LEADING INDUSTRY
- Medical Design Excellence Awards
- 2006 Executive Profiles

LEGISLATIVE AFFAIRS
- Preparing for Patent Reform
- Protecting Competition, Defending Innovation

Aspect Medical Systems’ Nassib G. Chamoun on establishing a new paradigm for patient care
Failing to Succeed

To improve patient safety, diverse stakeholders must come together to increase the collective knowledge surrounding device-related failures.

Yadin B. David

Today’s healthcare environment is significantly more technologically sophisticated than ever before. One popularly cited statistic maintains that over the past 20 years, the average number of medical devices at the patient’s bedside has increased from seven devices to 26.

Regrettably, this increase in technological sophistication has not been consistently accompanied by the greater use of standards, checks and balances, and redundancies that translate into increased patient safety. Achieving this laudable goal will require a concerted effort to bridge the gaps that currently exist among manufacturers, regulators, maintainers, end-users, and patients. In doing so, it will be essential for all of these stakeholders to share information in a way that will reduce postmarket problems and improve patient safety.

Missed Opportunities

The safety record related to the use of medical devices could stand some improvement. Perhaps borne of a fear of litigation or increased regulatory scrutiny, a record number of devices is now being recalled each year. At a recent seminar on risk management, FDA representatives reported a 20% increase in the number of device recalls in the two years between 2003 and 2005. They also reported that the most-frequent observation made during FDA inspections of manufacturing facilities concerned inadequate complaint-handling procedures.

At the same time, the healthcare and medical device industries face the problem of consumers’ and users’ underreporting of device failures and adverse events. Such underreporting hinders the ability of manufacturers and healthcare providers to take corrective action and adds an unknown number of incidents to the already worrisome dataset concerning safety in the healthcare environment.

Another symptom of the problem with medical device safety is the lack of modern standards for assessing and addressing safety risks. Earlier this year, at the annual meeting of the Healthcare Information and Management Systems Society (HIMSS), it was reported that caregivers frequently face suboptimal communication of alarm conditions as a result of poor systems integration. Healthcare providers may wish for a sophisticated plug-and-play environment that would facilitate the integration of multiple medical devices, but what they currently have is a plug-and-pray environment that is not capable of ensuring the safety of patients.

Furthermore, FDA has not always provided hospitals with clear guidance about what actions they should take in the face of a recall. Such a lack of guidance represents a serious gap in risk mitigation, especially in light of recent increases in the incidence of device-related recalls and hazard notices. ECRI (Plymouth Meeting, PA), a nonprofit health services research agency that alerts hospitals to device recalls and hazard notices, reported 948 alerts in 2005 compared with 302 in 1977.

Over the years, good efforts and plentiful resources have been invested to build an effective system for ensuring the safety of medical devices. By imposing design control and quality systems requirements on manufacturers, for instance, FDA has made major strides toward improving the design and manufacture of medical products. Nevertheless, the premarket review systems used by regulatory bodies worldwide cannot possibly evaluate all products fully – or establish a risk threshold for all
permutations of possible failure.

All indications are that we have not yet achieved the goal of a fully effective device safety system. A major reason for this is the fact that, when failures occur, key stakeholders habitually miss the critical opportunity to gather information about these failures, and then share and apply the knowledge they gain and the lessons they learn. Instead, on the occasion of a device-related adverse event, a scenario something like the following is typical.

An event involving a fire occurs in an operating room, and the hospital initiates an investigation into the cause of the fire. The investigators speculate that an extension tube was added to the end of a surgical laser just prior to its firing, thus causing an unsafe condition. The extension tube—manufactured by a third party and sold as an accessory—was made from a material that supports spontaneous combustion. The end-user who obtained the tube was not informed of any contraindication for its use on this laser device.

Seeking to validate its analysis, the hospital calls the manufacturer to ask whether it is safe to connect such an accessory to the end of its laser. Recognizing the potential for liability issues to arise, the manufacturer tries to determine whether the hospital’s question originated with a design or user error. In turn, sensing that the manufacturer is performing postincident risk management, the hospital ceases further communication, and the manufacturer is told that the hospital’s inquiry was based on a hypothetical set of events.

In such a scenario, none of the parties winds up possessing the complete set of facts relevant to the event. The hospital never gains a complete understanding of the technology and its limitations, and the manufacturer never fully learns of a risk that can arise under certain dangerous conditions. Such a mismatch in information sets leads to a missed opportunity to share knowledge that could otherwise be used to prevent a similar event from occurring in the future and harming a patient.

Although the recommendations in both these reports voice support for better collaboration, they focus on particular segments of the industry and do not provide a mechanism for the improvement in collaboration needed across the whole industry.

