Regulatory Challenges for Artificial Intelligence Applications in Healthcare

Posted 15 June 2018 | By Samyukta Rajkumar, MS Dr. Stephen F. Amato

This article addresses regulatory challenges associated with using artificial intelligence in healthcare. The authors explore challenges in regulating "digital health" and review various pathways to gain regulatory approval for artificial intelligence applications to be employed in healthcare. They recommend potential approaches for resolving regulatory challenges that may arise with the use of new technologies and discuss the variety of FDA initiatives aimed at helping to solve AI regulatory challenges.

Introduction

Artificial Intelligence (AI) originated in the 1950s with the goal of enabling a machine or computer to think and learn like humans.[1] AI has been extensively utilized by various industries, such as finance, aviation and marketing.[2] However, the use of AI is relatively new in health care, making only small steps toward a what promises to be a vast, multidimensional opportunity. The three areas for the utilization of AI in healthcare ARE the areas in which human healthcare providers make decisions: screening, diagnosis and treatment planning.[3] In these areas, AI can analyze complex patient data, consider existing research data, best practices and evidence (also referred to as machine learning), to identify the best course of action for the patient. In short, AI seeks to do what a human healthcare provider does, but do it more efficiently and effectively.[4] One important area for consideration is how regulators will view AI use and what, if any, regulatory requirements must be amended or instituted to "normalize" the use of AI where it may not only replace quality human intelligence, but potentially exceed it.

Examples of AI Applications in Healthcare

While there are many uses for AI in the healthcare industry, one of the most important is in radiology, where AI applications are being developed to automate image analysis and diagnosis.[5] For example, AI applications could highlight areas of interest for a radiologist and drive better efficiency as well as reduce human error.[6].

There is also an opportunity for fully automated AI applications to read and interpret an image.[7] For

example, Merantix, a German company, utilizes an AI application to identify lymph nodes in Computer Tomography (CT) images.[8] Radiologists can do this, of course, but they may charge $100 per hour and may be able to carefully read only four images per hour, much slower than AI can read and interpret an image. This is an example of how AI applications in healthcare are driving efficiency via reduced time and cost.[9]

Another current utilization of AI in healthcare is to identify at-risk patients. By analyzing vast amounts of historical patient data, research and best practices, AI applications can provide real-time support to healthcare providers by helping identify patients who may be at-risk.[10] AI applications have been used to identify re-admission risks and patients with an increased chance of returning to the hospital within 30 days of discharge. Such data helps reduce avoidable healthcare costs both to the system and to the patient and further, improves the quality of care as patients may be able to start treatment earlier than ever before.[11]

The increasing utilization of AI in the healthcare sector is altering operations and decision-making within organizations and improving efficiency and response times.

What are the regulatory associations to consider with AI?

While AI has been driving better data analysis, AI utilization in healthcare has been raising important regulatory issues that go to the heart of AI development. A fundamental concept of AI is the use of software algorithms to analyze data, learn from it and then make a determination or prediction. AI works best when significant amounts of rich patient data (also known as "big data") are available to optimize the performance of algorithms.[12] In healthcare, getting access to "big data" may pose a wide range of challenges and raise a multitude of concerns.

Accessing personal medical records is protected by strict regulations such as the Health Insurance Portability and Accountability Act (HIPAA) and the General Data Protection Regulation (GDPR) based on issues of patient privacy and the ethics of data ownership.[13] Privacy and confidentiality also refer to the scope, proper storage of, access to and dissemination of data, especially highly sensitive or personal data.[14] There is increased risk for privacy violations as the scope of the collected data continues to grow quickly and the data is being housed electronically in "the cloud."[15] Additionally, data anonymization does not ensure against patients being identified through joining of data sets, aggregated data, manipulation of data or other improper uses.[16]
In the context of "big data," the Internet and the potential for stored data to be "hacked" and mis-used, these become serious regulatory concerns.

Where AI applications in healthcare touch on "ownership" (who controls or possesses data), who allows access to the data and who may gain from having intellectual property that is subsequently developed, raises serious issues as well.[17] Medical information, the key source for AI applications in healthcare, is not "owned" in the same sense that a physical object or even intellectual property is owned in other settings. Patients, healthcare providers and hospital systems are all stakeholders who may have intersecting rights and responsibilities when it comes to individual medical records.[18] However, there is no single law that regulates ownership of healthcare data. Instead, healthcare data is a combination of federal, state and international laws regulating how patient and healthcare data should be governed.[19]

Another issue to consider is when the patient data required for building AI algorithms is of the quality

and usability of data required for building AI algorithms. In other industries, vast amounts of data are generally reliable and accurately measure, (e.g., aircraft engine sensors or car location and velocity data to predict highway traffic).[20] However, in healthcare, data is often subjective and inaccurate, based on documentation offered by healthcare providers. This kind of quality raises concerns about the algorithms associated with AI applications as they may be built on inaccurate data.[21] When AI algorithms are built on poor and "noisy" data, the results also may be inaccurate.[22] Unlike a healthcare provider who would have contextual information about a patient or even relying on intuition developed over years of practice, the results from applications can be narrow and incomplete.[23] Therefore, healthcare providers are needed to analyze and provide context for the results gained from AI applications.

