Power to the People: How Medical Mobile Apps Are Increasing Patient Knowledge and Changing the Doctor-Patient Relationship

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I. INTRODUCTION

In 2015, an estimated 1.91 billion mobile phones will be in use worldwide, creating easy access to the Internet and all of the information it has to offer.\(^1\) Nearly two thirds of all Americans own smartphones and nineteen percent of those individuals rely on their smartphone for access to the Internet.\(^2\) The way in which people access information is changing. More people turn to their cell phones for Internet access than ever before and those people are using the Internet for everything from online banking to submitting job applications.\(^3\) In fact, sixty-two percent of smartphone users in the United States turn to their phone to access information about health conditions.\(^4\)

With this increase in information accessibility and newfound dependence on smartphones, a new healthcare technology has emerged: medical mobile applications.\(^5\) These applications range in function from fitness trackers that collect information about an individual’s heart rate and the number of steps taken in a day to attachments that can be used to monitor blood sugar or track heart rhythms.\(^6\) In a survey performed by the Economist Intelligence Unit, sixty-four percent of healthcare executives interviewed believed the introduction of medical mobile technology could dramatically improve health outcomes for patients, and sixty-three percent believed that increased access to health information would allow individuals to make better decisions.

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3. Id.
4. Id.
6. Id.
about their health.  

Patients are more educated about health care than ever before, which has changed the relationship that patients have with their doctors. Traditionally, the doctor-patient relationship was one-sided – patients relied heavily on the opinion of their doctors and waded through red tape to access documents such as lab reports and doctors’ notes. The introduction of medical mobile applications is changing that relationship. Now patients have access to information that was previously only available to their doctor. As a result, patients are gaining more control over their own medical care.

The growth in popularity of medical mobile applications will forever change the healthcare industry and affect every area from patient care to physician reimbursement. Medical mobile applications are significantly changing the way patients seek care and the relationship patients have with doctors. Large-scale use of medical mobile applications can have a positive effect on the doctor-patient relationship. However, in order to do so the Food & Drug Administration’s (“FDA”) regulations must be expanded to cover a larger category of applications, the patient information stored on applications must be secure, and patients must take a more active role in their own health care.

II. MOBILE HEALTH APPLICATIONS

The use of mobile technology in medicine began in 2007 with the launch of the first iPhone. From that point on, anyone could develop a mobile application to be sold in the Apple Application Store (“App Store”). Currently, there are about 1.5 million applications in the App Store and this number is continuously growing. As technology progresses, these

8. Topol, supra note 5.
9. Id.
10. See id (Easy to access mobile applications are giving patients the ability to perform their own test at home and send the information to their doctors for interpretation or advice. Patients no longer need to schedule an appointment to get the tests done and wait hours or days for the results, but rather can perform the test themselves and get results almost immediately.).
11. ECONOMIST INTELLIGENCE UNIT, supra note 7.
12. Id. at 12.
13. Id.
applications have become increasingly sophisticated – allowing for smartphones to be transformed into tools as simple as a flashlight or as complex as a heart monitor. Medical mobile applications take advantage of a smartphone’s built-in features including touch screens, cameras, wireless connectivity, and software. There are an estimated 26,000 healthcare applications available for download today, and only 7,400 are intended for doctor use. Using the built-in features of smartphones to collect data in combination with medical mobile applications that process the data, a smartphone user can receive an individual diagnosis in minutes. These applications cover many different areas of the medical field ranging from fitness and nutrition to dermatology applications that analyze moles for melanoma.

Responding to the increase in medical mobile applications, the FDA has taken steps to regulate some applications for quality assurance. In doing so, the FDA has issued two statements regarding the use and development of medical mobile applications. In 2011, the FDA issued guidelines for those who wished to develop and use medical mobile applications. In 2013, the FDA moved beyond guidelines and began to impose regulations on specific medical applications – namely, those the FDA deemed to be medical devices. The FDA considers applications to be medical devices if the user utilizes the application as an accessory to an already regulated medical device or if the application transforms a smartphone into a regulated medical device. The FDA defines a medical device as an instrument intended to be

