Medical Mobile Apps and Dermatology

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Mobile medical applications, or apps, are rapidly integrating into the health care system. More than 80% of physicians own a mobile device and 25% of physicians utilize both a smartphone and tablet daily in their medical practices. In response to physicians’ rapid adoption of mobile technology, the mobile medical app market has exploded. Within iTunes alone, the number of health and medical apps increased 4-fold in the last 2 years. A new culture also has developed known as the bring-your-own-device policy in which physicians demand to purchase their own medical apps and utilize their own mobile devices rather than use employer-provided devices with employer-specified apps. Unique opportunities and challenges are just beginning to be discovered and addressed at the patient, provider, and federal levels.

Physicians
Physicians utilize mobile apps to save time, improve patient encounters, and access the most up-to-date information throughout all stages of health care delivery. Most physicians use apps to access medical reference materials and view patient information (ie, laboratory results, digital images). Other uses include accessing educational materials, receiving clinical notifications (ie, receiving statim laboratory evaluations), tracking work lists, securing communication, collecting bedside data (ie, vital signs), monitoring data from medical devices (ie, electrocardiogram telemetry), and capturing clinical images. The challenge for dermatologists is to find apps with high security and usability.

Usability is what makes an app worthwhile and constitutes the effectiveness, efficiency, and satisfaction with which specific users can achieve a specific set of tasks in a particular environment. Dermatologists should look for apps that are easy to learn, fit within his/her current workflow, provide usable information that is accurate and complete, and improve the speed of completing tasks. At this time, there currently are no robust and established resources for dermatologists or medical providers to assess usability; it can only be assessed through a demo or a colleague. Table 1 lists online resources that currently are available to help physicians bridge this gap.

Security is the main barrier physicians cite for integrating mobile medical apps into their practice. If physicians choose to use apps to access protected health information (PHI), they must follow the Health Information Technology for Economic and Clinical Health Act and the Health Insurance Portability and Accountability Act Security Rule, which “requires appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information.” For medical apps, physicians minimally should ensure the following: (1) their mobile device requires authentication (ie, strong password protection); (2) their mobile device is able to be remotely locked down or wiped clean of its data in case of theft; (3) all stored PHI is strongly encrypted; and (4) PHI is transmitted through a secure Web site connection or an encrypted virtual private network. As with usability, there are no well-established resources for dermatologists to assess security features of individual medical apps. Haaptique Mobile Health Source has developed a certification process that extensively evaluates security standards of medical apps and may become a leading physician resource for trusted medical apps. Johns Hopkins University, Baltimore, Maryland, also is researching mobile apps through its Global mHealth Initiative, promising validation of health benefits of individual mobile apps.

Patients
Patients have not adopted mobile medical apps as quickly as physicians. Although 88% of US residents own mobile telephones, approximately 50% are using smartphones and only 10% of smartphone users have downloaded a health-related app. Furthermore, the majority of these apps are focused on tracking fitness and diet, not chronic health management or other health concerns. One reason for the low adoption of health apps by the general population may be the confusing spectrum of apps available for each condition by developers of unknown reliability. Furthermore, these apps are grouped with the broad categories of medical or health and fitness in app stores with limited search functions.

Within the field of dermatology, patients with pigmented lesions would encounter a confusing selection of skin self-examination apps. None of the apps have been validated by clinical studies to be safe or effective. One app claims to inform users if a mole is low, medium,
or high risk, but it labeled 80% of textbook melanomas as low or medium risk in one analysis. Despite the lack of clinical data to support this app, one physician stated in a review, “I’m a family medicine resident and it works great as a screening tool on my iPhone 4. Highly recommended for primary care docs.” Because consumers are only able to evaluate apps based on customer reviews, the developer Web sites, and screenshots, there is likelihood for patients to be misled and potentially harmed by the inappropriate use of many of these apps. Until more adequate review processes are available for consumers, patients should be wary of health care apps for dermatology and should discuss medical apps related to skin care with their dermatologist.

Federal Regulation
The mobile medical app market largely is self-regulated. How a company markets a mobile app is more relevant than how consumers use it. For example, a CBS news affiliate reported a woman who used a commercial smartphone app as a “standby stethoscope” to monitor her infant daughter’s heart condition (supraventricular tachycardia) in her home. Because the app is advertised to “gatherv bio-feedback data” rather than diagnose a health condition, US Food and Drug Administration (FDA) approval is not required. Some skin self-examination apps are endorsed by dermatologists and claim to track your skin’s health. Obviously, there is a high risk for consumers to misuse these apps as medical devices, to delay appropriate therapy, and to suffer serious health consequences.

Unfortunately, there currently is only 1 federal law that specifically addresses mobile medical apps, the FDA Safety and Innovation Act, which was signed into law in July 2012. A commission of several agencies has been established to report back to congress within 18 months with a strategy proposal for regulating mobile medical apps. The FDA also has produced draft guidance on how to apply regulatory authority to mobile medical apps but has not released final regulations. Despite a lack of regulation specifically directed at mobile medical apps, several federal agencies do have some regulatory jurisdiction and have taken regulatory action regarding mobile medical apps (Table 2). A bill also is set to be introduced to the US House of Representatives by Representative Mike Honda (Democrat-California) called the Healthcare Innovation and Marketplace Technologies Act, which would establish an Office of Mobile Health at the FDA, streamlining the regulatory process for mobile medical apps. Hopefully, the federal role in regulating mobile medical apps becomes more clear to protect patient safety and promote useful innovation in this rapidly growing field.