Unquestionably, consumer safety is diminished when there is limited communication among the engineers who design devices, the clinicians who deploy them, the clinical engineers who support them, the regulators who monitor them, and the patients who experience them. Conversely, a coordinated investigation conducted by appropriate experts within an appropriate legal framework will help to supply critical knowledge that could lead to a safer return of malfunctioning devices to manufacturers. However, HRS neglects to recognize the role that engineering experts within the hospital can play in this process. It also ignores the fact that some devices are not easily transported. The draft calls for enhanced cooperation among industry, FDA, and physicians, but again neglects the contribution that clinical engineers and their knowledge of both the clinical setting and technology could bring to the table.

A report from an expert panel commissioned by Guidant last summer to review the recall-related actions of the company’s CRM business also pointed to the limitations of medical device reporting communications associated with postmarket surveillance. Among its many recommendations, the panel states that outside stakeholders with relevant clinical training and experience should participate in product performance reviews.

Sharing Knowledge

Driven by the goal of sharing knowledge in the interest of patient safety, a group of leaders at the American College of Clinical Engineering (ACCE) in 2003 created the independent, not-for-profit ACCE Healthcare Technology Foundation (AHTF). The foundation’s mission is to improve healthcare delivery environment in the future. This legal framework must allow free and effective communication without exacerbating manufacturers’ risk of litigation or denying wrongfully injured patients appropriate compensation. Along these same lines, impartial investigation could actually aid in more-efficient resolution of compensation issues. Moreover, patient safety can be significantly improved by facilitating communication and the free exchange of empirical experience and other knowledge among all of these stakeholders.
through the development and application of safe and effective healthcare technologies. The organization also focuses resources on the global advancement of clinical engineering research, education, practice, and other related activities.

In its quest to improve patient safety, the foundation has emphasized the need for improved communication of device-related knowledge, as well as improved interfacing among devices. For example, the foundation recently cosponsored a study designed to identify issues and opportunities for enhancement of clinical alarms. More than 1300 healthcare providers and clinical engineers were surveyed regarding their perceptions of alarm shortcomings. The results of the study will be shared with industry stakeholders, regulators, and other interested parties through open publication.

**AHTF is calling on leaders across industries and communities—including manufacturers, distributors, service organizations, end-users, regulators, and consumers—to join together to improve device safety.**

Subsequently, AHTF intends to repeat the study in two years to gauge whether progress has been made toward safer alarm features.

In addition, the foundation has created educational materials to assist consumers who are dependent on home-use medical devices. The materials provide information on how to safely manage equipment at home, as well as how to move the equipment into a hospital setting when necessary.

To validate its efforts, the foundation has created biomedical advisory councils that bring together clinical engineering leaders, representatives of the medtech industry, healthcare professionals, and consumer advocates. The council members share information necessary to assess the performance and features of a variety of medical devices. They discuss members' experiences with device shortcomings, including poor product performance and service support, as well as low-quality spare parts. Improvements in information sharing have already begun because of this collaboration, enabling hospitals to better understand device life cycles and better plan for device replacement.
In April, at AHTF’s annual meeting in Houston, the organization’s board of directors unanimously passed a resolution that calls on the medtech industry, regulatory agencies, and leaders from the end-user and consumer communities to identify a framework for enhanced cooperation among their diverse groups when evaluating adverse medical and surgical events. AHTF’s goal in the resolution is to facilitate the creation of a platform for collecting and sharing healthcare-related knowledge in a more-collaborative environment. If the initiative is to succeed, it will require forward thinking and trust on behalf of all stakeholders, as well as a firm belief that greater patient safety can be achieved by working together.

The foundation’s initiative advocates the creation of a regional or national coalition of independent health experts that can quickly respond to and analyze causation of a major adverse event. Such a coalition would be in a position to translate its findings into recommendations that could improve patient safety. With a mutually accepted entity such as the foundation administering this proposal, industrywide learning would be enhanced, and the independent coalition would serve as a mechanism for achieving collaboration among all stakeholders, rather than the limited groups noted in the HRS and Guidant panel reports.

AHTF is calling on leaders across industries and communities—including manufacturers, distributors, service organizations, end-users, regulators, and consumers—to join together to improve device safety. The foundation is seeking administrative and financial support for this ongoing collaboration initiative, as well as an entity that is willing to host an initial conference where stakeholders can discuss the scope and administration of the initiative. Interested parties can learn more by visiting the foundation’s Web site at www.acce-htf.org.

References
3. PM Steele, “Training Effectiveness” (paper presented at Risk Management, CAPA, and Training: An Educational Forum, Dallas, TX, April 28, 2006).

Thomas Edison wasn’t the first to invent the lightbulb, but his longer-lasting filament made history because he chose to patent it!

Patent No. 12,631
There’s always room for improvement and your idea might be one for the record books. That’s where our team of experienced patent lawyers and litigators can help turn your ideas into valuable assets and protect them.

Patterson, Thuente, Skaar & Christensen — a team of expertise in patent law and litigation. Call us at 1-800-331-4537 and protect your idea — before someone else does.

Patterson | Thuente | Skaar | Christensen
612.349.5740
www.ptslaw.com

Patent, Trademark, Copyright, Internet & Related Causes