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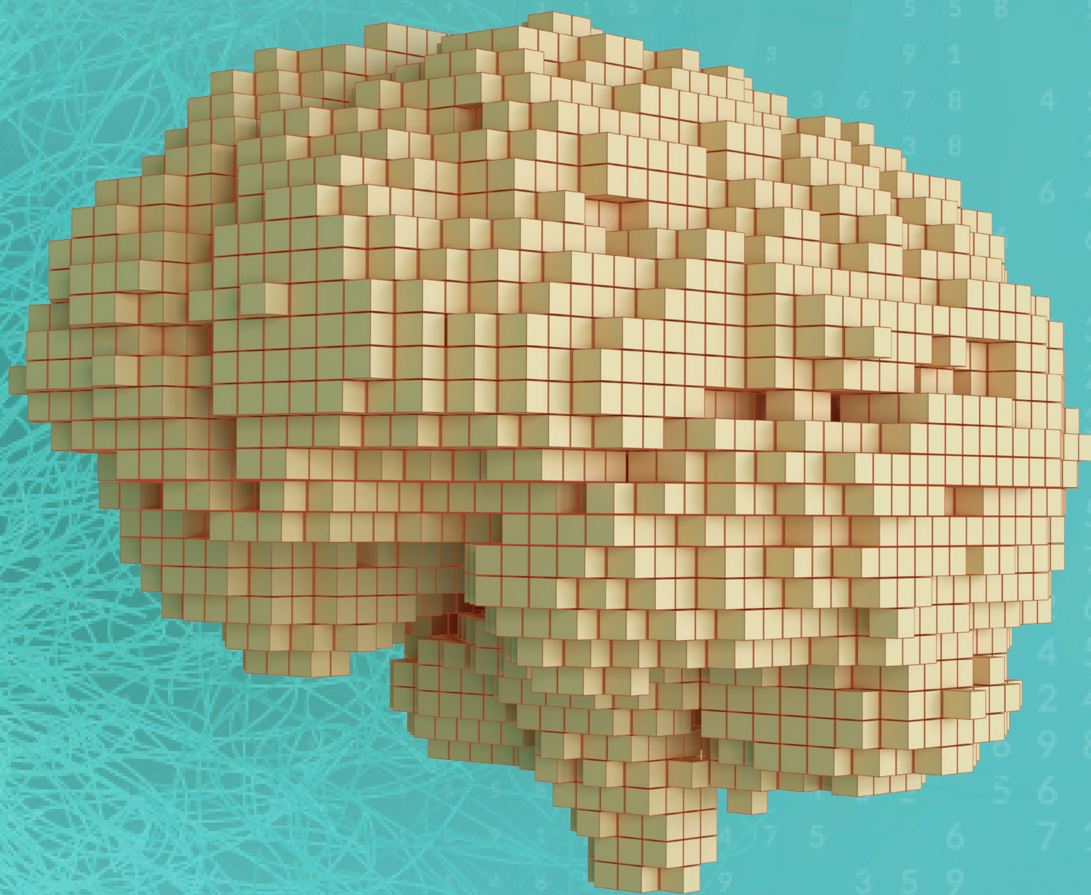

# Digital Health

## LEVERAGING TECHNOLOGY TO ENHANCE PATIENT CARE

Congress of Neurological Surgeons

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Congress of Neurological Surgeons

# EDITOR'S NOTE

**Ellen L. Air**
2022-23 Co-Editor

**Clemens M. Schirmer**
2022-23 Co-Editor

We are excited to present this issue of the *Congress Quarterly* which delves into the transformative power of digital health solutions in the field of neurosurgery and healthcare at large. Whether "digital health" conjures up thoughts of artificial intelligence (AI), augmented reality (AR), or merely digital records, the digital revolution has ushered in an era of unprecedented possibilities for healthcare providers and patients alike.

The CNS is here to partner with our membership on this journey. Key to this is our Data Science Committee. This interdisciplinary field aims to unearth actionable insights not apparent from traditional analyses. Eric Oermann and Mo Bydon highlight the pivotal work of this committee, from educational courses to scholarships in Data Science.

One standout feature in this issue is an in-depth look at how the Samsung Medical Center has harnessed cutting-edge technology to run a hospital more efficiently and effectively than ever before. From electronic health records to telemedicine solutions, their approach serves as a model for healthcare institutions seeking to leverage technology for improved patient care.

David Langer takes us on a journey through the world of patient communication and outcomes in the digital age. Through the lens of Playback Health, we explore how digital tools are not only enhancing patient engagement but also leading to better health outcomes, particularly in neurosurgery.

Dan Orringer's article sheds light on the exciting developments in automated neuropathology diagnostics, particularly his experience trialing such technology at Northwell Health. This breakthrough promises to revolutionize the way we diagnose and treat neurological conditions.

Wearable technologies are no longer confined to fitness tracking. Jang Won Yoon's exploration of the use of wearables in studying recovery after spine surgery demonstrates how these devices are becoming indispensable tools for monitoring patient progress and tailoring care plans.

Jason Ellis shares insights from his engaging discussion with Nate Gross, co-founder of Doximity. Current use cases for artificial intelligence in Neurosurgery are explored. The potential for artificial intelligence to revolutionize the delivery of neurosurgical care and make practices more efficient are explored.

Aimee Degaetano provides valuable insights into the regulatory landscape surrounding triage, diagnostics, and predictive technologies. Understanding these frameworks is essential for healthcare professionals and innovators seeking to navigate this rapidly changing terrain.

A notable example of how industry leaders are leveraging artificial intelligence to advance patient care, Dr. Joseph Osorio explores Medtronic's AiBLE platform and its implications for neurosurgery are far-reaching. Finally, Ali Alawich and Doug Konziolka reflect on how digital education will reshape neurosurgery training and practice.

In this age of digital transformation, our mission at *Congress Quarterly* is to keep you informed about the latest developments in neurosurgery and healthcare. We hope that this issue inspires you, provides valuable insights, and sparks discussions on how digital health can be leveraged to enhance patient care. Thank you for your continued support, and we look forward to your feedback and engagement as we continue to explore the exciting intersection of technology and healthcare in future issues.

