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ISSUE BRIEF

Artificial Intelligence in Clinical Care

The term artificial intelligence (AI) is now commonplace. Yet in spite of its ubiquity, few of us really understand what AI is, let alone how it works. AI refers to the programming of computers to solve large, complex problems in ways that simulate human learning from example. AI computer algorithms learn to solve problems by searching very large sets of data to identify patterns and deviations from those patterns: Think of the autocorrect function on your smartphone text message app.

One important use of AI in health care—AI used directly in clinical care to diagnose and treat patients—has been the subject of thousands of research studies, yet apart from the relatively well-developed field of diagnostic imaging, this effort has led to only a small number of real-world applications.

Some Prominent AI Applications for Clinical Care

An ***artificial pancreas*** is a partially implanted device for patients with diabetes that combines a continuous glucose monitor with an automated insulin delivery system to maintain a stable blood sugar level. Recent models have been developed that use an AI-based algorithm to adjust insulin dosage multiple times every hour. One of these newest models is in use throughout the European Union and has been submitted for US Food and Drug Administration (FDA) approval in the United States.

Sepsis—severe blood infection—increases the risk for major complications and death in hospitalized patients. An ***AI algorithm to predict the risk for sepsis*** in patients in intensive care units has demonstrated in multiple peer-reviewed studies, including a randomized controlled trial (RCT), that its use results in a nearly two-thirds drop in sepsis-related deaths.

A growing number of AI applications tell patients the likelihood of their having a given health condition based on symptoms entered into a phone-based app. These ***AI-based symptom checking apps*** have been in use without being subject to FDA approval, although several have been assessed in published trials.

KEY POINTS

- Artificial intelligence (AI) generally refers to the use of computer algorithms to solve large, complex problems in ways that simulate learning.
- AI applications are being used in all aspects of health care, including in diagnosis and care recommendations, as well as a small number in treatment delivery.
- Except for the interpretation of diagnostic images, the number of applications of AI currently in use or under development in clinical medicine is still relatively small and mainly limited to cardiovascular disease and diabetes.
- The market for AI applications is growing, although a number of challenges need to be addressed, including effectiveness and safety testing, bias, and interpretability.

But as AI makes greater inroads into healthcare delivery and decisionmaking, all of us—patients, consumers, caregivers, healthcare professionals, payers, researchers, and other stakeholders—need some understanding of what it can or may soon be able to do to improve health care. What challenges impede progress? And what is needed to overcome the barriers to implementing AI to improve health care?

To understand this emerging technology in clinical care beyond the well-established imaging-based applications and to answer those questions, we set out to identify AI-based products that have been developed for use in clinical care. We focused on nine conditions representing a spectrum of common patient health conditions, as well as general health (see table, AI Applications in Clinical Care).

Where Do AI Applications in Clinical Medicine Stand in 2021?

We found that as of early 2021, apart from diagnostic imaging applications, 109 applications—specific AI-based products—are in current clinical use (67 of the 109 applications) or are in development for possible near-future use (the remaining 42 applications). Nearly all these applications are focused on cardiovascular disease (CVD), diabetes, cancer, or general health, while only a few address the other six conditions we focused on: cerebrovascular, kidney, and respiratory diseases; dementia; substance use; or mental health conditions (see table, AI Applications in Clinical Care).

The functions served by those applications generally fall into one of three categories:

	**Patient Evaluation and Clinical Care**	**61%**
Assessing current health status or disease risk, such as a primary care patient's risk for developing diabetes based on her sociodemographic profile and personal history		
	**Health Recommendations**	**30%**
Providing guidance on patient treatment or self-care behaviors to address a health issue, such as a recommended medication dose		
	**Treatment Delivery**	**9%**
Directly delivering care to a patient; for example, a smart insulin pump		

Most applications were intended for use by healthcare professionals (55 percent), while others were designed for patient use (33 percent) or for use by both patients and providers (11 percent).

What Is the Evidence for AI in Clinical Medicine?

We also examined the extent and type of publicly available evidence concerning the use of these AI applications. While some applications were the subject of rigorous research studies, including RCTs, we found relatively little published evidence supporting the use of others.

