PATHWAY

To Your Perfect Practice

eyetube
Ophthalmic Video Resource

THE HIGH-TECH PRACTICE

SECTION EDITOR: JAMES D. DAWES

Pathway to Your Perfect Practice is a monthly feature section in *CRST* designed to help facilitate the realization of personal and business success through the delivery of exceptional patient experiences.

THE HIGH-TECH PRACTICE

DEVELOPING A HIGH-TECH PRACTICE: A SNAPSHOT OF INTEGRATION

You do not have to be the first to get every new device, so long as you continually investigate and adopt what is best for your patients.

BY JEFFREY L. MARTIN, MD, FACS

Our practice has never taken the approach of acquiring new technology just to be first. However, I do think it's important to constantly stay abreast of new developments that can benefit our patients. Medicine is changing quickly—and doctors who aren't willing to change with it can find themselves, in short order, being left behind.

My decision process in evaluating new technology is first to try to separate the marketing hype from reality: Does the device do what the manufacturer purports? Is it clinically superior to what I have now? If there are several different platforms, what are the pros and cons of each? If we invest in this device now, will the manufacturer continue to innovate and improve it going forward? The answers to these questions help me decide whether the device offers a true clinical advantage. Then we only have to figure out if the purchase is a financially viable one. Increasingly, this also means taking into account how our use of the device might be affected by cost containment pressures in health care.

"Pathway to Your Perfect Practice" relies on your input. Contact us with your challenges, successes, and questions. Send your e-mails to ppp@bmctoday.com.

CONTACT US

In the past 2 years, we have integrated a number of new technologies, including the Catalys femtosecond laser (Abbott Medical Optics) for laser cataract surgery; a new toric IOL platform, the Tecnis Toric (Abbott Medical Optics); ORA intraoperative aberrometry (Alcon WaveTec); and Sight Selector, an iPad-based tool from Patient Education Concepts. Each has played a role in improving patient outcomes to make our practice stronger.

INTEGRATION STEP BY STEP

The research does not end once you commit to buying a new technology. With the femtosecond laser, for example,

we sought out the advice of other users on whether to put our laser inside or outside the operating room and how to most efficiently alternate conventional and laser cases.

A major step in our integration process is to "sell" the new technology to our staff. No matter how convinced I am of the benefits, I know that success is heavily dependent on staff acceptance. Before we brought in the Catalys system, for example, we held an "all hands" dinner at a local restaurant so that staff from all eight of our offices could see what the new technology does, hear about the patient costs and benefits, and learn how to talk about it. This wasn't the end of the education process, but it was a valuable beginning.

Additionally, I think our hiring practices have had a big impact on our ability to successfully integrate new technology. Rigid, unpleasant people can quickly sabotage big changes, so we make a concerted effort to hire for personality traits—kindness, compassion, and openness to change—and teach the missing technical or practical skills if necessary.

Finally, I will say that when a major new device that alters patient flow is being introduced in the OR, it is best to embrace the chaos. If you are fully booked and expecting a smooth first day or week, you will likely be very frustrated. It is far better to schedule fewer cases in anticipation of glitches and delays.

GO ALL-IN

If I believe in the clinical benefits of a new technology enough to buy it for our practice, I'm not shy about recommending it to patients. After just a few femtosecond laser cases, I was thoroughly convinced that image-guided laser cataract surgery would be safer and more precise, that it would reduce the sources of trauma—ultrasound energy and fluid exchange—in cataract surgery, and that it would make astigmatic incisions more predictable. We ramped up quickly, and our laser cataract surgery procedures already make up 70% of all of our cataract surgeries within just 9 months of acquiring the laser.

This was certainly made easier by the fact that we offer premium IOLs and corneal refractive surgery, so we already had in place the infrastructure to counsel patients and help them afford the procedures. When you are giving patients options that require them to pay out of pocket, it is essential to offer financing. We offer CareCredit 2-year, no-interest financing to just about everyone; it makes it easy for patients to take advantage of the new technology we are telling them is so great.

Of course, not all new technologies have a huge price tag. Adding a new toric IOL to our armamentarium was an easy choice when the Tecnis Toric was introduced because we found that it had excellent rotational stability and is exceedingly quiet in the eye. Plus, it is easy to make clockwise or counterclockwise adjustments.

We have also found that our tablet-based patient education videos and animations have made a huge improvement in patient understanding of complex concepts. Instead of just telling a patient that his or her lens is cloudy and that I'm going to make an incision, I can now quickly show the patient on the iPad in my office. The Sight Selector app has quickly become an indispensable part of patient conversations.

In a high-tech ophthalmic practice, apps like Sight Selector are an indispensable tool for patient education.