20. Id.
21. See Topol, supra note 5.
23. Id.
24. Id.
25. Id. See also FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH AND HUMAN SERV’S, MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 33-37 (Feb. 9, 2015), available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf (the FDA regulatory requirements imposed on mobile application manufacturers include the registration of establishments to let the FDA know what applications each establishment is manufacturing, the running of clinical trials, product labeling requirements, quality system regulation, and adverse event reporting).
26. Bauer, supra note 22; see also Mobile Medicine Resources: FDA Approved Apps,
used for diagnosis of disease or prevention of disease.\textsuperscript{27} Medical mobile applications are thus separated into two different categories: 1) those considered medical devices requiring regulation by the FDA, and 2) those considered low risk applications not requiring FDA regulation.\textsuperscript{28} For example, the application BlueStar monitors a patient’s blood sugar and offers coaching to diabetic patients.\textsuperscript{29} The FDA has stated that because the application transforms a smartphone into a device to test blood glucose levels, FDA approval is required for its use.\textsuperscript{30} Conversely, the FDA considers the fitness application MyFitnessPal, which contains a database of foods and allows users to track the number of calories consumed, a low risk application that does not require regulation.\textsuperscript{31} Although the FDA has enforced regulations to protect medical application users, the majority of applications available for download do not require FDA approval.\textsuperscript{32} In today’s world, any information a person could ever need is available at the push of a button.\textsuperscript{33} Patients are beginning to demand quick and easy access to health care.\textsuperscript{34} While patients want faster health care, concern over the effectiveness of medical mobile applications as well as the security of patient information cannot be overlooked.\textsuperscript{35}

\textsuperscript{27} What is a Medical Device?, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/Transparency/Basics/ucm211822.htm (last visited Nov. 30, 2015) (the FDA defines a medical device as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article” which is “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.”).


\textsuperscript{30} \textit{Id.}

\textsuperscript{31} McInerney, supra note 28, at 165.

\textsuperscript{32} Scher, supra note 19.

\textsuperscript{33} \textit{See} Smith, supra note 2 (detailing the use of smart phones and how they are being used by Americans to access the internet).

\textsuperscript{34} Topol, supra note 5.

\textsuperscript{35} \textit{See} Scher, supra note 19 (explaining how doctors are concerned with the efficacy and accuracy of medical mobile applications and the security of patient information with the use of medical mobile applications).
III. CHALLENGES MEDICAL MOBILE APPLICATIONS FACE IN CHANGING THE DOCTOR-PATIENT RELATIONSHIP

The doctor-patient relationship is a crucial component of patient care. However, the relationship has historically been paternalistic—the doctor is responsible for making healthcare decisions for the patient while the patient holds little or no authority in the decision-making process. While a doctor is more educated in the area of medicine, the introduction of medical mobile applications into mainstream medicine gives the patient more power and access to medical information. This introduction of new technology is not without issues, which will serve as roadblocks to the potential effectiveness of medical mobile applications. The challenges medical mobile applications pose for the doctor-patient relationship vary significantly.

A. Regulatory Barriers to Medical Mobile Applications

As previously stated, the FDA regulates some medical mobile applications. FDA oversight guarantees that applications with higher potential for risk are evaluated to bring safe and effective products to the market. However, simply because an application is not regulated by the FDA does not mean that risk is non-existent. For example, in a recent study...
researchers looked at a non-FDA regulated dermatology application that analyzes moles and found that the application misidentified as many as thirty percent of melanomas. The study catalogued more than 200 different medical mobile applications specializing in dermatology that performed a variety of tasks such as monitoring psoriasis, connecting patients with support groups, and giving sunscreen advice. However, the applications that concerned researchers the most were those that dealt with the identification of melanomas, primarily because of the catastrophic consequences related to misidentification of a cancerous mole.

Doctors and patients alike must be careful about which medical mobile applications to depend on for health-related information. Patients need to understand that applications such as those used to diagnose melanoma or general symptom trackers cannot replace professional physicians and are not regulated by the FDA. Heavy reliance on medical mobile applications for diagnosis removes the possibility of discovering a secondary diagnosis – something a doctor may discover during a physical exam. However, with the growing number of smartphone users in the world today, complete avoidance of medical mobile applications is unfeasible. In order to better protect patients, the FDA must expand regulation of medical mobile applications beyond those deemed medical devices. Achieving such protection from medical mobile applications will require doctors and patients to discuss the potential uses and drawbacks involved in utilizing medical applications. This can help the doctor and patient reach a mutual decision on how to approach the patient’s health.

