Center Updates: a seasonal review

Health Apps and Health Policy: What is Needed?

Summary by Zoe Burns, Project Coordinator

In a JAMA opinion piece, Drs. David Bates, Adam Landman, and David Levine identify the gaps of mobile health apps, including their safety, privacy, and efficacy. Although 325,000 health apps have been developed, not all are safe, effective, or even targeted toward an at-need population. According to the authors, several reports have recognized that health apps are not meeting the needs of patients or clinicians. For example, 3 of 4 smartphone apps have incorrectly diagnosed 30% of melanoma cases as benign. Many current apps are intended for healthy people, while very few exist for those with chronic, high-cost conditions, or those with a low level of English literacy.

The current regulatory approach for these apps was created for hardware, not software, in 1976. With the goal of introducing a more appropriate method for regulating “software as a medical device”, the US Food and Drug Administration (FDA) recently created a “precertification” program for mobile apps. Pre-Cert will be piloted in 9 companies and is expected to report on the quality control processes of the software they produce. Unlike in other areas, such as medication approval, the FDA will not require evaluation of whether the apps improve outcomes. This is a major shortcoming of the proposed solution.

The authors offer a multipronged policy approach to enhance the value of health apps:

- Evaluations of health apps need to be more rigorous and standardized. The FDA should assess apps for safety, privacy, and false claims.
- Federal research support should be geared toward improving outcomes, particularly for the populations in need.
- Data exchange from health apps to electronic

Improving Electronic Health Record Usability and Safety Requires Transparency

Summary by Taylor Christiansen, Research Assistant

In a JAMA viewpoint piece, Ratwani et al. describe the need for transparency between clinicians, researchers, and developers in order to improve electronic health records (EHRs). Over recent years, the use of EHRs in US health care system has increased greatly. The transition from paper-based clinical record keeping to EHRs has many potential benefits for clinicians and patients. However, as the authors explain, this transition also brings some major challenges, including difficulty in using the EHR, additional time needed to perform certain tasks, and frustration in performing tasks. EHR usability describes the extent to which this technology can be used efficiently, effectively, and safely by clinicians to deliver care. There is an association between EHR usability and potential harm to patients, which is a cause for concern. One example of potential harm associated with EHRs described by the authors is medications being ordered incorrectly for a patient because of a cluttered visual display. Improving EHR usability and safety is a top priority of federal government agencies, like the Institute of Medicine and the Joint Commission.

Ratwani et al. emphasize that a major problem in addressing the issues related to EHR usability and safety is the inability of clinicians, researchers, and developers to communicate openly about the challenges associated with EHR technology. Medical device companies are required to report when usability and safety issues occur, but some EHR vendors resist sharing key information about such incidents. Many contracts signed between EHR vendors and health care organizations include “gag clauses” that prevent health care organizations from...
Sittig and co-authors identify nine key, short-term challenges that must be prioritized for successful integration into healthcare organizations.

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Current Challenges in Health Information Technology-Related Patient Safety

**Summary by Kerrin Bersani, Research Assistant**

While health information technology (IT) has potential to improve patient care, several challenges must be overcome to ensure effective implementation of new technologies into healthcare systems. The field must focus on shared responsibility, a sociotechnical approach, correct and complete use of technology by all healthcare providers, and collaboration between healthcare organizations and electronic health record (EHR) vendors to monitor and optimize technology. These requirements are taken into account in a recent article by Dean Sittig and co-authors, who identify nine key, short-term challenges that must be prioritized for successful integration of health IT into healthcare organizations. The challenges fall into one of three stages of the health IT lifecycle: 1. Design and Development; 2. Implementation and Use; 3. Monitoring, Evaluation, and Optimization.

Relating to the “Design and Development” stage, Sittig et al. introduce challenges that must be addressed during the planning of new, or improvements to existing, health IT. New estimates on severity and frequency of estimates, must be determined based on data to help prioritize efforts to develop controls that reduce future risk. There are also inconsistencies in designer interfaces across different EHR systems, which lead to data entry errors by providers, calling to attention the need for standardization in design, development, and testing of safety-critical software. To ensure interoperability of health IT, the authors recommend that the industry or government should develop regulatory guidelines. Lastly, there is a need to establish methods for accurately linking patients across organizations, locations, and time.