This leads to the question of "who is liable should the AI application provide improper results?"[24] The issue of liability is another concern. If diagnosis or treatment is controlled by this technology, does the AI company assume liability for the patient's wellbeing or is the human healthcare provider still responsible?

Of the many challenges associated with the utilization of AI in healthcare, such as the privacy, quality, usability and ownership of data along with accuracy and liability of AI applications, all must be overcome to truly gain benefit from AI applications in healthcare which, the hope is, could ultimately improve patient outcomes.

FDA's Position on Digital Health

The challenges discussed above regarding the AI applications in healthcare must be addressed by regulatory agencies such as the US Food and Drug Administration (FDA) to ensure that only safe and effective medical devices reach the market.

The Federal Food, Drug, and Cosmetic Act (FDCA) was initially crafted to address medical devices that created and existing in the mid-1970s.[25] During that period, medical devices were based on a "build and freeze" model—iterative technology and changes were relatively infrequent.[26] However, this is not how modern-day AI applications typically work. The algorithm associated with an AI application changes every time new data is introduced, thus producing, in effect, a "new" medical device every time new data is introduced.[27] Consequently, FDA will have to change its current "build and freeze" regulatory approach to account for iterative technology, such as AI applications that are constantly changing with data input.

Recently, both FDA and the US Congress have taken several steps to address concerns about regulation of the digital health sector, including AI applications. FDA launched a Digital Health Program responsible for developing and implementing a new regulatory model for digital health technology.[28] The Digital Health Program has developed and implemented a new regulator model by issuing several guidance documents, such as the *Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data Guidance* which explains FDA's oversight of digital health technology.[29] Further, Congress passed the *21st Century Cures Act (Cures Act*) in December 2016.[30] The *Cures Act* contains provisions clarifying FDA's jurisdiction over digital health products such as AI applications. Legislators singled out AI in the *Cures Act* for its ability to be used to support decision-making in healthcare and referred to this application of AI as "Clinical Decision Support" (CDS).[31]

FDA also introduced the Digital Health Software Precertification (Pre-Cert) Pilot Program, also offering insight into possible regulatory approaches for AI applications.[32] In this voluntary program, FDA is working on creating a tailored approach to regulating digital health technologies by analyzing the

developer of the software rather than the product; this is the opposite to how FDA currently regulates medical devices.[33] The Pre-Cert program is already undergoing a pilot program and pilot participants, including Apple, Fitbit and Verily have been selected to participate. The participants will provide FDA access to measures they use to develop, test and maintain software products, including those with which they collect post-market data.[34] Although this approach is promising, it is unclear how all of this will work under the existing laws and regulations governing medical devices, suggesting that a revamp of the law and regulations may be needed prior to implementation. FDA is also evolving its current regulations and ways to accommodate the new and iterative digital health technology, such as the AI applications that are entering the healthcare field.

Regulatory Implications for the Industry

Based on FDA's publications, experience and the current state of regulations, companies with AI products will have to contemplate how aggressive their intended use will be as this will determine the classification of the device.[35] Indications for use requiring a healthcare provider's interpretation are likely to be identified as Class II products, with several predicate options already existing. However, products with indications for use that are beyond a healthcare provider's interpretation are likely to require clinical trials via the means of a Premarket Approval (PMA). Depending on the product and the intended use, manufacturers could seek to "down-classify" the product through the *de novo* process. FDA has recently proven to be flexible in several instances by allowing AI to be added to existing technologies without placing the technology in Class III, and thus requiring a PMA.

Further, manufacturers should be ready to expect change as it is clear FDA is working toward evolving its current regulatory landscape to provide more guidance and redefine the regulatory approach for digital health products such as AI applications. FDA appears to be open to stakeholder input regarding the evolving regulation of new digital health products as the FDA has been engaged and listening to stakeholders.[36] This period of transition provides a great opportunity to engage FDA as a partner in shaping the future of digital health. FDA is exploring new approaches to regulating medical devices with iterative changes to encourage innovation, especially AI applications with the potential to significantly change the healthcare system. As a result, FDA is looking for opportunities to work with manufacturers toward evolving the current regulatory landscape to better suit iterative products such as AI applications.