CONCLUSION

Ultimately, being a high-tech practice is all about being first in patient care. When the decision of which technologies to acquire gets confusing, I try to keep that philosophy at the center of it all. ■

Jeffrey L. Martin, MD, FACS
- assistant clinical professor of ophthalmology at SUNY Stony Brook
- Managing Partner of North Shore Eye Care on Long Island, New York
- jmartin@nseye.com
- financial disclosure: has received speaker fees from Abbott Medical Optics, Alcon, and Bausch + Lomb

I HAVE AN APP FOR THAT: UNDERSTANDING LIABILITY RISKS FOR MOBILE APPS

The marketing of non-FDA-regulated apps is subject to the FTC's oversight, and the agency is actively policing them.

BY KEVIN M. HENLEY

As the number of physician-developed mobile apps increases, health care providers must consider and manage the potential litigation risks associated with apps that do not perform as intended or advertised.

THE IMPACT OF FDA REGULATION

In 2011, the FDA announced plans to regulate certain mobile apps as medical devices under the Federal Food, Drug and Cosmetic Act. The Act's definition of device includes instruments that are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease. In 2015, the Agency clarified that it intends to regulate "only those medical apps that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were not to function as intended."[1]

As a result, the Agency currently regulates a small subset of apps known as mobile medical apps (MMAs). These apps perform similar functions as other regulated medical devices. The Agency has declined to regulate most general health and wellness apps, which it believes are low risk. It has stated, however, that all app developers should implement quality management processes to ensure the quality, performance, and safety of their products.

Developers of MMAs must follow the FDA's Quality System Regulation, which describes good manufacturing practice requirements for devices. MMAs are subject to other requirements, including regulations governing labeling, adverse events, recalls, and manufacturing facility registration and device listing. Because these apps are regulated to the same extent as other medical devices, they are potentially subject to the same theories of liability that apply to traditional medical devices, including breach of warranty, negligence, and misrepresentation. For example, the FDA has classified as medical devices "apps that use patient information to calculate dosage therapies for radiation therapy."[1] If a patient alleges injury as a result of exposure to incorrect levels of therapeutic radiation arising from a defect of the dosing app, it is conceivable that the patient could sue the developer under numerous theories of tort liability. It is also conceivable that allegations of malpractice could arise from physician use or prescription of certain apps.

Similar theories would apply to health apps that the FDA has declined to regulate because they are deemed low risk. The low-risk designation may strengthen certain defenses available to developers and physicians in the event of litigation, but it is unlikely to eliminate the risk of liability altogether.

CONSUMER PROTECTION STATUTES

The marketing of non-FDA-regulated apps is subject to oversight by other regulators, including the Federal Trade Commission (FTC). The FTC Act bars "unfair methods of

FEDERAL FOOD, DRUG, AND COSMETIC ACT

Device = Instruments that are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease

"THERE ARE A NUMBER OF PRACTICAL STEPS DEVELOPERS CAN TAKE TO MANAGE LIABILITY RISKS, INCLUDING [ESTABLISHING] VERIFIABLE CLAIMS."

competition and unfair or deceptive acts or practices."[2] The FTC intends to enforce "truth-in-advertising standards" in the mobile app marketplace, and it has advised developers to, among other things, "tell the truth about what your app can do" and "disclose key information clearly and conspicuously."[2]

Recent enforcement actions confirm that the FTC is actively policing health apps. For example, the FTC recently initiated enforcement actions against marketers of acne treatment, cancer detection, and autism apps based on alleged false and misleading treatment and efficacy claims. While there is no private right of action allowing consumers to enforce the FTC Act, many state consumer protection statutes allow consumers to sue companies for injuries or loss arising from violations of those laws. These laws are modeled after the FTC Act, and they exist in every state. Potential theories of liability under these laws include false and deceptive advertising and fraudulent misrepresentation.

MANAGING THE RISKS

There are a number of practical steps developers can take to manage liability risks, including:

1. Verifiable quality and performance claims;
2. Legal and medical review of app promotional materials, labeling, and advertising; and
3. Clear and conspicuous disclosure of warnings.

Physicians who use or prescribe mobile apps should take steps to:

1. Assess the regulatory status of the app;
2. Read instructions for use and limitations on use;
3. Obtain appropriate training on app operation and maintenance;
4. Develop systems to ensure continuity of care in the event of malfunctions or data loss; and
5. Communicate policies regarding the frequency of monitoring of patient-generated health information that is created or shared through an app. ■

1. Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff. US Food and Drug Administration. February 9, 2015. http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf. Accessed April 1, 2015.
2. Marketing Your Mobile App: Get It Right from the Start. Federal Trade Commission. https://www.ftc.gov/tips-advice/business-center/guidance/marketing-your-mobile-app-get-it-right-start. Accessed April 1, 2015.

Section Editor James D. Dawes
- president and founder, J. Dawes Group
- principal and director, BK Ventures Group
- chief development officer, Vold Vision, Fayetteville, Arkansas
- registered member of the Cherokee Nation
- (941) 928-2589; jdawes@jdawesgroup.com

Kevin M. Henley
- associate at Arnold & Porter LLP in Washington, DC
- kevin.henley@aporter.com