The “Implementation and Use” stage focuses on implementing health IT into healthcare organizations with two targeted challenges. First, per the authors, health IT currently relies on “alerts” and “reminders” sent to clinicians that often trigger inappropriately, and in some cases may be ignored. Instead, technology should make it easier to do the right thing and catch errors by providing proper clinical decision support. The second concern identified by the authors is the need for smoother transitions across IT systems, for example between an in-house developed EHR and a commercial EHR vendor. Despite decades of research focused on health IT best practices, uncertainty around how to facilitate these changes remains.

The “Monitoring, Evaluation, and Optimization” stage of the health IT lifecycle focuses on continued improvement. The authors stress the importance of examining outcomes of health IT implementations by developing additional scientific knowledge, methods, and tools that will advance real-time measurement, automate surveillance, and initiate safety improvement efforts. When EHR-related safety concerns occur, the authors suggest the creation of a mandatory, blame-free, national or international health IT reporting system to consolidate and examine serious patient safety issues. Finally, as access to personal health records expands, patients and their caregivers will be able to take more responsibility in their care and may potentially play a role in improving health IT by reporting errors to clinicians.

Collectively, the challenges addressed by Sittig et al. represent some of the most compelling steps that need to be considered as health IT continues to grow. Addressing these issues throughout the health IT lifecycle will ensure the future of technology in healthcare will be more effective at improving patient safety.

Health Apps

(Continued from page 1)

Health records should be facilitated by interoperable application programming interfaces. The goal of this would be to automate processing of incoming data for clinician monitoring.

- The FDA should provide a way for the public to easily access information on the quality of each app. Assessment of quality could rely on factors such as: honesty of claims, health and technical information, security and privacy, ease of use, and popularity. Evidence could be presented via an open-source directory and the FDA could issue standardized facts labels for each app (much like a nutrition label).

Bates, Landman, and Levine contend that it ought to be a priority of the FDA to encourage and support production of easily identifiable, effective mobile health apps. While health apps have great potential to improve efficiency and lower costs, for their benefits to be realized they must be able to provide patients and clinicians with the assurance that they are both safe and effective.
Diagnostic errors and delays are increasingly being identified as significant, global patient safety concerns. They represent the leading cause of medical malpractice claims and a recent National Academy of Medicine report suggests that every person will experience at least one serious diagnostic error during their lifetime. Diagnostic tests, images, and labs can be crucial in determining a patient’s medical condition, assuaging fears, and reassuring clinical decisions. However, these diagnostic tests can be costly and potentially harmful to the patient, so medical systems and “Choosing Wisely” campaigns are urging their decreased use. In a recent article in the Annals of Internal Medicine, Schiff et al. suggest that under- and over-diagnosis are similar, and can both be addressed by using a more thoughtful, caring, and conservative diagnostic approach. To demonstrate this, the authors brought together an international panel of clinicians, health policy experts, educators, and communication experts to identify ten principles to improve clinical decision-making and guide health policy surrounding the diagnostic process.