Among the applications we identified, 94 have been evaluated in 173 studies. Nearly half of these studies were performance tests, in which AI applications were simply tested against various data sets without involving their actual use in patient care. Of the 22 FDA-approved applications, only four were evaluated in a peer-reviewed RCT, the most robust type of study, which requires careful protocols and often large numbers of participating patients. We found no published evidence available on 14 applications in current use.

Just as some conditions—like CVD and diabetes—are the focus of a greater number of applications, applications in these areas are also supported with a larger body of evidence. Interestingly, most studies of diabetes applications are RCTs, while most of the evidence for CVD applications comes from performance tests. Notably, the application with the largest number of RCTs was an algorithm for predicting sepsis in intensive care patients.

What Sort of Federal Approval Process Do AI Applications Undergo?

The FDA regulates some AI applications using the same review process it applies to medical devices and has approved 22 of the applications we identified. These included apps to detect abnormal heart rhythms, monitor patient deterioration, or aid patients with diabetes self-management. All were deemed Class II—moderate risk—devices, and most underwent a streamlined review process due to their similarity to already approved, non-AI-based products.

Another 45 applications are in current use without having undergone FDA review. A few are used only outside the United States. Most of the others—like symptom checkers or noncommercial risk calculators— are in use in the United States but have not been subject to FDA review as they pose less direct risk to patients.

The remaining 42 applications are in development. The FDA is likely to designate some of these, such as the new artificial pancreas currently undergoing clinical trials, as Class III devices, which carry the highest risk to patients and therefore undergo the most rigorous approval processes.

AI Applications in Clinical Care

	FDA Approval Status		
Health Condition	**FDA Approved**	**In Use without Approval**	**In Development**
Cancer	1	2, 1	2
Cardiovascular Disease	11	7, 1	4, 1, 4
Cerebrovascular Disease	None	1	4, 1
Dementia/Alzheimer's	None	3	2
Diabetes	1, 3	5	1, 4, 2
Kidney Disease	None	None	1, 1
Mental Health	None	3, 3	1, 1, 1
Respiratory	3, 1	1	1
Substance Abuse	None	None	1
General	6	10, 3, 1	8, 2

What Is on the Horizon for AI in Clinical Care?

Of the 109 AI applications we identified, 42 were still in development, though they show promise of being adopted for use by 2025—either because they are currently in field testing or have been submitted to FDA for approval. These include several applications for treatment delivery as well as for mental health and dementia evaluation.

Still, the use of AI applications in clinical care is an all too perfect example of the translation chasm—the barrier between technology development and real-world application. Crossing that barrier will require facing a number of important challenges raised by our stakeholders.

- The variability in the quality of the published evidence surrounding AI applications likely relates to uneven resources and incentives—many applications are being developed by small startup companies rather than by large research enterprises. In addition, until recently, a framework for designing and reporting these kinds of studies has been lacking: the recent publication of new voluntary guidelines for study design and reporting on clinical trials of AI applications is a promising step toward improving evidence quality in the future.
- Differences in algorithm accuracy and performance, especially among different ethnic and racial groups, must be addressed. This important concern, which has both clinical and ethical implications, will require resources to design better algorithms and evaluation methods and expand data sets to increase equity and representation.
- Interpretability—how to understand application findings—is a major concern, since many AI applications cannot reveal how they make decisions, making them essentially a black box. Understanding findings will require applications to provide users with meaningful context, e.g., what factors went into determining the findings.
- Patient privacy and data security are frequently voiced concerns, both for developing and using AI applications. A healthcare industry cybersecurity task force was mandated by Congress in 2015 to address these concerns and issued a report in 2017. Since then, both the federal government and healthcare industry have been taking steps to mitigate the threat, but many concerns remain.

CONCLUSION

The use of AI applications in clinical care is still in its earliest stages. Nevertheless, recent and near-term developments—along with earnest attempts to address problems—suggest that AI will play an increasingly important role in delivering care to patients in the years ahead.

This issue brief is based on a report. For more information, see:

Girosi F, Mann S, Kareddy V. Narrative Review and Evidence Mapping: Artificial Intelligence in Clinical Care. Patient-Centered Outcomes Research Institute; February 2021. Prepared by RAND under Contract No. IDIQ-TO#22-RAND-ENG-AOSEPP-04-01-2020. The full report may be accessed at: www.pcori.org/emerging-tech

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