RAPIDAI

Artificial Intelligence-Powered Clinical Decision Support:

The Value of Contextual Data in Vascular Medicine

"AI is the future of medicine, and the future of medicine is in AI." That statement doesn't come from a software developer. It comes from neurosurgeon Alejandro Spiotta, MD, professor of neurosurgery and neuroendovascular surgery, vice chair for neurosurgery, and division director of neuroendovascular surgery in the Department of Neurosurgery at the Medical University of South Carolina (MUSC).

While artificial intelligence (AI) will no doubt shape the future of medicine, it's already here. AI has streamlined clinical and administrative workflows for more efficient patient care. It also allows radiology departments to process vast amounts of images, and it converts doctors' notes into usable data for other analyses.

In addition, AI played a role in two landmark clinical trials—DAWN and DEFUSE-3—which led to a significant change in American Heart Association (AHA) and American Stroke Association (ASA) stroke guidelines. AI was used to identify patients who may benefit from mechanical thrombectomy outside the then-standard six-hour treatment window. The results of the two studies led AHA and ASA to extend the treatment window for select patients to up to 24 hours.[1]

AI also advanced clinical decision support (CDS) software, from simple reminders and drug information resources to sophisticated platforms that truly support clinical decision-making. AI-enabled CDS software analyzes information at a level unmatched by humans and complements physicians' empathy, clinical experience, and hands-on skills.

As the amount of available healthcare data has swelled and as developers apply more powerful techniques and algorithms, AI-enabled CDS software has far surpassed the abilities of traditional CDS systems.[2] Basic AI-enabled CDS products offer triage and notification. More sophisticated systems go beyond to offer interpretive, diagnostic, and predictive information that helps physicians make precise decisions faster.

Think of these tools as a combination of a whip-smart, 24/7 resident, a genius radiologist, and an intuitive administrative assistant, all in one. And although some developers may argue otherwise, these indefatigable tools won't replace trained medical specialists anytime soon, if ever. They stand at the ready to provide cognitive support to help physicians deliver more personalized care.

In vascular/neurovascular medicine, AI-enabled CDS software further supports physicians by confirming or denying their interpretations of images. A few select products identify anomalies that the human eye can't even see. This level of detail allows physicians to proactively treat conditions like aneurysms, potentially lowering the risk of rupture and improving patient outcomes.

Not all AI-enabled CDS tools provide this level of clinical depth. Basic triage and notification tools offer value by simply warning of a suspected condition, without additional context on the clinical parameters which led to the suspected determination. Tools with clinical depth go beyond this suspicion to help identify, locate, characterize, and quantify a condition with an unrivaled degree of accuracy.

To move the needle on outcomes for vascular/neurovascular patients—a necessity in value-based healthcare environments—physicians and healthcare organizations must integrate AI-based tools into their clinical workflow. When treating conditions where every minute matters—where every unnecessary transfer means tens of thousands of dollars lost—relying on manual measurements and time-consuming games of phone tag will no longer do.

This white paper explores the clinical and operational value of AI-enabled CDS with clinical depth, specifically as it relates to vascular conditions. It outlines the level of detail these tools provide, their unparalleled specificity and sensitivity, and what it all means for the future of healthcare.

The Value of Clinical Depth

Advanced, AI-enabled CDS software generally provides several functions:

- It sends reminders or alerts.
- It automates mundane, repetitive tasks, freeing up physicians and clinicians for higher-value activities.
- It standardizes processes and workflows that are subject to variability.
- It recognizes patterns in images, test results, and other large datasets.

All these features have value because they potentially improve productivity, reduce risk, and ensure consistency. The ability to detect patterns in data enables some tools to catch disease earlier than manual methods.

AI-enabled CDS software with clinical depth provides these functions and then some. They provide contextual information that typically takes humans years to learn. They may also provide information that's beyond current human capability. And they do it at a speed that no human can touch.

Despite its inhuman capacity, the source of clinical depth is human-generated. The contextual information provided by AI-enabled CDS software stems from a combination of

talented engineers who develop advanced algorithms trained on vast datasets. Software developers must also solicit input from experts in vascular and neurovascular medicine. Multiple clinical trials and ongoing retraining and refinement take that tool from effective to effective and remarkably accurate that, in the end, improves the overall outcomes of patients.

"The level of quantification and tissue characterization offered by tools with clinical depth requires a certain amount of fairness in your algorithms, as well as in-depth understanding of engineering, anatomical structures, and segmentation techniques," said Amit Phadnis, chief innovation and technology officer at RapidAI. When you put these characteristics together, it's a definite value add for physicians."

