Insight & Perspectives

A publication of Sompo International Insurance's Healthcare Practice

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Our U.S. and Bermuda teams provide healthcare professional liability coverage to non-profit and for-profit hospitals and other healthcare organizations.

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We are pleased to offer our latest installment of **Insight & Perspectives**. This newsletter is dedicated to sharing healthcare news, trends and developments impacting our brokers and insureds. This installment features ERC Risk Solutions' article *Digital Health Technology is the Brave New World: So, What's the Risk?* exploring the opportunities and challenges associated with today's increasingly digital healthcare landscape. As always, we appreciate your continued support and thank you for selecting Sompo International Insurance to be a part of your risk and insurance programs.
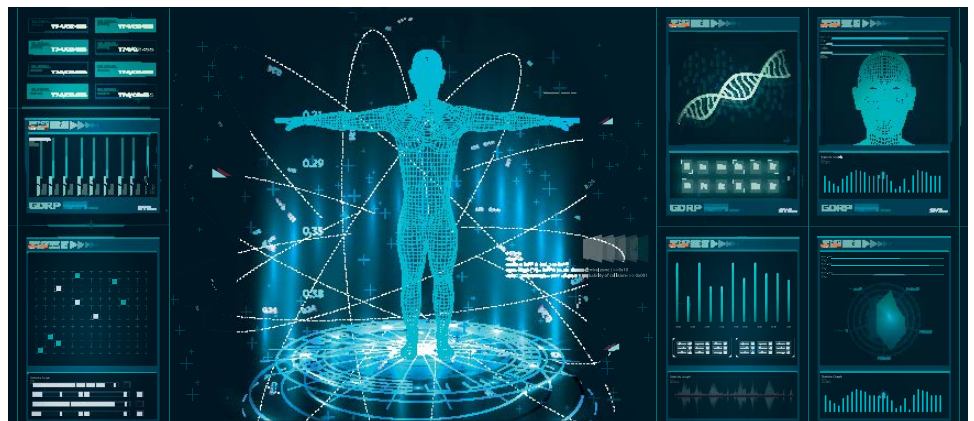
Digital Health Technology is the Brave New World: So, What's the Risk?

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According to an American Medical Association study on digital health, most physicians see potential for digital tools to improve patient care and ranked tools that improve patient safety and diagnostic ability highest in importance. Respondents also identified malpractice coverage, data privacy and workflow integration (with their electronic medical record) as essential requirements for adoption.[1]

This edition of *Insight & Perspectives* explores the broad range technological advances currently in use across the target classes we serve, along with some of the steps healthcare organizations can take to reduce potential liability and alleviate patient safety concerns.

The Future is Now

Advances in medical technology offer new and more efficient ways of delivering patient care. Today, healthcare technologies aim to perform a variety of patient care functions from cost-effectively predicting and preventing disease to enabling the management and treatment of a broad range of conditions. Understanding and managing the risks associated with these technological advancements can help adopters to reap the rewards of this brave new world of healthcare.

With the increasing use of artificial intelligence (AI) in healthcare technology, some futurists are predicting that **technology will reduce in-person clinical**.

Specifically, AI is enabling:

- Complex medical problem-solving through advanced analytics
- Healthcare providers to rapidly recognize patterns in large data sets, shortening the time and improving the accuracy of diagnoses
- The reduction of human cognitive bias and fatigue among healthcare practitioners, increasing diagnostic accuracy, and providing valuable information to treating providers for care planning

Further, smartphone apps and other remote monitoring devices help to make healthcare available at patients' fingertips. From millennials to gen Xers and tech savvy boomers, today's digital patients are connected by technology and engaged through social media by wearables and smartphones.

Mobile apps now offer patients the same digital control over their medical information as they have for their banking, purchasing, and online social interactions.[2] Digital patients are no longer passive recipients of medical treatments, but rather active participants in their healthcare, sharing medical information via digital tools to determine their own health status and increase their control over outcomes.

Current Applications

Clinical Decision Support System (CDSS) apps are helping to drive the development and adoption of technology across the healthcare industry. Companies such as Cerner, First Databank, Allscripts, Truven, Elsevier, Zynx Health, Medispan[3] and others are introducing a range of CDSS tools that include:

- evidence-based order sets,
- drug interaction and allergy alerts,
- reminders for preventative care,
- calculation of prediction rules and severity of illness assessments (e.g., Pneumonia Severity Index), and
- duplicate testing alerts

Advanced CDSS tools, such as the computerized algorithms used for the early identification and treatment of sepsis, can retrieve information from a patient's electronic medical record, match it to a diagnostic database and offer suggestions for possible diagnoses.