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46. Id.
47. Id.
48. Id. (explaining that misidentification of a cancerous melanoma could allow the cancer to spread to other parts of the body and decrease a patient’s likelihood of survival or significantly complicate a patient’s treatment).
49. McInerney, supra note 28, at 167.
50. Id.
51. See id. at 168 (symptom-checking applications are only programmed to present the most likely diagnosis and fail to take into consideration that more than one condition could be causing a patient’s symptoms to occur).
52. See id. (stating that the majority of Americans own smartphones with the ability to access medical mobile applications).
53. See Spotswood, supra note 45 (explaining that applications not regulated by the FDA can pose a significant risk to patients).
55. See generally Topol, supra note 5.
B. Security and HIPAA Concerns

Many doctors are hesitant to use medical mobile applications because of concern for the security of their patients’ personal information.\textsuperscript{56} Now that many hospitals and doctors’ offices have shifted to electronic medical records, the safety of patients’ personal information has been a serious concern of doctors and patients alike.\textsuperscript{57} Recently, hackers broke into patient records at the University of California, Los Angeles and stole patient names, medical information, social security numbers, Medicare numbers, birthdays, and addresses.\textsuperscript{58} The increase in security breaches at large institutions such as hospitals and universities has heightened awareness about the safety of personal information.\textsuperscript{59} Due to the increasing popularity of medical mobile applications, doctors and patients should be cautious about using an application that could be lacking security protection.\textsuperscript{60}

In a survey performed by The Economist Intelligence Unit, forty-nine percent of individuals interviewed believed that consumer wariness and privacy concerns would be a barrier to the adoption of mobile health applications.\textsuperscript{61} If doctors do not believe the applications to be safe, they will not use them in their practice, which could stop the mobile health movement before it truly begins.\textsuperscript{62} The federal government has said that it will better define HIPAA standards to ensure patient privacy and safety; however, until safety can be assured the number of physicians who choose to use medical mobile applications will likely remain relatively low.\textsuperscript{63} Until physicians can be sure that confidential patient information is safe they will continue to be reluctant to introduce medical mobile applications into their practice.\textsuperscript{64} Without physicians willing to actively pursue the use of medical mobile applications, they will never reach the numbers necessary to disrupt the doctor-patient relationship on a large scale.\textsuperscript{65} If the use of medical mobile applications is to become a driving force in the healthcare market, security

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\item \textsuperscript{56} Scher, supra note 19.
\item \textsuperscript{57} Jose Pagliery, UCLA Health Hacked, 4.5 Million Victims, CNN Money (July 17, 2015), http://money.cnn.com/2015/07/17/technology/ucla-health-hack/.
\item \textsuperscript{58} Id.
\item \textsuperscript{59} See id. (explaining that large institutions are popular targets for hackers).
\item \textsuperscript{60} Scher, supra note 19.
\item \textsuperscript{61} ECONOMIST INTELLIGENCE UNIT, supra note 7, at 4.
\item \textsuperscript{62} Scher, supra note 19.
\item \textsuperscript{63} See id. Forty six percent of health care professionals say that they will introduce medical mobile applications into their practice in the next five years, however, only sixteen percent of health care professionals already use mobile medical applications in their work with patients. Rajiv Leventhal, Survey: Doctors and Patients See Benefits in Mobile Apps, HEALTHCARE INFORMATICS (Mar. 24, 2015), http://www.healthcare-informatics.com/print/news-item/survey-doctors-and-patients-see-benefits-mobile-apps.
\item \textsuperscript{64} Scher, supra note 19.
\item \textsuperscript{65} ECONOMIST INTELLIGENCE UNIT, supra note 7, at 4.
\end{itemize}
must be a priority for companies developing medical mobile technology.66

IV. THE SHIFT IN POWER TO THE PATIENT

The final and perhaps most important challenge to ensuring that medical mobile applications have a positive effect on the doctor-patient relationship is increasing patient autonomy.67 Medical mobile technology makes information that was once only seen by physicians readily available to patients.68 Patients will soon be able to conduct tests in the privacy of their own homes using attachments or images on their cell phone.69 Patients with chronic conditions will be able to remotely monitor their conditions, making patients better equipped to discuss their condition with their doctor and in turn make health decisions as a team.70