The Shallow Pool: Triage and Notification Tools

Many AI-enabled CDS products simply notify physicians of a suspected condition. They alert physicians to the possibility of a problem, and the physician uses his own judgment to determine how to respond.

"These tools serve as a heads-up for the physician to prioritize a scan and find the problem," said Greg Albers, MD, chairman, cofounder, and scientific lead RapidAI. "It puts the scan to the top of the queue, which is useful because if a patient does have a brain hemorrhage, you want to know about it right away."

Notification tools can also produce false positive alerts, however. When combined with alerts from other systems integrated into the electronic medical record (EMR), these "false alarms" contribute to alert fatigue and the tendency to override alerts.[3] Inappropriate override puts patient safety at risk—the opposite of CDS's intended purpose.

CDS software must go through rigorous training and validation to get the algorithms to work as accurately as possible. With that, alerts sound when it matters.

"It's frustrating for physicians when software gives a false positive five percent of the time," said Dr. Albers. "We retrain our algorithms with additional data to eliminate those false positives. We also conduct additional studies to get programs to perform at a higher level and later retrain systems to integrate with a new protocol or a new scanner."

The Deep End: CDS with Contextual Data

While notification tools get physicians' attention, true clinical decision support must provide specific, relevant contextual data to make a significant impact on clinical care. Instead of signaling a suspected problem, the tool must accurately identify the problem, its severity, and its location or region of interest.

For example, RapidAI's Rapid CTP is the only clinically validated software with an FDA indication to aid in the selection of acute stroke therapy patients. It provides color-coded CT perfusion (CTP) maps that identify the following:

- Areas of the brain with tissue death
- A prediction of how quickly damage will progress
- How much tissue is salvageable

- Brain regions with reduced cerebral blood flow, volume,
- and transit time that exceed pre-specified thresholds
- Whether the patient appears to be a candidate for
- mechanical thrombectomy

The software delivers CTP maps within two minutes of a scan through PACS, email, and/or a mobile application. Physicians can determine whether a patient is suitable for a thrombectomy in minutes from anywhere.

"Physicians have to synthesize a lot of information to put together a story of the patient," said Rachel Witalec, vice president of product and strategy for RapidAI. "The less they have to hunt for that information, the faster they can decide what to do next. Clinical depth with context from EMR data gives them that synthesized view. Even if it doesn't affect timelines, the impact on cognitive load is significant."

Aneurysms are another use case for how AI-enabled CDS software impacts patient care. Software with clinical depth does more than notify physicians of a suspected bulge. These products accurately identify and measure aneurysms to help physicians determine a course of action based on the risk of rupture.

In a retrospective study of 51 patients, Rapid Aneurysm identified cerebral aneurysms on CT angiography with a sensitivity of 95%, specificity of 100%, and accuracy of 99.7%.[4] Another retrospective study found that by calculating both volume and surface area measurements—detail radiologists can't measure manually—the tool detects changes in aneurysm size more accurately than current methods.[5]

"If the patient develops a new bleb, maximum linear diameter may not change, but there's a bulge that increases the risk of rupture," said Dr. Albers. "Having that detailed information allows physicians to better assess rupture risk and provide treatment if necessary."

How AI-Enabled CDS Helps Identify and Prioritize Patient Care

Early intervention is paramount to reducing the risk of death and disability for acute vascular conditions. Efficient processes help ensure patients receive treatment as fast as possible, whether from their local hospital, a vascular center, or a comprehensive stroke center.

However, pervasive physician and clinician shortages, as well as a scarcity of beds, negatively impact the timeliness of care and, therefore, patient functioning and survival.[6] If a patient presents with stroke symptoms, for example, a regional hospital may not have a neurologist available. They may also not have the staff or the systems in place to assess, discuss, and transfer patients to the comprehensive stroke center fast enough to prevent serious disability. Out of an abundance of caution, they may transfer patients who may not have a stroke at all.

A study examining futile transfers in France hospitals found about 45% of transfers were unnecessary. Of these, over half (58.4%) showed clinical improvement or reperfusion upon arrival, while others either clinically worsened or experienced longer than expected inter-hospital transfer time.[7] Futile transfers not only add unnecessary hospital costs but also place an undue burden on patients and families.

An advanced AI-enabled CDS system with in-app communication facilitates faster, more accurate patient selection and transfer in two ways:

1. It eliminates phone tag. When physicians need to discuss a suspected stroke patient, they don't have 15 minutes to wait on hold. Yet, they do. One-way lines of communication waste precious time they could otherwise spend delivering care.