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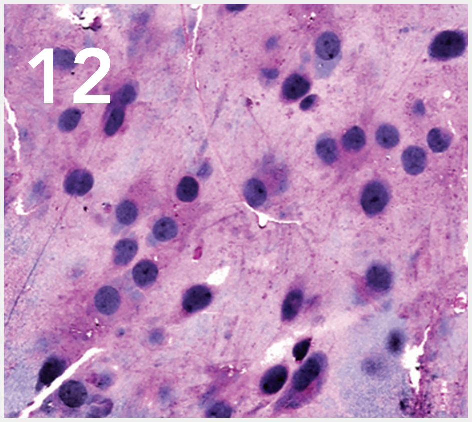
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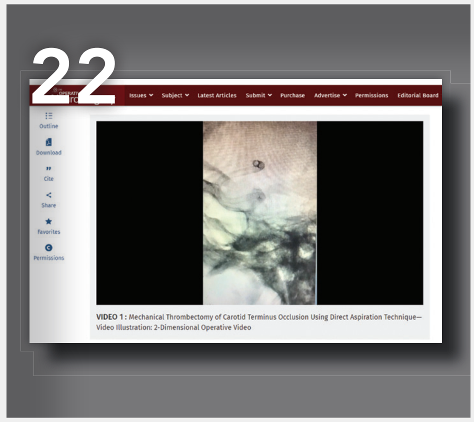
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# PRESIDENT'S MESSAGE

Alexander A. Khalessi, MD, MBA
President, Congress of Neurological Surgeons

**Dear Colleagues,**

It is a great privilege to serve the Congress of Neurological Surgeons (CNS) as your 2024 CNS President, and to bring you this issue of *Congress Quarterly*, which has been carefully curated by co-editors Ellen Air and Clemens Schirmer, as well as vice-editor Jason Ellis.

Neurosurgery has long embraced technology and novel techniques to improve outcomes and deliver the best care for our patients. With this legacy, combined with the breadth and complexity of the conditions we treat, it is only natural that neurosurgeons be at the forefront of the digital health revolution.

The CNS too has a rich history of fostering innovation—not only in the educational programs and services we offer, but also in our ability to bringing together neurosurgical experts and thought leaders across subspecialties to foster the conversations that move our specialty forward. In my presidential year, digital health will be a key focus of that innovation and collaboration.

We will continue to explore these topics throughout our educational programs this year, including the CNS Data Science Symposium this spring and, of course, the 2024 CNS Annual Meeting in Houston, Texas September 28th-October 2nd. In addition to the groundbreaking original science, expert insights and engaging presentations you have come to expect from the CNS, this year's Annual Meeting will also feature a new special symposium on AI and Data Science, as well as a focused Data Science Abstracts session. I want to personally invite you and your family to join us in Houston September 28 - October 02, 2024 for this outstanding gathering.

At the opening of this issue, Drs. Eric Oermann and Mohamad Bydon share an update on the work of the CNS Data Science and Technology Committee, including a collaboration with **Neurosurgery Publications** to bring you a new *Neurosurgery Papers with Code*. This initiative will allow readers to reproduce published findings with the provided source code, and facilitate iterative advances in computational research specific to neurosurgery. *Neurosurgery* Editor-in-Chief, Douglas Kondziolka also offers a review of advances in surgical video and its role in enhancing neurosurgical educational and training, as well as development of best practices and the refinement of surgical approaches.

The CNS is committed to helping our members leverage digital health capabilities to improve their neurosurgical practices, and this issue of *Congress Quarterly* is a great step in that direction. The editors have taken care to feature digital health advances across the spectrum of patient care—from improved diagnostic precision and enhanced surgical planning, to applications for more effectively monitoring patient outcomes and progress. You'll also find several articles in this issue on ways artificial intelligence technologies can alleviate some of the administrative burdens of neurosurgical practice, giving your more meaningful time for patient care at the beside. Dr. Orringer's exploration of point-of-care histopathology,

"It is a great privilege to serve the Congress of Neurological Surgeons (CNS) as your 2024 CNS President"

ALEXANDER A. KHALESSI, MD, MBA

Dr. Langer's platform discussion on patient communication, and Dr. Ahmad's discussion of wearables in quantifying spine outcomes all demonstrate the potential for digital health advances to empower neurosurgeons in decisive care moments.

I hope you find this issue to be valuable in understanding and applying these digital health tools to work for you and your patients. And I hope you will continue to rely on the CNS to keep you abreast of new advances in these areas and to advocate on your behalf for their appropriate utilization in health care.

I am honored to be working alongside my colleagues in the CNS Executive Committee to advance these important digital health initiatives, as we may continue to serve you and help you elevate neurosurgical care in your communities and practices. I encourage you to reach out to me or the CNS Executive Committee (info@cns.org) to let us know how the CNS can better help you address your practice challenges and advance your neurosurgical career. Thank you for being a CNS member, and for your commitment to leading our specialty forward.

Sincerely,

Alexander A. Khalessi, MD, MBA

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# Digital Health

## LEVERAGING TECHNOLOGY TO ENHANCE PATIENT CARE

Eric Karl Oermann, MD

Mohamad Bydon, MD

The Data Science and Technology Committee is excited for the 2023-2024 academic year following the successes of 2022-2023 under the leadership of Sharona Ben-Haim. We plan on continuing the educational initiatives, including the CNS Data Science Fellowship and the Spring Symposium, while exploring a new focus on the software engineering behind data science.

Attendees of the CNS Annual Meeting this year had the chance to see Dr. Douglas Kondziolka talk about "The Nature of Things" and to see multiple examples of technology accelerating and shaping the nature of modern neurosurgery. We hope to start bringing those accelerating technologies to members of the Congress of Neurological Surgeons (CNS) through the Data Science and Technology Committee. Large language models (LLM), most famously ChatGPT, have become the modern face of generative AI, and the Neurosurgery Language Model promises to be the first of its kind —an LLM trained specifically on the subject matter of a medical specialty (neurosurgery). Making this novel technology available to our members, in addition to providing educational material on language models and AI, is one of our goals for this year and captures our focus this year on both educating and building.

In coordination with *Neurosurgery* we will be promoting a first-of-its-kind article type dedicated to publishing computational research, *Neurosurgery Papers with Code*, as part of *Neurosurgery Practice*. This new article type will explicitly include links to code, datasets, and other necessary resources for reproducing and building upon computational research in neurosurgery. By facilitating the sharing of code as well as ideas, we also hope that this will help elevate the state of neurosurgical data science by disseminating best practices and software implementations throughout our community.