While CDSS tools are not yet fully autonomous, they are currently augmenting the work of medical professionals. For example, an FDA-cleared ECG smartphone app now enables patients engaged in their heart health to get a low cost medical grade ECG anytime they want or need it. The app can detect abnormal heart rhythm and atrial fibrillation, with the ability to send the reading to the patient's doctor with the push of a button.[4]
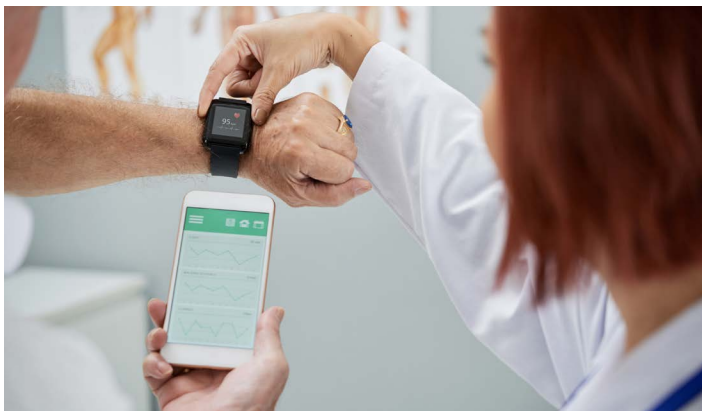
A variety of other devices are being used to collect patient health status and data for remote patient monitoring, as well as real-time medical interventions and care management. Examples include a spirometer that when used more frequently by a patient indicates increased asthma symptoms and a scale that monitors and alerts a provider to certain weight gain/loss parameters for intervention.

Some devices are used in combination with telehealth services or in-person visits. One diabetes intervention study that combined digital programs with human coaching realized sustained patient engagement and notable improvements in glucose control and weight loss, demonstrating a successful model that optimizes digital health with provider interventions.[5]

Risks to Implementing Digital Healthcare

Despite the benefits that digital healthcare tools offer, many providers have been hesitant to adopt and offer mobile and digital care options to patients because of the privacy and security risks.[6] It's important to understand the risks and take steps to eliminate or mitigate them before implementing any new digital healthcare tools. This should begin with a comprehensive digital health liability risk management program that addresses four key areas of consideration: technology risks, legal and regulatory requirements, patient safety and insurance.

Technology Risks

Potential cyber breaches, data security threats from hackers, ransomware and other cyber-attacks are increasingly part of the digital healthcare technology landscape. As a result, information systems and electronic health records, as well as medical devices and technologies and digital tools used for patient care and monitoring should be part of an overall technology risk management program that utilizes firewalls, encryption, secure storage, and other measures to prevent loss or theft of protected health information.

User training and validation of competency, scheduled maintenance, the establishment of protocols for use, security measures, quality controls, and back-up systems should be considered as part of the healthcare organization's technology management program.

Digital tools and devices should also be assessed for the potential severity and probability of harm related to failure prior to implementation.

Legal and Regulatory Requirements

Legal risks of using digital tools in patient care include compliance with the privacy and security requirements for the protection of personal health information (PHI) under HIPAA (Health Insurance Portability and Accountability Act) regulations. Careful assessment and planning is necessary in conjunction with the organization's information services team, legal counsel and privacy officer.

Patient informed consent should be obtained and recorded to ensure patients understand the purpose of the digital tools and consent to their use for medical care and monitoring. Patient education about the tools should also be provided and documented. Digital tools should be integrated with the patient's electronic medical record so that monitoring, reports, alerts and interventions are noted as part of the record for continuity of care.

Patient Safety

To help ensure patient safety, digital monitoring devices should be supported on the back-end with the resources necessary to receive and act on reports and alerts as the device transmits them. Further, patients and providers should take steps to reduce the potential for

alert fatigue or the over reliance on monitoring systems, which can lead to failures or delays in identifying or acting on medical problems when they occur. When integrating digital tools into patient care and remote monitoring, healthcare organizations should:[7]

- Establish protocols that define monitoring parameters and accountability for responding to reports, alerts, and communications

- Ensure that patient-specific parameters are set for reports and alerts and are approved by the provider

- Require training and education for providers and staff on the devices, monitoring systems, and protocol

- Establish an auditing system to verify that the reports and alerts are received and acted on in a timely manner and that reports, alerts, and interventions are documented in the patient's medical record

Insurance

In addition to medical liability coverage and business insurance, cyber liability coverage is recommended to protect against losses and claims resulting from patient data being stolen, exposed, held for ransom, or improperly shared. Cyber liability insurance should cover both first-party losses (i.e., damages suffered by the policy holder for business interruption, data restoration and third-party losses), as well as claims and legal costs resulting from patient lawsuits.[8] Organizations should also verify that the vendors and developers of any digital tools and devices being used also have cyber liability coverage.

Take Away

Healthcare organizations looking to keep pace with the rapidly changing world of digital healthcare should take steps to ensure close collaboration between technology vendors and their information technology, health information, risk management and legal teams in order to safely implement and optimize digital and mobile applications.

Patient communication, treatment and monitoring along with the storage of healthcare information are all being enhanced to function more efficiently through innovative healthcare technology. However, the best technology and AI are still no substitute for provider experience[9] or effective provider-patient communication. New technology must be thoroughly evaluated and incorporated into an organization's overall technology risk management program prior to adoption to ensure its ability to promote enhanced, safe patient care protecting patients and providers alike.

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