Instead of multiple phone calls, a treating physician or clinician can notify the entire care team with one message through a smartphone app. Instead of waiting for a report or making decisions based on reports read over the phone, clinicians can access images concurrently.

> **"AI empowers physicians to review images and make decisions simultaneously. By communicating in parallel instead of in series, we can reduce patient triage evaluation times by 20 or 30 minutes, which is invaluable for patients suffering from stroke."**
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> **– Alejandro Spiotta, MD**
> Department of Neurosurgery at MUSC

2. It reduces futile transfers. With AI-enabled tools and mobile apps, referral centers can quickly review images from outside hospitals. With information available via a mobile or web-based app, providers can identify patients who are likely to benefit from transfer and who can be managed safely at community hospitals. Paper-based algorithms and decision trees also live within an app, which allows care teams to activate and manage the workflow more efficiently.

Jeremy Heit, MD, PhD, a neurointerventional surgeon and interim Chief of Neuroradiology at Stanford University, estimates that before adopting AI-based CDS software, about 30 to 40% of stroke patients transferred to his department needed a procedure. Before AI, a physician at a regional hospital may have, out of an abundance of caution, transferred a patient that exhibited stroke symptoms but was later found to have had a seizure or other non-stroke cause of their symptoms.

With AI (Rapid), the scenario changed significantly. Dr. Heit estimates since the adoption of RapidAI, Stanford's facilities have transferred fewer patients with stroke mimics. Of the transferred patients, the main campus treats 10 to 20% more. Considering one helicopter transfer costs nearly $30,000, the cost savings from fewer transfers add up significantly.[8]

AI in Action: Stanford Medicine

A patient exhibiting stroke symptoms was admitted to a hospital in the Central Valley, about 75 miles away from Stanford Medicine in Palo Alto, California. The treating physician suspected the patient needed more comprehensive care.

"I asked the physician, 'What does the imaging look like? Is the patient a good candidate for a procedure?' By the time they say yes, I've already looked at the images on my app," said Dr. Heit. "I'm on my phone at 2 a.m., and I say, 'I can see on the perfusion study that they've got a small amount of injury to the brain. I can see they've got a lot of tissue that looks salvageable. I can see whether quality of the blood flow actually looks favorable. This patient can probably be transferred without having a lot of growth and injury to the brain. And I see that you've done a CT angiogram, and RapidAI has detected the presence of a blockage in the first part of the middle cerebral artery that I can get to.' I can be very focused in my questions with the ER doc while focusing more efficiently on transferring the patient to Stanford quickly. All of that from a few succinct summary images on my phone. That's a huge difference from 10 years ago. When you have that information in front of you, the number of people you treat goes up significantly."

Early intervention also means detecting and diagnosing disease in its earliest stages when it's easier to treat. "Prognosis, treatment efficacy, and cost of care all move in a more favorable direction for both patients and health systems if disease is caught at an early stage of evolution," said Phadnis. "AI is instrumental in detecting weaker disease signals that humans may not be able to catch."

A tool like Rapid Aneurysm finds abnormalities that may otherwise go undetected. Physicians can then offer treatment options and monitoring to help prevent a rupture. AI-based tools and techniques have also been used to diagnose various types of cancer, Alzheimer's disease, chronic heart disease, and other conditions in their early stages.[9]

Improve Speed and Accuracy of Diagnosis

The clinical advantages of AI-based CDS software with clinical depth translate to potentially fewer complications and deaths from vascular and neurovascular conditions. Those advantages lead to potential financial and operational gains—gains much needed during one of the healthcare industry's most challenging times.

Implementing AI-enabled CDS software gives vascular/neurovascular care teams immediate access to standardized expertise as well as faster access to specialists at comprehensive centers. The technology allows facilities to make more informed transfer decisions and keep patients local when possible, improving patient experience and assuring the right level of treatment while conserving resources.

"Imagine a system in which all your referring hospitals have access to the same high degree of expertise in interpreting critical image," said Dr. Spiotta. "It would only take minutes to log into the system, interpret an image, and determine the level of care that's required. In some cases, it's more valuable to the patient and family to stay close to home. With limited EMS, ambulances, and helicopters, we want to reserve them for the patients that need them most."