We also hope to start building a new home for neurosurgical data science and artificial intelligence on the web by expanding the CNS web content offerings around data science and artificial intelligence. In addition to discussions around a stronger web-presence, we've begun brainstorming ways to use generative AI to augment the world-class content within CNS Nexus. By making CNS Nexus more searchable and accessible, we will hopefully further drive users to experience and benefit from the case-based knowledge stored within Nexus.

The field of neurosurgery is intimately related to technology and technological innovation, and finding ways of expediting the integration of data science and artificial intelligence has always been the goal of the Data Science and Technology Committee. This year we hope to provide a glimpse of a new way to accomplish this mission, by starting to develop and engineer digital technologies for the CNS and its members.

**The CNS Data Science scholarship, designed to provide residents with structured mentorship in the use of advanced data science techniques, including artificial intelligence, for research and practice improvement in neurosurgery.**

*Dr. Lauren Stone was selected as the 2023-24 recipient for her work studying adaptive, AI-driven learning as the next frontier in educational theory. Dr. Stone will be working with CNS SANS to develop an adaptive learning module for ABNS written boards preparation that will use both a spaced-repetition algorithm and a subject-repetition algorithm, recognizing the patterns in user's answers and targeting questions and resources to bolster understanding in areas of deficiency.*

Katherine G. Stark

David J. Langer, MD

# Leveraging Digital Health to Improve Patient Communication and Outcomes

## Introduction

Traditionally, healthcare technology has been focused upon the backend processes of email, security, and the Electronic Medical Record (EMR). As patient experience becomes increasingly valued, new technologies are entering the patient-facing space, rather than behind closed doors. Chief technology officers are now combining forces with marketing teams and clinical practitioners to develop new strategies for communicating with patients. This has resulted in a variety of new opportunities for doctors, nurses, and advanced care practitioners to develop unique methods of communicating at the point of care.

Lenox Hill Neurosurgery has been at the advent of this process since the early 2010s. Initially, the team was focused on developing strategies for direct patient communication through video, photo, audio, and text media that could be uploaded to a patient-facing web or mobile app. Due to the ubiquitous presence of smart mobile phones in New York City's physician and patient community (research suggests over 80% of patients and providers own a smart phone)[1], it makes sense to utilize the power of these computers in the healthcare space. Further, our research indicates that 89% of providers and 84% of patients at Lenox Hill are iPhone users.

While we have found that improving patient communication is valuable, and the workflow required for new technologies is relatively straightforward for providers, the adoption of these programs has remained slow due several factors. Overwhelmed with the current workflow related to EMR documentation, physicians are reluctant to learn a new software system. Further, most patient-facing features do not create obvious substantial benefits to the provider. While hospitals are focused on patient experience due to ratings and Medicare reimbursement, providers are not often directly incentivized to improve patient experience. Without incentive, it can be challenging to get physicians and advanced care practitioners to adopt new strategies that are directed primarily toward the experience of the patient.

## Leveraging Clinical Intelligence in Clinical Settings

Interestingly, the EMR presents a unique opportunity for physician incentivization to improve patient communication. The EMR has traditionally relied upon the written word, an approach that has led to a loss of conversational depth and subjectivity. Manual data entry is prone to errors and omissions, and it diverts healthcare professionals' attention away from their patients. Additionally, the administrative burden of EMR documentation adds time to a physician and nurse's day, greatly contributing to burnout.

While some practitioners use medical scribes to address these challenges, they are costly and require extensive training. Other physicians use Dragon, a speech-to-text technology that allows physicians to create dictations with their voice. However, the process of seeing a patient and creating a dictation occurs in series, as physicians must set aside time after an interaction to create their notes.

Given Lenox Hill Neurosurgery's experience with the creation of non-structured data through video and audio, alongside the advent of artificial intelligence (AI), our team was uniquely situated to tackle the problem of EMR documentation.

In 2018, Lenox Hill adopted a third-party clinical platform called Playback Health, which allows physicians to create multimedia documents in order to enhance patient-provider and provider-provider communication. One of Playback Health's features lets practitioners record patient encounters using a microphone and upload it to the patient's platform, allowing them to review the appointment or share details with family members.

Due to the large volume of video and audio files that have been collected at Lenox Hill Neurosurgery, the Playback Health team was able to develop a new feature that automatically generates documentation. This program falls under the category of Ambient Clinical Intelligence, which empowers practitioners to capture patient histories and physical examinations without the need for typing or writing. More specifically, Ambient Clinical Intelligence utilizes voice recognition software and natural language processing to identify speakers, extract medical information, and produce deliverable medical notes. Since this note is created in parallel with the patient's appointment, doctors are no longer required to engage in data entry or dictations after an encounter. Without the need to enter data, this feature ultimately gives providers an opportunity to reconnect with their patients.

To develop this feature, Playback Health uses Whisper, an open source, automatic speech recognition (ASR) library released by OpenAI in September 2022. Whisper takes an audio or audiovisual file as input and returns a transcription of the audio as output. This involved de-identifying approximately six months' worth of clinical audio data (roughly 4 TB), transcribing it, and reviewing the data for accuracy.

To safeguard patient privacy and comply with HIPAA regulations, patient information is transcribed within the Playback Health platform, encrypted, and sent to Whisper. After processing, the data is returned to Playback Health and decrypted. This information is then compiled into a SOAP (Subjective Objective Assessment Plan) note and delivered to physicians via email in under a minute. Playback Health's modern "API-first" architecture allows providers to edit, sign-off on, and deliver notes directly to their hospital's EMR.

Additionally, Playback Health offers a screen recording feature, enabling physicians to record image reviews, teach patients about their conditions, and share this video to the patient's platform. Research suggests that sharing notes with patients significantly enhances patient satisfaction.[2] Additionally, studies have demonstrated that implementing a smartphone application into patient care increases adherence to treatment.[3] Finally, this feature also improves accessibility for patients with hearing loss, as closed captions and transcriptions can be generated from the appointment's audio and video files at the patient's request.

## How Ambient Clinical Intelligence Improves the Patient and Physician Experience

Physicians and other practitioners at Lenox Hill Neurosurgery have been employing Ambient Clinical Intelligence in their practice since July 2023, and the results are impressive.

