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# Insights

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## INTO RISK MANAGEMENT



### @RISK: DIGITAL HEALTH: NOT YOUR PARENTS' EMR

By Meghan Ranney, MD

This article is an enduring activity approved for AMA PRA 1 Credit(s)<sup>™</sup> and category 1 credit in Risk Management Study.

Many healthcare providers instinctively associate “digital health” with electronic health records, malfunctioning computers, and government mandates; however, digital health is a different and wider entity than traditional “health informatics.”

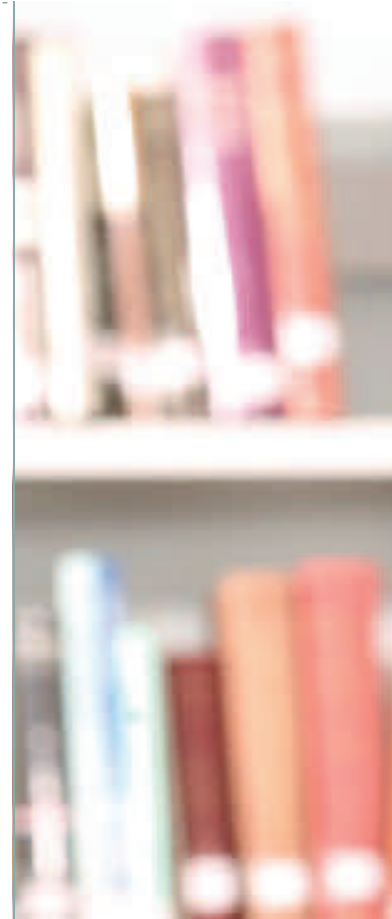
The concept of digital health was first made popular by Eric Topol’s 2012 book, *The Creative Destruction of Medicine*, and is defined as the use of new technologies such as social media, text-messaging, mobile “apps,” and wireless sensors to improve health. Digital health includes software or programs that purport to engage patients (e.g., *PatientsLikeMe*), improve diagnosis and treatment (e.g., *iTriage*), facilitate behavior change (e.g., *Text4Baby*), or improve monitoring (e.g., *AliveCor*).

Whether we welcome digital health or not, it is quickly becoming part of our patients’ lives. Almost 20% of adult Americans report using some kind of wearable device, and 80% have tried some form of digital health in the past year.

Many of these digital health solutions can be used primarily by patients, independent of the healthcare system. Others are meant to be used in tandem with their healthcare providers to address the gap between the short period of time that patients are seen in the office or hospital, and the long period that patients are at home, outside of provider oversight. Increasingly, the various modalities of digital health interact and overlap.

As with any developing field, digital health contains the promise of enormous potential. Studies suggest that well-designed tools can increase smoking cessation, improve weight loss, reduce CHF re-admissions, reduce appointment no-shows, improve influenza vaccination rates, improve compliance with taking prescribed medications, and improve diagnosis and treatment of serious mental illness.

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Interested in learning more about  
Digital Health?

@ Risk Live Lecture Series:

**Digital Health—Not Your  
Parents’ EMR**

**January 21st — 12 Noon  
George Auditorium**

*This presentation will be repeated on  
June 9 @ 7am and September 27 @  
5pm*



## RISK: *What You Need To Know About Digital Health*

What concerns associated with digital health can you identify in the following situation?

C.D., a 36 year old woman, presents to your clinic for a new patient visit. She tells you that she “Googled” you, and is here because she likes the way you talk about medicine online. She explains that she’s been tracking her blood pressure and heart rhythm using “apps” downloaded from the web. Based on this, she is concerned that she has undiagnosed atrial fibrillation. She asks you to look at the data on her phone.

***What should you do?***

On this page is a focused discussion of the ethical and medico-legal concerns associated with using digital health technology.

**D**igital health presents some unique, and as yet, unresolved risk management concerns.



**Privacy and Security**  
*Perhaps the Most Obvious Risk*

**Remind your patients to talk with you before acting on any diagnoses, drug recommendations, or medical information.**

The fact pattern above illustrates some significant risks associated with the use of social media. It is not only permissible, but often encouraged for healthcare providers to be active online. Studies show that hospitals with an active social media presence have better satisfaction scores and higher retention rates. However, be aware of the risks, both for yourself and your patients. As an important reminder, do NOT post any protected health information OR non-IRB-approved research information online. It’s important to remember that many forms of social media that you consider “private” may not be. Patients can find your tweets, Facebook page (depending on your privacy settings), blog posts, and even lists of your charitable contributions!