The first principle is to promote clinician caring and listening. While clinicians often rely on tests to eliminate diagnoses, this can decrease the weight placed on the patient’s history and physical examination, which may diminish the patient’s collaborative efforts. Furthermore, it is important to prioritize patients by addressing their concerns rather than solely focusing on establishing a diagnosis. Since diagnoses can change with time, Schiff et al. suggest an integration of scientific medicine, patient-centered care, and mutual decision-making to focus on more greatly on caring, thorough, and respectful listening. The second principle is the need to develop better ways of acknowledging, understanding, and communicating uncertainty in a clinical context. This can be achieved with awareness of clinicians’ and medicine’s limitations, understanding uncertainty in the medical field, and developing effective methods to communicate this uncertainty with patients, and better ways to characterize this uncertainty, such as more thoughtful differential diagnoses. Third, clinicians should be more thoughtful in how symptoms are matched with diseases, including patients with “medically unexplained” symptoms, mental illnesses, problems rooted in social circumstances, and homogeneous symptoms often misattributed to other diseases. Fourth, clinicians and practices should work towards maximizing the continuity of care. This can be achieved through better scheduling, increased telephone and virtual contact, and continuous insurance coverage. Fifth, clinicians should devote more time to the diagnostic process. Notably, practices should develop better systems to monitor patients longitudinally, which would allow clinicians to utilize watchful waiting, an instrumental part of a conservative diagnosis. The sixth principle recommends establishing a closer link between a diagnosis and possible treatment options, which can be attained by involving patients more closely in decision-making. Seventh, diagnostic testing must be utilized more strategically. This can be achieved using better test selection, timing, and interpretation coupled with improved understanding of test benefits, limitations, costs, and potential harms. The authors’ eighth principle urges clinicians and practices to learn from their previous diagnostic errors and to be aware of specific red flags and key pitfalls. In addition, practices should incorporate patient safety culture lessons, while staff and patients should be encouraged to discuss, reflect, and learn from errors and near misses. The ninth principle addresses the fears and challenges associated with cancer diagnosing. They discuss the need for a balance: clinicians should educate patients on the adverse consequences of false positive tests and over-diagnosed cancers while continuing to stress prevention. The final principle Schiff et al. describe is aimed at enhancing the diagnostic stewardship of specialists and emergency departments. Beyond ensuring appropriate triage and strategic diagnostic test use, specialists and emergency department clinicians can provide evidence to guide more conservative diagnostic strategies and then use them in practice.

Given the significant patient safety concerns that diagnostic errors pose, it is important to find ways to decrease their frequency and potential harm. Schiff et al. promote the use of “safety nets” to ensure conservative diagnosing, such as increasing continuous and trusting patient relationships and facilitating patients to question their diagnoses. The authors hope to improve the quality, safety, and efficiency of the diagnostic process through the use of their ten key principles for more thoughtful, conservative diagnosis.

Calling All Runners! — Join 10K Road Race Representing DGIM’s Team Patient Safety

Please join the DGIM Team Patient Safety to run for charity as part of the Boston Athletic Association’s (B.A.A.) 10K® road race presented by BWH. Patti Dykes PhD, RN is the Team Patient Safety’s captain. Please consider joining the team as a runner, a walker, or by contributing to this worthy cause!

The money raised will support the Brigham and Women’s Hospital’s Center for Patient Safety Research and Practice directed by David W. Bates, MD, MSc which is recognized as a world leader in developing knowledge and technology to safeguard patients. Established in 2004, the Center has an extensive track record for excellence in making innovative contributions to building safer healthcare, particularly in the area of medication safety, and reengineering healthcare delivery by using and developing advanced technology tools and concepts intended to reduce medical errors and to improve healthcare quality with a focus on patient-centered care.

To Register:

Team Member Instructions to register on CrowdRise
1. Go to: https://www.crowdrise.com/o/en/campaign/Patricia-Dykes
2. Select ‘Register’ in yellow on the right-hand side
3. Choose ‘Team Member – Early Bird’
4. You have the ability to choose your fundraising commitment
   a. $300 fundraising commitment per individual runner
   b. $500 fundraising commitment per individual runner which includes guaranteed access to post-race party following the 10K
5. Select ‘Team Member’
   a. Team Patient Safety should pre-populate!
6. Fill in the information for registration
7. Complete your registration!

Schedule:
- February 27-March 13: Early bird registration*
- March 14: General registration opens
- June 21: Reception for team captains
- Sunday, June 23: B.A.A. 10K road race
  - 6:30am: BWH tent opens
  - 7:15am: Join teammates on the Boston Common Baseball Field for a team photo
  - 7:40am: Walk to start line corrals
  - 8:00am: Run the 2019 B.A.A. 10K
  - 8:30am: Join BWH for a cool down stretch in front of the awards stage
  - 9:30am: Enjoy the B.A.A. awards ceremony on Boston Common
- Exclusive BWH post-race party: Teammates who raise $600 and teams with a fundraising average of $600/per runner are welcome to come back to the BWH tent after completing the race to enjoy brunch and beverages!