The primary benefit of Ambient Clinical Intelligence is that it releases the practitioner from the necessity of taking notes during a patient visit, dictating after an encounter, or inputting data into the EMR. This has freed the physician from their computer station, so they are able to engage in a face-to-face conversation with the patient. Additionally, physicians no longer struggle to remember every detail of the patient interaction, as this technology allows the AI to collect the conversation in its entirety as a dataset. Moreover, the program composes the most important components of the patient's history and physical into a nuanced SOAP note. Once the note is generated, the physicians at Lenox Hill either use the note in their entirety, or edit it as appropriate, before directly placing it into the EMR.

Ambient Clinical Intelligence provides the physician with the time to be a doctor, rather than an administrator. Increased time spent face-to-face improves the patient's experience and medical record quality. Given that the SOAP note is generated through robust data collection and natural language processing, physicians at Lenox Hill notice that the note's accuracy and detail are often better than what manual entry would have produced, but in a fraction of the time, and at a fraction of the cost.

Further, patients frequently express great excitement about many of the patient-facing features. For example, patients can add family and friends by request, so that loved ones can listen to the interaction if they are unable to attend an appointment. Further, patients can share appointment recordings with other physicians in order to keep them in the loop. Finally, patients experiencing hearing loss appreciate the ability to have their appointment transcribed so that they can review the interaction on their own time.

## Conclusions

Historically, information technology resource has been isolated to the backend to improve billing, scheduling, and the EMR itself; however, it often hinders patient care. While these developments are important, and the value of the EMR cannot be underestimated, the way these systems detract from the provider and patient experience is clear: not only does the creation of the medical record require valuable time, but it detracts from care at the bedside. Further, research demonstrates that the administrative burden on physicians has resulted in high burnout rates and increased stress in the workplace.[4] Ambient Clinical Intelligence presents an opportunity to improve both patient and provider experience for the first time.

Through the utilization of mobility and ambient intelligence, a new age for the medical record is on the horizon. In the future, it is likely that the human hand will no longer be necessary for information input and that the keyboard will disappear. Instead, AI paired with the human voice has the potential to radically improve the creation and consumption of the EMR.

It is evident that this technology holds vast potential in various healthcare applications, such as operative reports, billing, and inter-physician communication. This feature enables the collection of large datasets via microphones, enhancing the searchability of patient information, and improving accuracy. More importantly, however, this technology allows physicians to focus on their clinical responsibilities and spend more meaningful time with their patients. By reducing burnout and increasing energy devoted to patient care, this innovative solution is poised to enhance patient relationships and outcomes.

### Disclosures

**Dr. David Langer** is Co-Founder and CMO of Playback Health.
**Katherine G. Stark** has no conflicts of interest to disclose.

## References

(Continued on page 31

Hoon Choi, MD, PhD

Wonchul Cha, MD,

Yunsu Lee, PhD

Ryan H. Choi, PhD

# How Samsung Leverages Technology to Enhance Patient Care

Samsung is a South Korean multinational conglomerate that employees over 270,000 people in 74 countries and manufactures a wide range of products from computers to cars to clothing.[1] Samsung Electronics is the world's largest smartphone manufacturer and chipmaker.[2,3] Samsung also operates a medical school and a tertiary medical center in Seoul, South Korea. The 1,989-bed Samsung Medical Center (SMC) is ranked one of the top hospitals in the world by Newsweek, and recently became the world's first hospital to attain the highest stage in three of HIMSS (Healthcare Information and Management Systems Society) maturity models: electronic medical records (EMR), medical imaging, and infrastructure.[5,6] Given Samsung's unique position in technology and healthcare, CNS spoke with key representatives from Samsung Electronics and Samsung Medical Center SMC about how they leverage technology to enhance patient care. Dr. Wonchul Cha, Chief Medical Information Officer and Director of Digital Innovation Center discusses their use of robotics and 5G technology in achieving these key HIMSS milestones in Part 1 of this article. In Part 2, Dr. Yunsu Lee, Corporate VP and Dr. Ryan H. Choi, Principal Engineer at Samsung Electronics, demonstrate how Samsung's newly launched Health Stack v1.0 leverages wearable smart technology to enhance patient care and healthcare research.

## Part 1: Samsung Medical Center's Journey to HIMSS Stage 7 and Beyond

In April, SMC garnered international acclaim as the inaugural hospital to attain Stage 7 in three distinct HIMSS maturity models: the EMR Adoption Model (EMRAM), the Infrastructure Adoption Model (INFRAM), and the Digital Imaging Adoption Model (DIAM). Coinciding with these accolades, SMC also achieved a world-leading score on the Digital Health Indicator (DHI). These accolades underscore the breadth and depth of SMC's commitment to digital excellence across multiple domains of healthcare technology, from infrastructure and EMR to digital imaging and the overarching digital ecosystem.

The HIMSS maturity models serve as a compass, guiding healthcare institutions towards digital sophistication. INFRAM assesses the foundational digital architecture of servers and networks; EMRAM evaluates the deployment and utilization of EMR technology by healthcare providers and patients; DIAM appraises the integration and application of medical imaging technologies. The DHI synthesizes these components, offering a holistic evaluation of an institution's digital health ecosystem. SMC's strategic and insightful application of the HIMSS models has accelerated its digital transformation journey and produced measurable improvements in daily clinical practice (**Figure 1**).

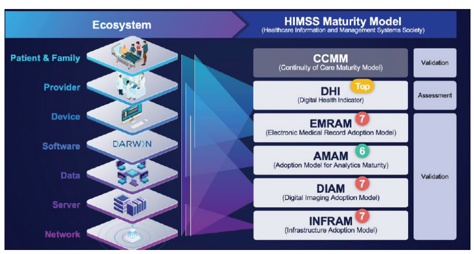


**Figure 1.** *Hospital IT and HIMSS maturity models layers.*

At the nexus of this transformation is SMC's robotic logistics system, a testament to the potentialities unlocked through digital progress. The increasing complexity of medical service provision has been met with innovative solutions to alleviate provider burnout and enhance patient care. By assuming the burden of repetitive, non-clinical tasks, robots have become an integral component of the care delivery process, enabling clinicians to reallocate their focus to patient-centric responsibilities. The integration of such technologies necessitates a robust IT infrastructure, capable of supporting complex integrations across 5G networks, building information systems, and EMR. (**Figure 2**)


**Figure 2.** *Multi-robot operation system in SMC that is connected to clinical pathways*

The implementation of robot-based logistics at SMC exemplifies the tangible benefits of this digital revolution. By reducing non-clinical workload, enhancing spatial efficiency, and optimizing delivery processes, the hospital has reduced costs while also enriching the qualitative aspects of healthcare provision. Healthcare professionals report a renewed sense of dignity and pride in their work, liberated from mundane logistic tasks. With the advent of technology, many time-intensive, morale-dampening duties can now be transferred from human to machine, allowing medical providers to return to the heart of healthcare: patient care and innovation.

