Committee on Science, Space, and Technology, Subcommittee on Research and Technology
U.S. House of Representatives hearing on
"Smart Health: Empowering the Future of Mobile Apps"

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Subcommittee Chairwoman Comstock and members, thank you for reviewing this important topic in the new era of using personal technology to support health care. I am a professor of neurology at Johns Hopkins Medical Center and the co-inventor of EpiWatch, the first research app to use the Apple Watch. I would like to describe our app to make several points about issues in supporting innovation and safety in medical applications for mobile devices.

EpiWatch is a medical research app that collect physiological data from sensors on the Apple Watch during seizures from participants with epilepsy. This data is being used to create a seizure detector which will use changes in movements, heart rate and alertness to detect seizures and alert caregivers when their family members have seizures.

The app has several novel features:

a) Participants enroll for the research using a novel electronic consenting process in which they review the aims of the research and required activities, receive study screening and testing for comprehension of the research, all on their iPhones. Those agreeing to participate sign the consent on their phones and receive signed pdf consent forms via email;
b) Participants' data is anonymized—physiologic data collected with Apple Watch sensors, health information from questionnaires, participants' seizure and pill taking logs—are sent to JHU in encrypted form and stored securely with registration information kept separate from research data;
c) The EpiWatch research uses a novel data management program integrated with the Apple Watch and iPhone operating systems called ResearchKit. ResearchKit supports electronic consenting and encrypted data transfer from mobile devices for research use. Apple has no access to the participant registration or research data. ResearchKit requires research app software to be open-access and non-commercial.

The EpiWatch app helps patients with epilepsy manage their condition, but does not provided direct medical care. Participants submit information about their seizures and treatment and receive brief daily surveys asking whether they had seizures and had taken all their medications. Seizure tracking and survey data are logged in journals which are displayed graphically to participants as feedback on their seizure control and treatment adherence. Additional support activities being implemented screen for problems often associated with epilepsy, including depression and anxiety, drug side effects and measures quality of life. These results provide participants with helpful feedback on their condition – they then may choose to share this information with their physician to help manage their epilepsy.

Advantages of research performed on mobile devices:

a) A large national study can be conducted rapidly that enrolls participants of all ages and demographics; and
b) Research data collected on mobile devices can be quickly accumulated to permit rapid development of medical apps which will help patients and potentially save lives.

For example, 1 in 500 persons with epilepsy die each year with sudden unexpected death with epilepsy (SUDEP); we are implementing risk screening in the EpiWatch app for SUDEP. Our research priority is to complete a seizure detector which accurately detects the most serious seizure type associated with SUDEP—tonic-clonic convulsions in sleep. This detector will alert caregivers to allow them to aid patients during serious seizures: repositioning and stimulating them to reverse respiratory dysfunction.

Potential data confidentiality and safety issues with medical app development

EpiWatch research was implemented with careful review by JHU data safety engineers, a research data safety committee and computer scientists at a medical research server support company. It is important that participant confidentiality be maintained while performing this type of minimal risk research and to prevent data confidentiality breaches. It is also important to the public that medical apps be effective and safe before being used to support patients and that false promises about medical apps not be made. A seizure detector apparatus which does not accurately detect seizures might, for example, provide false reassurance to patients and caregivers. Disclosures and cautions about the limitations of medical apps are important in providing medical app support in managing serious medical conditions.

Recommendations on regulation of medical apps

The Supreme Court recently narrowed the patentability of mobile apps, ruling in *Alice Corp. v. CLS Bank Int'l*, that app may not be simple software representations of existing techniques. This seems appropriate: patents for medical apps should require an innovative application of a new technology representing ingenuity and invention.

The FDA recently issued a preliminary guidance for regulation of mobile medical applications.[1] In these nonbinding recommendations, non-significant medical apps are defined as applications which help patients monitor medical condition, but do not provide medical interventions; non-significant medical apps do not currently require a FDA review. Significant medical apps involving medical interventions may require FDA review of the safety and effectiveness of the medical app. For example, EpiWatch tracks seizures and pill taking for participants, but does not provide medical interventions, such as triggering an injection during prolonged seizures. Participant may choose to show seizure and treatment adherence graphs to their physicians to help adjust their treatment, but the app does not implement changes in therapy. The preliminary FDA guidance is helpful, but continued development of sophisticated medical apps will require policy development and elaboration of the FDA guidance in order to promote innovation, protect patient safety and adjudicate liability.

With our EpiWatch app, for example, participants may choose to insert phone numbers so that caregivers receive alert messages when the participants' seizures are tracked. We did not, however, implement emergency messaging to 911 with GPS localization if a patient did not respond to prompts

[1] http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf

after prolonged seizures. This possibly lifesaving feature was deferred, since it would represent a form of medical intervention which might require FDA review during a period of app development.

Thank you for allowing me to testify on the exiting new medical field.

The opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University.