To Donate: https://www.crowdrise.com/donate/project/patricia-dykes/patriciadykes1
Comparison of a Prototype for Indications-Based Prescribing with 2 Commercial Prescribing Systems

Summary by J.P. Garcia, Research Assistant

Over the last 40 years, many medication safety organizations have endorsed the inclusion of the reason for a medication, or indication, on written prescriptions and medication bottle labels to enhance the safety and cognizance of prescriptions. Yet, several obstacles have impeded the implementation of this adjustment into prescription practice, such as the increase in the time burden on the prescriber for this additional step, inadequate software design, and ambiguity surrounding the benefit of including the indication. Still, physicians, pharmacists, and patients all support this practice when surveyed. In a study published by JAMA Network, Garabedian et al. describe their development of a prescribing prototype that captures indications and evaluate its performance against the prescribing interfaces of two vendor electronic health records (EHRs) in a simulated test environment.

The authors designed an indications-based prescribing computerized provider order entry (CPOE) system that allowed a prescription order to be placed through either the search of an indication or the selection of a problem from a problem list. Based on the selected indication, patient-specific medication options, informed by factors like evidence-based guidelines and patient contraindications due to drugs, allergies, or intolerance were presented in green (suggested choice), yellow (alternative choice), or red (not recommended choice). The indication was automatically displayed, except in cases where the prescriber had concerns about sensitive information, such as instances of sexually transmitted infection. Internal medicine faculty, residents, and physician assistants who were using either Epic or Cerner EHR systems to prescribe electronically in the outpatient setting were recruited as participants from Partners HealthCare and the University Illinois Hospital. Garabedian et al. tested usability by having participants review a medication option and calculate a mean time for the prototype that was significantly faster than both vendor systems. Out of the 256 test scenarios, 7 out of the 128 (5.5%) prescribing orders completed on the prototype were categorized as an error. In contrast, 38 of the 128 (29.7%) completed on a vendor system were considered an error. Errors were calculated based on independent review by two pharmacists and one physician arbiter.

The study results demonstrate that Garabedian et al. developed a novel CPOE prototype system that transformed how prescribers order medications by allowing them to start with prescription indication, thus authorizing the computer to recommend optimal drug regimen options. They observed that this method outperformed two prominent vendor electronic prescribing systems in terms of efficiency, error reduction, and satisfaction. The study team acknowledged that this intervention was performed in a simulated test environment with only eight scenarios. Additional usability issues will likely arise when the simulation is scaled up. Furthermore, a bias in favor of the prototype may have been introduced by the lack of blinding the study participants. However, participants had less experience with the prototype compared to their respective vendor systems, which theoretically should have advantaged the speed and comfort of those established systems. Despite this, the results showed that orders were completed using the prototype in roughly half of the time and entry clicks required for the vendor systems to perform the same tasks. Therefore, this study suggests current applications have substantial gaps in effectiveness, and the adoption of this kind of prescription module configuration could increase efficiency and decrease prescribing errors while providing patients with useful information to assist with proper use of and adherence to medication.

Francois Bastardot, MD is a research fellow who joined the Center for Patient Safety Research and Practice in September 2018. To describe Dr. Bastardot in few words, he is a compassionate physician, forward thinker, wonderful husband, avid hiker, and a pleasant person everyone in the Center should meet.

Dr. Bastardot grew up in Colombier, a small village near the city of Lausanne in French part of Switzerland. He has a younger brother and sister, who work as a professor in engineering and a nurse, respectively. After studying Classical Studies (Latin and Ancient Greek) in Morges, Dr. Bastardot attended medical school at the University of Lausanne, where he also completed his residency in General Internal Medicine. During medical school, Dr. Bastardot spent two years working on the CoLaus study, which seeks to better understand the causes of cardiovascular and mental diseases. From this experience, Dr. Bastardot improved his skills tremendously in epidemiology.

Following residency, Dr. Bastardot worked for the “Medical Direction Team” at the University Hospital of Lausanne, where he developed, implemented, and taught prescription modules in the electronic health records (EHRs). Although he faced many challenges in this position, Dr. Bastardot was one of the first clinicians in Switzerland to work with nurses, information technologists, and professors to develop modules in the EHR. Through this experience, Dr. Bastardot developed a profound interest in clinical informatics, which he strives to learn more about here at the Center.