Conclusion

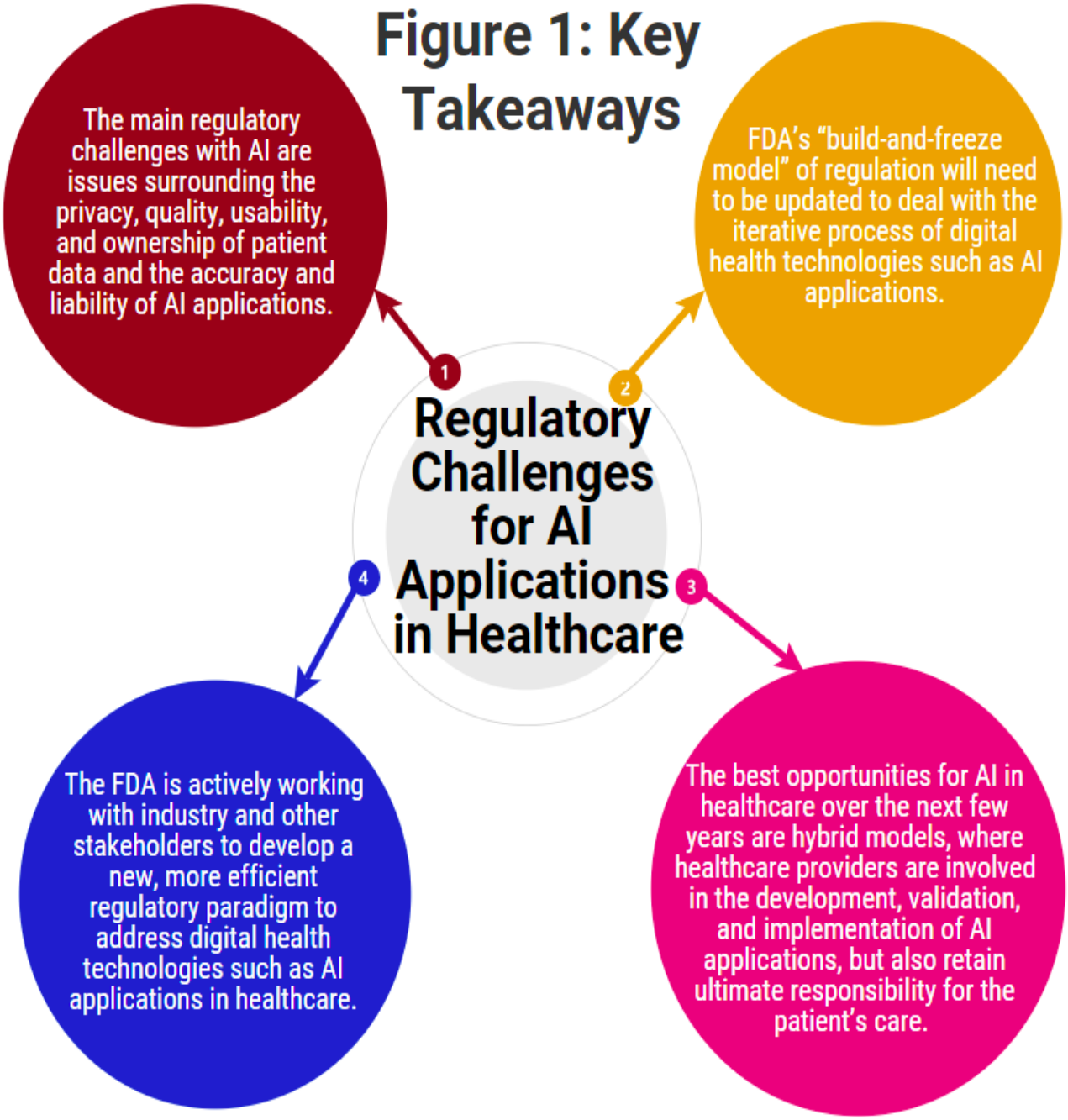
What are the next regulatory steps?

While AI-based medical products hold tremendous potential, the question of their regulation has challenged regulatory authorities. Healthcare applications of AI are dauntingly complex with little transparency and therefore are creating concerns about privacy, quality, usability, ownership of data and the accuracy and liability of AI applications. FDA introduced the *21st Century Cures Act (Cure Act)* and the Digital Health Innovation Action Plan to improve regulation of AI applications in healthcare. However, despite these attempts to enhance the regulation of AI, there are still gaps and challenges surrounding the AI applications. FDA has demonstrated their investment in improving the regulatory oversight of digital health products in consultation with industry. This "partnership" will likely aid those developing AI-based products. If several key challenges can be addressed by FDA in the coming years, AI

could play a leading role in how medical devices of the future operate and help ensure optimal patient outcomes.

Key Takeaways

Figure 1. Key Takeaways



- The main regulatory challenges with AI are about privacy, quality, usability, the ownership of patient data and the accuracy and liability of AI applications.
- FDA's "build-and-freeze model" of regulation will need to be updated to deal with the iterative process of digital health technologies such as AI applications.
- The best opportunities for AI in healthcare over the next few years are hybrid models, where healthcare providers are involved in the development, validation and implementation of AI applications, but who also retain ultimate responsibility for the patient's care.

- FDA is actively working with industry and other stakeholders to develop a new, more efficient regulatory paradigm to address AI applications in healthcare.

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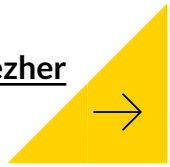

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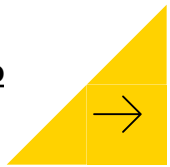

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