The foundational principle of medicine has always been the provision of care and healing through the compassionate touch of one human to another. In today's challenging healthcare landscape, the judicious and strategic application of information technology and robotics holds the key to realizing the heart of medicine.

## Part 2: Samsung Health Stack v1.0 for Personalized Healthcare

Technology can enhance people's lives. Smart technology exists all around us and can be adapted to fit our lifestyles and needs. Smart phones, watches, tablets, computers, televisions, washers/dryers, refrigerators, lightbulbs, and even vacuum robots can now be linked and personalized. With the advent of smart wearable technology, Samsung is working to personalize and enhance healthcare and research. Currently, healthcare predominantly takes place in a medical facility, limiting health data collection to snapshots, prone to false positives and negatives. Whitecoat hypertension is one example. Holter monitor is an early example of how portable technology can be used to collect continuous data for diagnosis and management. Patient compliance and data collection would be enhanced by leveraging technology patients already use for their daily life, such as smart watch and smart phone (**Figure 1**).

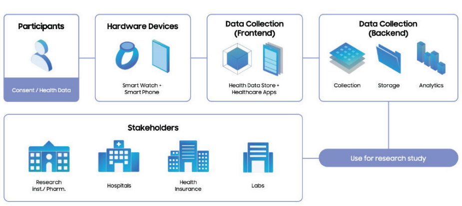


Figure 1. *Samsung Health Stack Workflow*

Samsung Health Stack was developed to bridge the gap between healthcare and wearable smart technology. It is an open-source project available for all developers, researchers, healthcare providers, and study participants (**Figure 2**). Samsung Health Stack comprises App SDK, Backend System, and Web Portal (**Figure 3**).

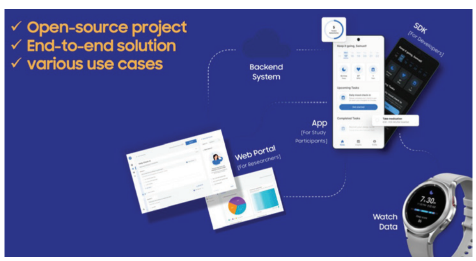


Figure 2. *Open-source project*

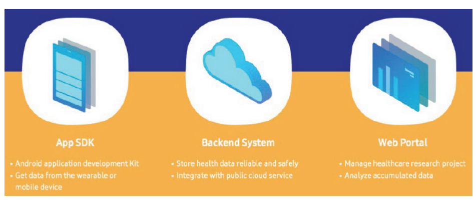


Figure 3. *Samsung Health Stack 1.0 Components*

Samsung Health Stack has been used in sleep medicine, cardiology, oncology and rehabilitation to assist with recruitment, data collection, data transfer, and data analysis (**Figures 4,5**).

Figure 4. *Clinical Example: Sleep Study*

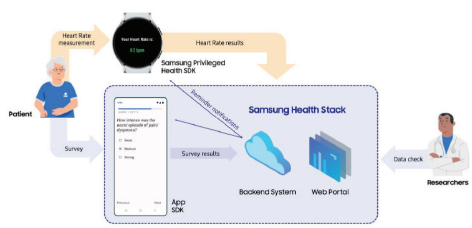


Figure 5. *Clinical Example: Cardiology*

Current and future efforts include development of disease-specific digital biomarkers and the use of artificial intelligence in expedited data management and analysis.

## References

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Jason A. Ellis, MD

Randy S. D'Amico

# AI in Neurosurgery: Current Progress and Future Horizons

The medical community as a whole has witnessed a remarkable surge in the adoption of advanced artificial intelligence (AI) systems. Physician Nate Gross, who is the co-founder and Chief Strategy Officer at Doximity, notes that "…traditionally doctors have been skeptical of AI." However, he's seen significant early interest in generative AI use cases among physicians and health systems. The neurosurgical community, in particular, has rapidly begun introducing these programs into patient clinics, research labs, and operating rooms with the promise of improving many aspects of current practice. These technologies hold great potential for transforming neurosurgical practice, from clinical decision-making and intraoperative precision to research initiatives and patient outreach. AI's promise of offering opportunities to elevate patient care and enhance scientific investigation seem manifold. When asked if GPT will be the answer for the administrative headaches many neurosurgeons encounter during daily practice today, Dr. Gross explains that AI and GPT technologies represent "…the beginning of a really exciting period for medical efficiency".

## The Current State of AI in Neurosurgery:

Dr. Gross explains that the current era of med tech was really ushered in by the exigencies of the COVID pandemic. He says that the pandemic created an environment where:

"Physicians became more acutely aware of the need to be efficient. The pressures were greater than ever and healthcare was at a breaking point. They will adopt tools that help them to do the job. The rapid, universal adoption of telehealth was only the beginning."

Artificial intelligence has already yielded tangible benefits for both patients and healthcare professionals. One of its primary applications lies in imaging-based diagnosis and interpretation. AI algorithms have proven to be proficient in assisting radiologists and clinicians in accurately interpreting complex medical images, such as MRIs and CT scans and even intraoperative pathologic specimens. They excel at rapidly and precisely digesting large amounts of data and detecting potential abnormalities thereby enhancing the precision of diagnoses.

AI has further ushered in a new era of surgical precision through the integration of AI-assisted robotic systems. These advanced technologies better enable us to perform more precise and minimally invasive procedures potentially leading to quicker recovery times, less postoperative pain, and a lower risk of complications.

Most notably however, the power of AI extends beyond the operating room. AI's data analysis capabilities have proven instrumental in uncovering previously hidden patterns and insights within complex datasets. These data can better inform the development of personalized treatment strategies tailored to individual patients' unique requirements. The result is that patients receive care that is not only more effective but also more personalized, ushering in a new era of precision medicine in neurosurgery.