Allegheny Health Network, a nonprofit academic medical center based in Pittsburgh, Pennsylvania, reported in a study that it lowered its CT angiography to groin puncture time from 93 minutes to 68 minutes in patients with LVO or high-grade stenosis. The improvement occurred during a one-year period of using Rapid CTA to detect these conditions.[12]

A savings of 25 minutes per stroke patient helps save millions of neurons, which can directly impact morbidity. It also saves physicians and clinicians precious time they can devote to patient care.

Limitations: The Black Box and Bias

For all its potential, AI-enabled CDS software isn't without challenges. True accuracy depends largely on the data used to train and validate the device. In addition, the algorithms that draw conclusions from these data are difficult, if not impossible, to understand and explain. That mystery is referred to as the "black box." Questions around both the data and the outputs have impacted the trust users have in these devices.[13]

What is the Black Box in AI?

W. Nicholson Price II, a law professor at the University of Michigan Law School who focuses his practice on innovation in the life sciences, defines the black box this way:[14]

> Sometimes, algorithms are nontransparent because, while they may rely on explicit rules, those rules are too complex for us to explicitly understand…In particular, these rules may be impossible to explain or to understand by following the process of scientific/medical discovery: mechanistic lab experiments followed by confirmatory clinical trials. Other times, the relationships used in a black box algorithm are literally unknowable because of the machine-learning techniques employed—that is, no one, not even those who programmed the machine-learning process, knows exactly what factors go into the ultimate decisions. A key distinguishing feature of black-box algorithms, as the term is used here, is that it refers to algorithms that are inherently black box (i.e., their developers cannot share the details of how the algorithm works in practice)—rather than to algorithms that are deliberately black box (i.e., their developers will not share the details of how the algorithm works). Black-box algorithms are especially likely to evolve over time as they incorporate new data into an integrated process of learning and applying.

"Black box algorithms put clinicians in a bind," said Phadnis. "They don't know if they should trust themselves or if they can trust AI. If the machine is wrong two out of three times, they're going to abandon the tool and only use their judgment."

Engineers are developing techniques called "explainable AI" to overcome the black box issue and gain trust among both patients and providers. While even the FDA admits that some of the most powerful models are the least explainable, an improvement in transparency will help improve the adoption of AI in clinical care.

Data Bias

AI-enabled CDS software relies on data—lots of data—for training and validating algorithms. However, homogenous or limited data affects how well the tools apply to a wide, diverse population.

Large, heterogenous, multicenter datasets are crucial for generalizability. Data must come from a diverse segment of the population and be obtained from a range of devices that represent what's available in healthcare practices.

Data used for training must also be significantly diverse from the datasets used for validation. "If I use 10,000 cases to train and validate the model, both from the same hospital, the knowledge is biased," said Phadnis. "Your sensitivity and specificity are going to be very high, but there is not enough diversity of data. The model won't perform well in actual practice. This is one reason why the FDA has been insisting on medical device software developers to show them the diversity of the data sets used—because the numbers can be misleading at times."

Conclusion

For decades, physicians and researchers have worked to improve morbidity and mortality rates for a host of vascular conditions. Advances in treatment and imaging have helped lower mortality in cardiovascular and peripheral vascular disease over the past 10 years.[15]

Technology—specifically CDS powered by AI—will play a pivotal role in making continued improvements in these areas. We've seen the beginnings of these potential improvements in the way AI-powered CDS catches early signs of disease. We've seen it in the way it gives physicians the contextual information they need to make informed treatment decisions faster. And we've seen it in the way it helped identify patients in two studies that enabled more patients to benefit from endovascular thrombectomy.

"The combination of AI and human intelligence is what will lead to better outcomes," said Dr. Albers. "Software can pick up anomalies that a physician would miss, and a physician can pick up things the software might miss. If they work together, you have an optimal environment for clinical decision-making."

"There's no question adoption of this type of software will continue, not only in stroke care and neurovascular but also in other areas of medicine," added Dr. Heit. "It will be exciting to see their predictive capabilities evolve. What we have now is only the tip of the iceberg."

About RapidAI

At RapidAI, the work we do is anchored in a commitment to patient-centered clinical excellence. By driving confident and prompt decision-making through AI-driven medical imaging insights, clinical teams can push the boundaries of care, reduce time to treatment, and improve patient outcomes. Our platform-enabled collaboration and efficiencies drive one clear path to expanded access, because every patient deserves the best possible care. We do AI better – today and tomorrow – because we go beyond the algorithm.

This is AI Beyond the Algorithm™.

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Disclosure

Dr. Heit and Dr. Spiotta are medical advisors of iSchemaview, Inc.