***In this case:*** After the patient leaves, double-check that you have the maximum privacy safeguards on your Facebook account. You may consider changing your cover photo so that it isn’t a picture of your kids. You are thankful that you have been careful about what you post on blogs to present a professional image of your work.

Digital health software also presents privacy and security risks. Digital health companies are not required to meet HIPAA standards unless they have a business agreement with a “covered entity.” One review of publicly available apps showed that 72% violated basic privacy and security rules; for instance, they sell information to 3<sup>rd</sup> parties without asking for consent! Before recommending an app or program to a patient, make sure you know whether it meets your standard for privacy protections. Also, before using an app or text message program to deliver care, make sure you’ve vetted it through Lifespan.

***In this case:*** You explain to the patient that you’re excited to hear about her findings, but can’t automatically import the information into LifeChart because you don’t know if the app is HIPAA compliant. You tell her that just as you would review findings on paper, you’d be happy to review her findings on her phone. You also mention that it’s worthwhile for her to check into the privacy safeguards for these apps.

Very few digital health tools have evidence to back them up. A number of apps have been pulled from the market after they made a few too many claims for FDA’s comfort. Many digital health solutions also lack guidance as to how to interpret their output data.

**In this case:** You ask the patient what apps she has been using to track her blood pressure and heart rhythm. With a quick Google search, you can ascertain whether these apps have any data to support them. You find out that the blood pressure app the patient is using has been discredited by multiple independent researchers. The heart rhythm app is FDA approved for detecting atrial fibrillation.

Although our instinct as healthcare providers is to not adopt a new technology until it has been “proven,” we have a responsibility to listen to our patients and recommend best-possible care. When a patient asks about or mentions being engaged in digital health, be careful to avoid being dismissive.

**In this case:** You explain to Ms. D that you are not familiar with the programs she is using, but are supportive of patients engaging in their own health. You provide her with a couple of suggestions for programs that you have used in the past. You explain that although the heart monitoring app is often used, she would be better served by using a home blood pressure monitor, because the app she is using has been shown to be inaccurate. You suggest that she can message you through the Lifespan patient portal, MyChart, if she has any issues in the future.

**Closure:** C.D. thanks you and lets you know that she’ll be sure to leave a good review on Yelp, as a thank you for your listening to her. After cautioning her that Yelp is not the most trustworthy source of data for healthcare, thank her for her feedback!

Digital health is a new frontier for many of us in organized healthcare. As it becomes more prevalent, we need to use the same common sense for these applications that we would use for nutritional supplements, new pharmaceuticals and devices, or any other patient-generated form of data.

To earn CME credit for reading this article, please go to <https://www.surveymonkey.com/r/6TDB8BM>

Feel free to contact Dr. Megan Ranney or any of the collaborators at the Emergency Digital Health Innovation program at [www.brownedhi.org](http://www.brownedhi.org).

Their mission is to use digital health to transform the care of patients with acute care needs—before, during, and after their visit. They are working to:

- Show evidence that digital health tools are *acceptable* and *effective* for both clinicians and patients in the emergency care setting
- Provide expertise in the *implementation* of these tools to minimize the burden on providers and patients
- Provide *training* in their use in clinical care

They are happy to assist with your efforts to understand or use digital health in your practice.

You may also contact the Peters’ Library at Rhode Island Hospital @ [LLibrary@lifespan.org](mailto:LLibrary@lifespan.org) or 4-4671 to obtain a mHealth Bibliography.

<b>PY 2016 @ Risk Live Lecture Series</b> <b>Presented by Lifespan Risk Services, Inc. - Loss Prevention</b> <b>Rhode Island Hospital - George Auditorium</b>			
Diagnostic Error	Digital Health*	Transitions of Care	Disclosure/ Apology
03/17/2016 12 - 1pm	*01/21/2016 12 - 1pm	02/11/2016 7 - 8am	04/28/2016 12 - 1pm
09/08/2016 7 - 8am	06/09/2016 7 - 8am	09/15/2016 12 - 1pm	05/12/2016 12 - 1pm
	09/27/2016 5 - 6pm		

**Trustworthiness**  
Another Important Risk



**Communication**  
The Final and Biggest Risk

References used for this article:



<https://rockhealth.com/reports/digital-health-consumer-adoption-2015/>



<http://www.ncbi.nlm.nih.gov/pubmed/25785892>



[www.pewinternet.org](http://www.pewinternet.org)



<https://www.privacyrights.org/mobile-medical-apps-privacy-alert>

## MOBILE APPS AVAILABLE THROUGH LIFESPAN



### BROWZINE

A browsable newsstand of our top journals. Easily discover, read, and monitor the key journals in your field.