## Exploring AI's Future Potential in Neurosurgery:

As we look to the future, the potential applications of AI in neurosurgery are both extensive and exciting. Conversational AI leverages natural language processing and models like the generative pre-training transformer (GPT) to enable communication between AI systems and patients. These systems, often in the form of chatbots or virtual agents, offer a myriad of benefits. They can help neurosurgeons directly by assisting in research conceptualization and design, and can assist with generation of primary documents. However, maybe more importantly, they can be trained to be a transformative point of contact between patients and physicians that is always available, thereby increasing the efficiency and effectiveness of a neurosurgical practice with associated improvements in patient care. There are innumerable possible intervention points for generative AI in neurosurgery and medicine as a whole.

For instance, health literacy is one area poised to benefit greatly from AI-driven interventions. AI can be designed to engage in dialogue with patients, asking questions and providing answers that summarize the best available medical information or materials specific to a provider's practice. This information can be conveyed in an ambient manner, where patients simply speak to their smart device and an AI prompts them with relevant information and more probing questions. This approach not only empowers patients with knowledge but can also foster a deeper understanding of their health conditions for clinicians who are delivered a succinct summary, a differential diagnosis, and evidence-based treatment recommendations based on the conversation.

Patient- and physician-facing AI systems can also provide on-demand access to prescribing information, training materials, and educational resources, all available 24/7. This continuous accessibility ensures that both patients and healthcare professionals remain well-informed and up-to-date.

Language translation capabilities, an inherent strength of AI, have the potential to bridge communication gaps in healthcare. The immediate and accurate translation of medical information can ensure that patients from diverse linguistic backgrounds receive the care they need, reducing misunderstandings and improving overall healthcare delivery.

Patient engagement can be greatly enhanced through AI. These systems can potentially facilitate patient communication, enabling symptom checking, triage, and appointment scheduling. Additionally, AI can provide tailored experiences by assisting with appointment reminders, identifying individualized resources, and improving communication between patients and healthcare providers.

In terms of interventions, AI can extract essential health information from patient records, rapidly organize and contextualize textual data, and focus on patients' specific needs. This approach streamlines the healthcare process and ensures that healthcare professionals have access to critical patient information when making decisions.

Taking this one step further, AI's role in enhancing decision-making is set to expand further. It can provide rapid decision support, offering accurate differential diagnoses and assisting in determining the most appropriate treatment plans for individual patients. By integrating AI into clinical practice, neurosurgeons will be able to access a wealth of information and guidance that helps them make informed decisions quickly and effectively.

One potential application being looked at now is based on the fact that AI can revolutionize the identification and access to clinical trials. AI will be able to pinpoint potential trial opportunities for patients, ensuring that they have access to cutting-edge treatments and therapies that may not have been otherwise available.

Finally, and most simply, AI has a role to play in enhancing both the physicians and patient's healthcare experience. By automating mundane tasks, such as appointment scheduling and administrative paperwork, AI can alleviate the workload of healthcare staff, allowing them to focus on more critical aspects of patient care. AI can simplify the process of creating discharge summaries and clinical notes. These automated systems not only save healthcare professionals valuable time but also improve patient comprehension by providing clearer and more accessible information. Additionally, AI can simplify the process of drafting letters, particularly in tasks like appeals, ensuring that essential communications are handled efficiently and accurately.

**Dr. Gross puts it in simple terms by saying that:**

*"Physicians simply want to save time. In some cases, 13 or more hours per week can be saved by cutting back on common administrative tasks. Doximity AI applications such as DocsGPT aims to help physicians do this. We are taking AI tech to the patient-facing front. It's not just in the backroom anymore with automated radiology or pathology analyses that the early AI tech focused on."*

## Ethical Considerations and Collaborative Integration:

While the potential benefits of AI in neurosurgery are profound, it is crucial to approach its implementation with meticulous care and consideration. Ethical concerns, privacy issues, and potential risks must be addressed comprehensively to ensure that AI remains a force for good in healthcare.

Collaboration is key in navigating the integration of AI into neurosurgical practice. Healthcare professionals, data scientists, policymakers, and regulatory bodies must work together to establish robust frameworks and guidelines that govern AI's use. These frameworks should prioritize patient safety, data privacy, and ethical considerations.

To mitigate potential biases in AI algorithms, continuous monitoring and refinement are essential. The data used to train AI systems must be diverse and representative to avoid reinforcing existing disparities in healthcare. It is incumbent upon the healthcare community to ensure that AI serves all patients equitably.

## Conclusion

As we peer into the future, the potential applications of AI are vast and promising. The journey has just begun, and the possibilities of AI are boundless. As we navigate this path, our unwavering commitment to patient well-being, ethical responsibility, and collaborative innovation will be our guiding principles in unlocking the full potential of AI. When we asked Dr. Gross "Is AI in medicine just a fad?", he confidently responded that "…use cases that deliver real value in an efficient way are here to stay."

## Acknowledgments

We would like to thank **Nate Gross, M.D**. for his valuable insights and perspectives that have been incorporated into this article.

Daniel Orringer, MD

# The Promise of Automated Neuropathology Diagnostics for Improving Outcomes in Glioma Surgery

Surgeons are often faced with uncertainty about the diagnosis of mass lesions at the time of biopsy or resection. Some lesions with features commonly seen in neoplasms may represent inflammation or infection. Amongst malignancies, surgical management can vary: CNS lymphoma, for example, generally does not warrant aggressive surgical resection. In other cases, like diffuse low-grade IDH-mutant astrocytoma (1p19q intact) and IDH wild type glioma, even though complete resection of all tumor cells is virtually impossible, maximal safe resection often represents one of the most efficient ways to confer a survival benefit. In contrast, low-grade, well circumscribed pilocytic astrocytoma or ependymoma, complete surgical resection is possible and may be curative. Because differentiating amongst pathologic entities is often a challenge preoperatively, one of the most vital elements of the surgical management of brain masses is intraoperative diagnosis.