### Table 1.
**Online Resources for Medical Apps**

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<thead>
<tr>
<th>Resource</th>
<th>Description</th>
<th>Notable Link</th>
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<tr>
<td>iMedicalApps (<a href="http://www.imedicalapps.com">www.imedicalapps.com</a>)</td>
<td>Physician reviews and advice indexed by app type, specialty, and device platform</td>
<td><a href="http://www.imedicalapps.com/2012/09/tutorial-physicians-ipad-medical/introduces">http://www.imedicalapps.com/2012/09/tutorial-physicians-ipad-medical/introduces</a> physicians to essential apps for any iPad owner who wants to integrate apps into their workflow</td>
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<tr>
<td>Happtique (<a href="http://www.happtique.com">www.happtique.com</a>)</td>
<td>Mobile medical app store developed by health care professionals with reviews by medical professionals indexed by specialty</td>
<td><a href="http://www.mhealthzone.com">www.mhealthzone.com</a> keeps you up-to-date by reviewing mobile health news as it applies to Happtique</td>
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<td>KLAS (<a href="http://www.klasresearch.com">www.klasresearch.com</a>)</td>
<td>Provides reviews of mobile data systems that provide physicians with access to census results and other patient information on a handheld device</td>
<td><a href="http://www.klasresearch.com/segment/26">www.klasresearch.com/segment/26</a> provides a list and reviews of EMR extension apps, which are mobile apps that provide interfaces for EMR/EHR access</td>
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<tr>
<td>mHIMSS (<a href="http://www.mhimss.org">www.mhimss.org</a>)</td>
<td>News, white papers, trends, policy reviews, and several other resources related to the use of mobile technology in health care</td>
<td><a href="http://www.mhimss.org/resource-topics/apps">www.mhimss.org/resource-topics/apps</a> overview of medical apps</td>
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Abbreviations: EMR, electronic medical record; EHR, electronic health record.
### Table 2.  
**Federal Agencies Involved in Mobile Medical App Regulation**

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<tr>
<th>Agency</th>
<th>Mission</th>
<th>Role in Mobile Health</th>
<th>Example Actions Taken</th>
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<tr>
<td>FCC</td>
<td>Manage RF communications to ensure that RF devices operate efficiently and without interference</td>
<td>Authorizes RF-based medical devices if implanted (i.e., pacemakers) or external (i.e., wireless telemetry); authorizes carriers whose networks are used by mobile devices (i.e., smartphones) to access, store, or transmit health information</td>
<td>Enforces the Communications Act, which prevents other users from jamming other devices and prevents interception of RF communications by carriers without appropriate legal instruments</td>
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<td>FDA</td>
<td>Promote and protect public health</td>
<td>Oversee the safety and effectiveness of mobile medical applications that present a potential risk for patients if they do not work as intended; provide manufacturers and developers of mobile medical applications clear and predictable outlines of expectations to promote innovation while maintaining patient safety</td>
<td>Produced draft guidance on July 19, 2011, on an oversight approach for mobile apps specific to health care and those mobile apps that impact the performance or functionality of currently regulated medical devices</td>
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<td>FTC</td>
<td>Work for consumers to prevent fraudulent, deceptive, and unfair business practices and to give consumers information they need to spot, stop, and report them</td>
<td>Enforces the Health Breach Notification Rule, which requires certain entities to notify consumers if there has been a breach involving their electronic health information</td>
<td>Released “Mobile Apps for Kids: Current Privacy Disclosures are Disappointing,” a report showing that neither app stores nor app developers give parents the information needed to determine what data are collected from children, how it is being shared, or who has access to it; took action on mobile apps that claimed to clear acne by shining light close to consumer’s faces</td>
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<tr>
<td>NIST</td>
<td>Promote US innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life</td>
<td>The technology laboratory information of NIST develops standards, guidelines, tests, and metrics for the protection of nonnational security federal information and information systems</td>
<td>Established National Cybersecurity Center of Excellence to accelerate widespread adoption of integrated cybersecurity tools and technologies; released multiple standards and guidelines for mobile devices related to security, information processing, remote access, telework, and cloud computing</td>
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<td>US Department of Health and Human Services’ Office for Civil Rights</td>
<td>Ensure understanding of and compliance with nondiscrimination and health information privacy laws</td>
<td>Implements and enforces HIPAA</td>
<td>Annually resolves &gt;10,000 citizen complaints alleging discrimination or a violation of HIPAA</td>
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Abbreviations: FCC, Federal Communications Commission; RF, radiofrequency; FDA, US Food and Drug Administration; FTC, Federal Trade Commission; NIST, National Institute of Standards and Technology; HIPAA, Health Insurance Portability and Accountability Act.

Data from the US Department of Health and Human Services.17
Conclusion
The exciting emerging field of mobile medical apps may result in large profits for medical app developers. The market is large, rapidly growing, and overwhelming. One reporter noted that “[t]he problem with this kind of gold rush is that it attracts not only the best and brightest but also the fast and furious—IT developers looking for quick profits with minimal investment of resources.”

REFERENCES


