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PROTECT YOUR PRACTICE:
Medico-Legal Considerations *of* Remote Monitoring

Cardiovascular Business hosted a roundtable discussion on the medico-legal considerations of the remote monitoring of patients with cardiac implantable electronic devices (CIEDs) with wireless capabilities. Despite data supporting its clinical benefits, some practices are resisting adoption due to the potential liability of receiving continual alerts. Here, four experts share opinions on how practices can navigate these waters.

PARTICIPANTS:

- **Victor R. Cotton, MD, JD** Healthcare Attorney, Hershey, Pa.
- **Anne M. Gillis, MD** President-elect of the Heart Rhythm Society (HRS) and Professor of Medicine, University of Calgary, Alberta, Canada
- **Debra Halligan, RN, BSN** Clinical Leader, Pacemaker/ICD Clinic, North Shore Medical Center, Salem, Mass.
- **Colin M. Movsowitz, MD** Cardiac Electrophysiologist, Cardiology Consultants of Philadelphia

Beyond the hearsay

Remote monitoring of wireless devices allows for web-based access to critical clinical information, including system integrity, arrhythmias and heart failure parameters, through daily remote interrogations. Thus, these remote interrogations often negate the need for patients to make in-person visits to their clinic. Due to benefits demonstrated in such trials as CONNECT, TRUST and ALTITUDE, facilities have begun remotely monitoring patients with CIEDs as "the standard of care," says Gillis.

"From the patient satisfaction and quality-of-life perspectives, remote monitoring has been enormously valuable, especially due to the elderly nature of this population," says Gillis, who adds that remote monitoring allows for the capability to program in specific alerts to detect certain events earlier than can be detected within the typical in-person 90-day or six-month follow-up.

However, the responsibility of monitoring these alerts has led to legal questions. The law typically follows the data, says Cotton. "Because the current findings are strong, there appears to be no downside to using the technology, as there is no apparent risk to the patient and insurers are reimbursing for its use."

However, some practices are hesitant to adopt the technology, says Movsowitz, because they are uncertain about liabilities.

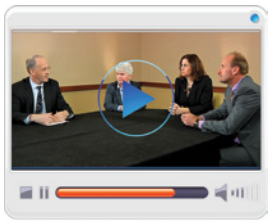
From "a lawyer's perspective," Cotton says that practices cannot absolve themselves of liability by simply not adopting the technology, especially when the clinical data associated with wireless pacemakers and CIEDs "are all leaning toward benefit." Physicians cannot acknowledge the clinical benefits of remote monitoring on one hand, and then simply not provide the service to their patients on the other hand, he says. When assessing the legal considerations with not implanting a wireless device, Cotton says it's "more of a gray area." A clinical argument can be made, says Cotton, that not implanting a wireless device could cause harm because an event might have been detected earlier. However, the legal argument for not implanting a wireless device "may be more difficult to sell to a jury, as it requires a series of if-then scenarios."

However, if a practice uses a wireless device in which data are being generated, and a patient's arrhythmic event is ignored for too long, Cotton says this case may be more challenging to defend in court, "as it's a clearer case." Thus, facilities should establish protocols for regularly tracking the data, he adds.

This uncertainty, Movsowitz says, may be one of the reasons that practices shy away from adopting the technology, in spite of its benefits. However, Cotton stresses that this is "not really acceptable," and it presents an example of "medico-legal paranoia pointed in the wrong direction." He also recommends that those practitioners consider the opposing argument in court, as it could be damning if someone suggests there is technology available to detect events sooner—at no risk or inconvenience to the patient.

In fact, from a clinical standpoint, practices are alerted to events sooner with remote monitoring, says Gillis. "There are unexpected, but critical alerts [that get automatically transmitted to an online dashboard] indicating evidence of a lead malfunction or a lead fracture. We can review the data and then decide whether we need to see the patient immediately or can a visit be scheduled that's more convenient for the patient."

As for industry's role, Gillis says that the companies' responsibility is "to produce technology that works and it's our responsi-



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From left to right: Colin M. Movsowitz, MD, Anne M. Gillis, MD, Debra Halligan, RN, BSN, and Victor R. Cotton, MD, JD

bility to implement the technology, to follow patients and to treat them appropriately. The companies are not responsible for our decision making about how frequently to follow up with patients, the follow-up practices of an institution and how the practice should respond to critical alerts."

Also, Movsowitz questions the responsibility of the patient, if he or she cannot be reached by medical staff after an event is detected. Cotton says that patients should be expected to be compliant after "a reasonable amount of effort is expended" on the part of the provider. He adds that patient responsibilities should clearly be addressed when the device is implanted, and reiterated whenever possible. "Ultimately, if the patient is not going to use the technology properly, there is nothing the practice can do about it," says Cotton, likening it to medication adherence.

Patient Engagement & Protocols

The panel agreed that each facility needs to institute protocols for patient follow-up. Importantly, the patient must be informed and engaged in his or her own treatment and expectations. One way to engage the patient is through the consent form process, which should be introduced as the patient is educated about the treatment plan, according to Halligan. When a consent form is reviewed at North Shore Medical Center, the ICD clinic team informs the patient about the treatment plan, such as the hours of device monitoring, how the alerts are handled as well as his or her shock plan.

Patient education is integral, says Halligan. "You have to offer the same care to each patient, but use [of the technology] is up to the patient. It's still the patient's responsibility to let us know if they receive a shock. This is a tandem effort, as I receive alerts to my cellphone during off-hours," she says. Because the patient signs the document, he or she is now engaged with the process.

It's important to establish protocols for all possible clinical scenarios, even for the "snow-bird effect," wherein patients live in different regions at different times of the year. In these cases, Halligan advises her patients to find cardiology care wherever they plan to regularly travel, but North Shore can continue to remotely monitor CIED patients anywhere in the U.S., and also bill for that service. Gillis says that it's even stickier when monitoring crosses international borders. While University of Calgary encourages patients to take their monitors when they travel, the national physician insurance body, the Canadian Medical Protective Association, advises Canadian providers "not to get involved in the management of patients across borders for fear of liability," says Gillis.

One of the biggest questions typically surrounds monitoring patients during off-hours. While North Shore monitors about 500 CIED patients at home, Halligan typically only receives one alert to her phone per weekend that requires her to follow up with two phone calls. "It's not an overwhelming process," she says. Also, the caregivers can switch whose cellphone receives the alerts.

"With our protocols in place, we believe that we have been able to prevent patients who have a lead fracture from receiving multiple shocks," confirms Halligan, who adds that practices can tailor the alert system to include ventricular arrhythmias, for instance.

North Shore provides "a model way of following patients remotely," says Cotton, "and model ways tend to become standards, and those standards tend to become standards of care from a legal perspective. Protocols and patient consent are a legal necessity in the absence of guidelines, which would provide the strongest legal authority."

Gillis confirms that "practices have to set up protocols, but I am comfortable if practices notify their patients that they don't monitor data on the weekends. If patients are aware, they can't expect someone on-call 24x7 to review these data. You have to establish regular work hours and protocols, establishing a clear-cut understanding between physicians and patients about expectations."

Until guidelines or a legal precedent has been established, fears of liability should not deter practices from employing wireless devices because the current technology and protocols appear to deliver the best possible follow up for CIED patients.

Dr. Gillis did not receive an honorarium related to her participation with this article or video. CVB

This important discussion was organized with the industry leadership of: St. Jude Medical

The views and opinions expressed within this article are those of the authors and participants and do not necessarily reflect those of St. Jude Medical.

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