### LEXICOMP Lexicomp®

A point-of-care drug database, providing drug information, dosing, administration, warnings and precautions.

### UPToDate UpToDate

Physician-authored, evidence-based clinical decision support resource of synthesized recent medical literature.

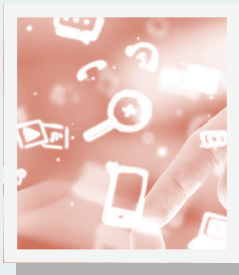
### NURSING REFERENCE CENTER



An evidence-based, clinical decision support tool designed for nurses and allied health professionals.

Contact the Peters' Library at Rhode Island Hospital @ [LLibrary@lifespan.org](mailto:LLibrary@lifespan.org) or 4-4671 for assistance in downloading these apps.

For a list of additional recommended free medical apps and more, visit [imedicalapps.com](http://imedicalapps.com).



## Update from the Graduate Medical Education Office: *Outcomes from the CLER Visit*

Rhode Island Hospital had its first institutional *Clinical Learning Environment Review* (CLER) visit from the Accreditation Council for Graduate Medical Education (ACGME) in November of 2014 to assess from a global standpoint the environment in which residents and fellows work and learn. This visit served to establish a baseline for RIH with the next one expected in 9-12 months.

In addition to seeing whether official program requirements were met, the review allowed ACGME field representatives to observe residents and fellows in action, assessing the role of trainees in the institution's quality and safety programs. This included system wide and departmental quality committees, as well as institution-wide initiatives such as event reporting, OpX projects, and our EPIC implementation.

As part of the CLER, ACGME site visitors met extensively with members of hospital administration, 98 faculty members and 57 residents and fellows.

Some key findings were:

- Nearly all of the residents believe the hospital provides a safe, non-punitive environment for reporting errors, near misses and unsafe conditions.
- Most residents reported they received formal training in patient safety and were involved in quality improvement projects.
- Lifespan's patient safety event reporting system, SafetyNet, newer at the time of the visit, was relatively underutilized by residents and faculty with only 1.8 and 2.0% of reports, respectively, placed by these groups.

CLER identified formal training in quality as a goal in our institution. As part of our strategy for improvement, the Rhode Island Hospital GME office started a GME Quality and Safety Committee. This group meets quarterly and is made up of residents, faculty, nurses, pharmacy staff and members of OpX.

## Digital Health Technology at Lifespan!

A major initiative of the committee currently in development is a **GME Quality and Safety Video Series**. The videos will be emailed to residents and faculty, and will emphasize topics in patient safety, recent SafetyNet reports, pharmacy near-misses, and quality keys points. The 3-5 minute snippets will be accessible "on the fly" on cell phones and other portable devices, as well as on the GME website to view at any time, thus creating a database of key teaching points in quality and safety. The first GME Quality and Safety Series Video will be distributed in January so please look out for it!



Additional involvement on the GME Quality and Safety Committee is welcome, along with suggestions for topics for the video series. Please feel free to contact Jerry Carino, MD, Assistant Director of GME at [gcarino@lifespan.org](mailto:gcarino@lifespan.org).

## TIPS FOR USING HEALTH APPS/DIGITAL TECHNOLOGY

- Be aware of privacy implications of apps that you use yourself or recommend to patients.
- Be aware of the evidence for or against what you're recommending.
- Think first before incorporating digital health into an EMR.
- Be cognizant of the potential for patient engagement and improved outcomes.
- Be aware of some good digital patient health resources in your field (e.g., AliveCor, PatientsLikeMe, SmokeFreeText and QuitStart App).
- Remember that text messaging is NOT secure. Texting with patients is limited to appointment reminders, missed appointment notices, requests to contact the office and the like. Healthcare providers should refer to the [Lifespan Corporation Mobile Device Policy issued by Information Services](#) for more information on texting PHI or other confidential information.
- When posting on blogs, social media, or other areas of the internet, be certain not to represent your views as those of Lifespan.\*

\*For additional guidance and information relating to social media, see the Lifespan Social Media policy (MC-1), available on the [Intranet](#) under Marketing and Communications policies, along with additional physician-specific [guidelines](#).

*“Don’t Lie,  
Don’t Pry  
Don’t Cheat,  
Can’t Delete,  
Don’t Steal,  
Don’t Reveal”*



*~The Mayo Clinic Social Media Guideline*

**T**he FDA has said it will avoid regulating any apps that coach patients on managing their diseases or organize medical information for user lookup.

## WHO WILL REGULATE MEDICAL APPS?

Under the definition set by the Federal Food, Drug, and Cosmetic Act (FD&C Act), if a mobile app is intended to perform a medical function, such as diagnose, cure, treat or prevent disease, it is considered a medical device. The FDA refers to these as “mobile medical apps.”