At the best equipped centers, surgical pathology labs performing frozen section, smear or squash preparations represent the most effective means for ascertaining diagnosis. These labs are typically adjacent to operating suites and are staffed by pathologists who read the slides and communicate diagnostic information back to neurosurgeons. The turnaround times (from tissue being sent to the lab to a pathology report being communicated back to the OR) are commonly 30 or more minutes. Long turnaround time can result in downtime in the OR, extending anesthesia time, inefficient OR utilization, and increased costs. Moreover, the limited workforce of board-certified neuropathologists (approximately 785 in the US) serving the >1,500 hospitals where brain tumor surgery is performed, combined with the concentration of neuropathologists in tertiary centers, dictates that expert interpretation is not uniformly available to neurosurgeons.[1]

Complicating intraoperative diagnosis further is the fact that traditional intraoperative tissue preparations are inherently limited. Frozen sectioning generally preserves tissue histoarchitecture but cytologic features are distorted and freezing artifacts may obscure diagnostic morphologic features. Smear and squash preparations preserve cytoarchitecture but inherently destroy tissue histoarchitecture. Moreover, the technical expertise of clinicians and histology technicians required to execute slide preparation is variably abundant. The technical limitations of intraoperative specimen preparation contribute to the imperfect accuracy (>90% being deemed acceptable by the College of American Pathologists) inherent in the process of intraoperative diagnosis.

The necessity and inaccessibility of rapid, accurate intraoperative tissue diagnosis has created a window for innovation. Advances in optics and artificial intelligence now offer the possibility of dramatically extending neurosurgeons' access to salient intraoperative diagnostic data, including the ability to access molecular forecasts, which is not possible with traditional techniques. The explosion of computer vision techniques has given rise to a number of approaches that have shown promise in detection and classifying neurosurgical biopsies.

Molecular diagnosis has virtually supplanted morphologic diagnosis in the classification of gliomas and taken on new meaning for glioma surgeons in light of recent data that demonstrates profound differences in the impact of surgery on the predominant classes of IDH mutant gliomas: oligodendroglioma (1p19q co-deleted) and astrocytomas (1p19q intact). A recent 20-year retrospective analysis of gliomas that had been classified based on IDH and 1p19q status demonstrated that extent of resection (subtotal, gross total or "gross total-plus") has a profound impact on survival for patients with IDH mutant 1p19q intact tumors (astrocytoma) but much less of an effect on survival for patients with IDH mutant 1p19q co-deleted tumors (oligodendroglioma).[2]

Recently, a pair of strategies have emerged that promise to put glioma genetic classification within reach of surgeons in a timeframe that can inform surgical strategy. Both strategies utilize deep learning algorithms that forecast tumor genetic status based on histologic images. CHARM, developed by Nasrallah et al., utilizes a deep neural network that incorporates a hierarchical vision transformer to analyze digitized images of frozen sections to forecast molecular alterations most essential to glioma diagnosis per the 2021 WHO Classification.[3] Nasrallah et al. reported AUROC 0.79-0.82 for distinguishing IDH mutant from wild-type tumors and AUROC 0.89-0.97 for differentiating amongst astrocytoma (IDH mutant, 1p19q intact) from oligodendroglioma (IDH mutant, 1p19q co-deleted). CHARM also demonstrated promising ability to forecast alterations in CDKN2A, a strong negative prognostic marker in IDH mutant gliomas. One of the drawbacks of the CHARM approach is the approximately 30+ min turnaround time which mirrors that of slide preparation and digitization.

With our collaborators, we developed DeepGlioma, an artificial intelligence algorithm utilizing a transformer architecture which incorporates both histoarchitectural features of glioma and the semantic genetic landscape of adult diffuse glioma (ie 1p19q alterations are almost always found in the context of IDH mutation).[4] We reported balanced accuracy of 94.2% for differentiating IDH wt and mutant gliomas and 91.5% accuracy for differentiating IDH wt vs IDH mutant 1p19q intact vs IDH 1p19q co-deleted tumors. Enabled by rapid virtual histologic images obtained through stimulated Raman histology (**Fig 1**), DeepGlioma provides genetic forecasting in a timeframe that is both unparalleled and highly relevant to intraoperative decision-making. However, reliance of DeepGlioma on images generated by SRH imaging systems (currently deployed in 13 centers across North America and Europe) and regulatory considerations limit the availability of this approach.

> "Rapid methods for genetic forecasting arising from advances in digital pathology and artificial intelligence are poised to enable us to take a more nuanced approach to glioma surgery."
>
> DANIEL ORRINGER, MD

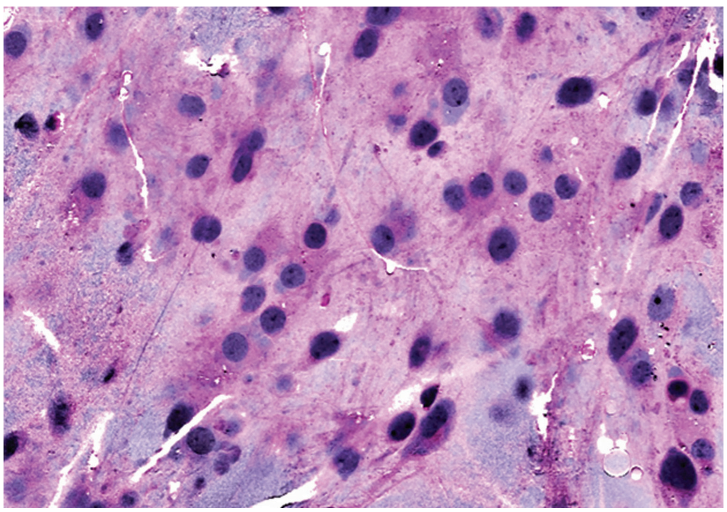

**Figure 1:** Representative stimulated Raman histologic image of IDH mutant 1p19q intact adult diffuse glioma

In light of new data demonstrating that cytoreductive surgery has a variable impact on outcome in adult diffuse glioma patients (ie astrocytoma vs oligodendroglioma) it will be incumbent on neurosurgeons to reinterpret the mantra of maximal safe resection. Rapid methods for genetic forecasting arising from advances in digital pathology and artificial intelligence are poised to enable us to take a more nuanced approach to glioma surgery, reserving the most aggressive resections for the patients who stand to benefit most and avoiding the risks associated with more aggressive resection in patients where it is less impactful.

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Hasan S. Ahmad, BS

Yohannes G. Ghenbot, MD

Jang W. Yoon, MD, MSc

# Rebooting Recovery: Leveraging Big Data from Smartphones and Wearables After Spine Surgery

In the span of just a few decades, mobile phones have evolved from mere communication devices to our constant companions. Smartphones and, more recently, wearable devices, have become repositories of our thoughts, habits, and behaviors, understanding the intricate nuances of our daily lives. Although consumer technology companies were quick to realize the potential of these miniature gadgets, the healthcare industry has only recently begun tapping into and utilizing these rich stores of data.