Dr. Bastardot is involved in multiple projects with the Center. He is an active contributor in:

- The Safe Care Study
- A project involving validation of a machine-learning approach for opioid prescriptions
- The Measuring Outcomes in Orthopedics Routinely for development of a ‘Care goal achievement following hip and knee arthroplasty’ patient-reported outcome-based performance measure (PRO-PM) study
- MED2DAY for allocation of Internal Medicine resident time in Switzerland, where he uses geolocation and IT log trail
- A personal project examining the clinical decision support in Heparin-Induced Thrombocytopenia (health information technology)

Through these projects, Dr. Bastardot hopes to improve his knowledge and skills in medical informatics, including patient safety, clinical decision support, SAS, SQL, EPIC, and Swift just to name a few. Dr. Bastardot is planning to publish an article regarding documentation approaches in the EHR and physician typing skills in the coming months. But most importantly, he hopes to bring his new knowledge, expertise, connections, and ideas back to the University Hospital of Lausanne (and collective Switzerland) to improve medical informatics education and practices there. Dr. Bastardot states that there is currently a lack of "medical informatics experts" at Lausanne. He therefore aspires to become the first Chief Medical Informatics Officer to implement this field at the hospital. In doing so, he aims to promote stronger patient safety culture and clinical decision support tools and knowledge base that will eventually expand beyond Lausanne. Moreover, he hopes to change the mindset of physicians in Switzerland who are not accustomed to sharing EHR information and notes with patients through services like Patient Gateway.

Dr. Bastardot is grateful to have this opportunity to be here at the Center for Patient Safety Research and Practice. He is impressed with, and inspired by, the strong innovation culture, as well as excellent mentorship and collaborations across Partners HealthCare. Dr. Bastardot expects that Switzerland will face health information technology challenges similar to those which Boston clinicians have encountered, but 10 years down the road when their EHR implementation is more widespread. Dr. Bastardot hopes to prepare his nation for these challenges, and the hospital of the future, by preemptively strengthening and adapting medical

(Continued on page 8)
Selected Publications by members of the Center


Improving EHR Usability and Safety

Ratwani et al. propose a culture of safety that encourages identification and dissemination of usability and safety issues related to EHR products.

sharing specific information about the purchased EHR product—such as visual examples (screenshots, videos, etc...) to illustrate a specific issue—without authorization from vendors. Furthermore, the authorization process to get content reviewed is often lengthy, without guarantee of obtaining permission at the end. While it is important to recognize the need to protect intellectual property, the inability to share critical usability and safety information influences product improvement and patient safety initiatives.

A policy enacted in the 21st Century Cures Act in 2016 stipulates that a condition of EHR certification is that vendors cannot prohibit or restrict the communication of usability-related information. While this is a major step forward, Ratwani et al. believe that three main criteria still need to be considered when defining the blocking of usability and safety information.

The first criterion is “Blocking to prevent the Conduct of Usability and Safety Research.” Criterion 1 requires that basic EHR functionality for usability and safety testing be made available for researchers using test cases or simulated clinical scenarios to study EHRs. The second criterion is “Blocking to Prevent Participation in Usability and Safety Research.” Criterion 2 prohibits adverse actions from being taken by EHR vendors to dissuade health care organizations and clinicians from participating in usability and safety studies. The final criterion proposed by the authors is “Blocking the Dissemination of Usability and Safety Information.” This requires EHR vendors to permit the release of information in a timely manner when the material informs the usability and safety of the EHR product.

In summary, the policies recommended by Ratwani et al. propose a culture of safety that encourages identification and dissemination of usability and safety issues related to EHR products. Government policies should enable research on usability and safety, and comparisons of usability among EHR vendors. These policies are important for patient safety and clinician satisfaction and will help improve patient care and EHR technology.

Global Fellows Corner


informatics systems and education in anticipation of this paradigm shift and associated obstacles.

Dr. Bastardot currently resides in Boston with his wife Isabelle, who is a nurse. If you want to learn more about Dr. Bastardot, including his work, background, experience in Switzerland, hobbies, and stories from his amazing two-month road trip in South America with his wife, he welcomes you to kindly reach out to him at fbastardot@bwh.harvard.edu.

The Center is elated that Dr. Bastardot has joined its community of researchers, and excited to see how he shares the lessons learned from his clinical informatics projects with his colleagues in Lausanne.

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