With the direction healthcare monitoring is headed, patients will soon be able to analyze their health in real time, and mobile applications will soon take the place of routine visits to the doctor.71 However, visits to a primary care physician are not the only service in the medical field that will likely decrease.72 With increased ability for patients to perform lab tests at home, patients will have the opportunity to directly receive the results of their tests before sending them to their doctor.73

The increase in mobile technology gives healthcare providers the ability to expand care to individuals in areas where hospitals and doctors are sparse.74 In a study performed by the U.S. National Institutes of Health and Qualcomm in Arizona, fifty individuals suffering from congestive heart failure were given home monitors to allow the individuals to self-monitor and have direct contact with a doctor if a medical issue arose.75 The results of the

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66. See David Lee Scher, Critical Considerations in Designing Medical Mobile Apps, QMED http://www.qmed.com/mpmn/article/critical-considerations-designing-mobile-medical-apps (last visited Nov. 30, 2015) (explaining that companies and individuals developing applications must consider security issues when developing their product and not just as an afterthought).
67. ECONOMIST INTELLIGENCE UNIT, supra note 7, at 12.
68. Topol, supra note 5.
69. ECONOMIST INTELLIGENCE UNIT, supra note 7, at 13.
71. Sundar Subramanian et al., Personalized Technology Will Upend the Doctor-Patient Relationship, HARV. BUS. REV. (June 19, 2015), https://hbr.org/2015/06/personalized-technology-will-upend-the-doctor-patient-relationship (arguing that if patients will have the ability to perform routine procedures outside of the office and on their smart phones they will no longer feel the need for regular doctor visits).
72. ECONOMIST INTELLIGENCE UNIT, supra note 7, at 12.
73. Id.
74. Id. at 6.
75. Id.
study were shocking: the average number of days a patient spent in the hospital plummeted from fourteen days per month to five days per month, saving patients more than $90,000 per person.\textsuperscript{76} The monitors gave patients the ability to address health problems before they became more serious and taught patients which symptoms were not signs of more threatening conditions requiring hospitalization.\textsuperscript{77} The change to a more remote doctor-patient relationship has educated patients, causing them to better understand their medical conditions.

While the doctor-patient relationship will experience drastic changes in the years to come, it will not disappear. The focus of care will likely shift from reactive care, which treats diseases after symptoms begin to occur, to proactive care, which attempts to prevent diseases before they occur.\textsuperscript{78} The relationship will be more remote, resulting in yearly visits as opposed to regular appointments to treat colds and illnesses.\textsuperscript{79} Medical mobile applications, as well as doctors, must focus on encouraging patient involvement in order to be successful.\textsuperscript{80} However, this shift will only occur if patients are willing to accept a more active role in their own health care.\textsuperscript{81} A study performed by The Healthcare Information and Management Systems Society found that patients who were more involved in their own health care showed better outcomes in the long run.\textsuperscript{82} By creating patient engagement, medical mobile applications and doctors can work to help patients help themselves.\textsuperscript{83}

V. CONCLUSION

With increased availability of technology, more people will have access to previously unattainable medical information.\textsuperscript{84} Medical mobile applications offer both patients and doctors a chance to enhance the doctor-patient relationship through transparency and communication.\textsuperscript{85} Unfortunately, without increased security and regulation this may not be possible. Until applications can guarantee that patient information is secure and that mobile

\begin{thebibliography}{99}
\bibitem{76} Id.
\bibitem{77} Id.
\bibitem{78} Id. at 12.
\bibitem{79} Id.
\bibitem{81} Id. (patients are the driving force behind the mobile medical application movement).
\bibitem{82} Id.
\bibitem{83} See id. (by encouraging patient involvement doctors and medical mobile applications will encourage a healthier community and cause patients to be healthier).
\bibitem{84} Topol, supra note 5.
\bibitem{85} Id. at 5.
\end{thebibliography}
applications will be accurate, use of mobile applications will remain low among doctors and the doctor-patient relationship will largely go unchanged.