Many mobile apps are not considered by the FDA to be medical devices; therefore, the FDA does not regulate them. While some meet the definition, they pose a low risk to the public, and the FDA will not enforce requirements under the FD&C Act.

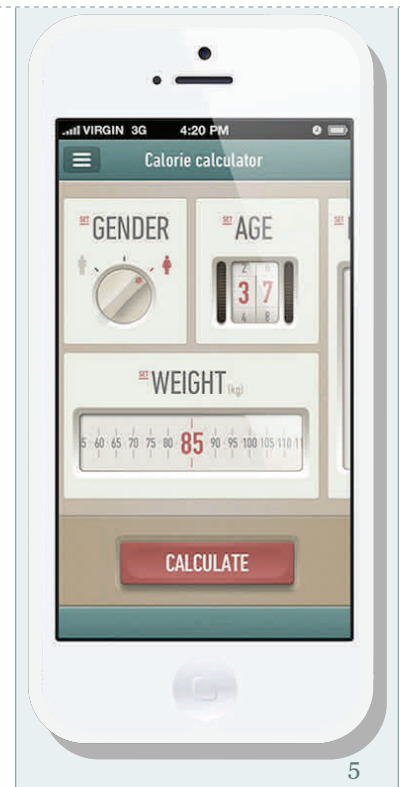
In **2013** the FDA indicated its intent to focus on regulating only mobile apps posing the biggest risk of harming patients when the apps don't work as intended; for example, mobile apps that serve as an accessory to a regulated medical device,

such as those that help doctors monitor their patients' implanted pacemakers, or those that transform a mobile platform into a regulated medical device.

- As of **2014**, the FDA had approved roughly 100 mobile medical apps.
- By the end of **2015**, the FDA predicted 500 million users of mobile apps worldwide.
- By **2018**, the FDA believes their use will become widespread, expecting half of all smartphone owners worldwide to have downloaded a medical app.

For more information, see:

<http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf>





# FOCUS ON NURSING:

## Every Picture Tells a Story, *Don't It?*

*The purpose of this section is to share summaries of closed cases that have occurred in the New England area and represent real life issues that provide risk management educational opportunities. The cases used may come from Lifespan affiliates or other institutions or practices, or may be composites of several cases with very similar fact patterns. We present those cases because we believe they have some relevance to situations that you may encounter in your daily practice.*

- Spencer was an eight year old boy who had won his three year battle with leukemia. Spencer and his two siblings had grown quite close to the oncology office staff while Spencer was undergoing treatment. On Halloween, Spencer's Mother brought the three children to the hematology/oncology office to show the staff the kid's matching superhero costumes. She was delighted to be asked, and agreed when the office manager asked if she could take a picture of the children for the office staff bulletin board.
- The office manager also posted it on her personal Facebook page with the caption, "Spencer conquers cancer! My favorite patient and his two adorable siblings."



### **ISSUE: Unpermitted disclosures of protected health information, even when incidental or unintentional, constitute a breach of the patient's privacy, and may lead to a violation of the HIPAA statute.**

- The next day, Mrs. K, the mother of a new patient who had been seen the day before, called the office manager, alleging that her child's privacy had been breached. Further, Mrs. K threatened to call the Office of Civil Rights and allege a HIPAA violation.
- The office manager questioned Mrs. K, and it was revealed that Mrs. K and her child were accidentally captured in the background of the photo the office manager took of Spencer and his siblings in their costumes. A Facebook "friend" of the office manager who saw the post was also a neighbor of Mrs. K. The neighbor called Mrs. K in a panic, assuming now that Mrs. K's son had cancer.
- Mrs. K's son was in the process of being worked up and it was not known at that time exactly what his diagnosis was. Mrs. K was an intensely private person and did not want to reveal her son's illness to schoolmates, friends or family until absolutely necessary.
- Fortunately, Mrs. K's son was not diagnosed with cancer, and instead received short-term treatment for a transitory blood disorder. Mrs. K consulted with an attorney, but did not bring suit. It is unknown whether Mrs. K contacted the OCR. The practice instituted a policy eliminating the use of photography and social media for any reason in the workplace.



*All healthcare workers have an ethical and legal obligation to protect patient privacy and confidentiality in accordance with state and federal law, and according to the Lifespan Social Media Policy, "may not publish any content that is related to a Lifespan affiliate patient."*

*Insights is published by Lifespan's Department of Risk Management Loss Prevention division.*

*Submissions and ideas are welcome and may be submitted to the department or faxed to **401-444-8963**.*

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