreement
- company evaluation of the vendor
- infection control practices
- occupational safety requirements, such as fire, radiation, and electrical safety
- dress code
- restricted areas in the OR
- appointment requirement
- loss of privileges policy.

*Adapted from information provided by Susan Nielsen, RN, MSA, CNOR, director of central processing at Beaumont Royal Oak in Royal Oak, Michigan; Mary Johnston, RN, MSN, division director, surgical services, Highline Medical Center in Burien, Washington; and AORN and American College of Surgeons position statements.*

## New products in the OR

A common issue is the vendor who arrives with a new product right before surgery. The OR manager has no assurance that the device is approved for use or that other key questions have been answered, such as whether reimbursement is available.

"We've had to really crack down on this because there have been times we haven't been paid," says Amy Bethel, RN, MPA, CNA, executive director of surgical services for Iowa Health in Des Moines.

In her organization, vendors must provide at least a week's notice that a device or product is arriving so she can answer questions about reimbursement and sterilization.

"If we don't know it's coming, they [vendors] will not be paid," she says.

Surgeons have been educated on the process and the need for vendors to follow appropriate protocols.

Mary Johnston, RN, MSN, division director, surgical services, Highline Medical Center in Burien, Washington, requires vendors to complete a product worksheet that includes:

- product information (description, manufacturer, purpose/function, utilization assessment, and whether it is a replacement product)
- documentation of Food and Drug Administration clearance
- product cost
- coding (CPT, DRG, IDC-9 codes)
- the product's intended patient population (0 to 18 years of age, 18 to 65 years, or older than 65 years).

Equipment must be checked by the biomedical engineering department and wiped with a disinfectant before being brought into the OR.