While technology adoption is historically protracted in medicine when compared to other, less conservative environments, the 21st century's emphasis on data quality and quantity is not groundbreaking for clinicians and medical researchers. In fact, accurate quantification of patient health information has long been a cornerstone of evidence-based medicine, and is currently playing an essential role in the development and delivery of personalized care, a medical model of tailoring medical and surgical treatment for individual patients. Though smartphone- and wearable-enabled data collection is gaining traction across many specialties, the intimate and visceral nature of neurosurgical procedures, and the resulting close relationship between neurosurgeons and their patients, has accelerated the integration of smartphones, wearables, and other digital health tools into the care continuum before and after neurological surgery.

Perhaps this is most evident in the development of activity-based outcome metrics in spine surgery, an attempt to augment traditional evaluation systems known as patient-reported outcome measures (PROMs). While commonly employed by spine surgeons across the world, PROMs – such as the Oswestry disability index (ODI) and visual analog scale (VAS) – rely on aperiodic subjective assessments of patients' pain symptoms, and therefore are vulnerable to recall bias, selection bias, response fatigue, and day-to-day variability. Furthermore, because the timing of post-operative clinic visits and survey administrations are discrete and not standardized, it becomes very difficult to establish a longitudinal understanding of a patient's symptoms before and after surgery. Implementation of these clinical questionnaires and the associated licensing and data entry is also quite costly, running upwards of $150,000 per year.[1]

While existing qualitative outcome metrics do offer valuable insight into patients' experiences and perceptions of their disease and post-operative course, the limitations of current PROMs have motivated the development of more robust methods to quantify patient outcomes after spine surgery. To this end, smartphones and wearable devices have emerged as powerful tools to remotely convey patient information to surgeons. High-fidelity accelerometers in both smartphones and wearable devices such as smartwatches and other fitness monitors can accurately quantify the degree of physical activity a patient is engaged in, which in turn can act as a proxy for understanding the functional limitations of patients due to spinal pathology. Additionally, the retroactive storage of these devices offers a more complete source of data to understand how specific pathologies have affected patients' mobility and the degree to which patients may have benefited from surgical intervention. With datapoints collected as frequently as every hour, smartphones and wearable devices grant surgeons a unique window into patients' pre- and post-operative courses with much finer temporal resolution compared to traditional PROMs, which may only be administered two or three times across patients' entire interaction with the surgical team. Furthermore, the passive transmission of this activity data, which oftentimes is already being collected by device manufacturers for their own internal use, alleviates compliance-related barriers to data collection.

A growing body of literature is dedicated to the development and validation of objective outcome measures following spine surgery, based on patient mobility metrics such as steps taken-per-day and gait velocity. Early investigations utilizing this type of data have shown that patient mobility correlates with the expected peri-operative timeline: a decrease in pre-operative activity secondary to, for example, spine pathology; a decrease in activity during the immediate post- operative period as patients recover from surgery; and, in the case of a successful surgery, a subsequent increase in activity commensurate to or greater than pre-operative baseline.[2] Other analyses using these data are now emerging to compare the accuracy of these data-driven metrics to traditional PROMs, to compare the efficacy of different surgical techniques in improving patient mobility, and to better understand patient-specific factors driving differential outcomes following surgery.

"…smartphones and other digital health tools promise to transform the way surgeons communicate with, interact with, and assess patients."

As researchers and clinicians increase their patient datasets and sophistication of their analyses, machine learning techniques can enable the development of predictive models that, based on patients' pre-operative activity patterns, can assess the likelihood of a successful recovery after surgery. These predictive analytics have the potential to greatly aid the art of patient selection, a skill that spine surgeons are constantly refining as they develop and grow their practice. For patients in whom surgery is indicated, real-time monitoring of patient mobility data can help surgeons actively track patient recovery and identify if patients need to return to the clinic for further evaluation. Tailoring this post-operative follow-up timeline to individual patients instead of adopting a one-size-fits-all approach saves valuable clinic time and resources, as patients who are recovering at different speeds are not treated homogeneously. This individualization and personalization in the post-operative period paves the path towards value-based care, a healthcare delivery model where reimbursement is based on individual patient outcomes, thereby incentivizing appropriate and effective utilization of healthcare resources.

Looking towards the future of smartphone and wearable device integration into neurosurgery, it is conceivable that additional metrics such as heart rate variability, blood pressure, and other parcels of patient health information could be used to inform decision making and post-operative monitoring. The expansion of digital health tools into current healthcare frameworks should also account for a gradual evolution in surgeon-patient collaboration, ranging from incentives and gamification of rehabilitation after spine surgery to new avenues for clinicians to virtually provide feedback, guidance, and support. Still, as with the adoption of any new technology into healthcare spaces, care should be taken to fully understand the implications and limitations of these data sources before relying on them for clinical decision making.

Our smartphones and wearable devices, once confined to the realm of communication, have emerged as indispensable tools that weave into the intricate tapestry of our lives. This evolution is particularly pronounced in healthcare, where the data collected by these devices is reshaping the landscape of spine surgery outcomes. From real-time monitoring and personalized rehabilitation plans to early intervention and enhanced doctor-patient collaboration, smartphones and other digital health tools promise to transform the way surgeons communicate with, interact with, and assess patients. As we navigate this intersection of technology and healthcare, the potential for harnessing digital health data is profound, enabling a future where our digital companions play a pivotal role in our well-being.

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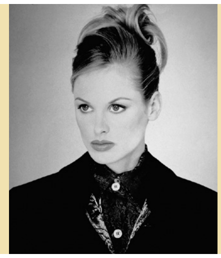


Aimee C. DeGaetano, RD, MPH, Doctoral candidate

# Regulatory Frameworks for Triage, Diagnostic, and Predictive Technologies

Imagine cutting-edge medical technologies seamlessly integrating into our healthcare systems, predicting diseases before they strike and triaging patients with unparalleled precision. As we stand on the cusp of this medical revolution, the regulatory compass guiding these innovations becomes paramount. Dive into the realm of regulatory frameworks, where safety and effectiveness meet innovation, and where guidelines pave the way for the next big breakthrough in medical triage, diagnostic, and predictive technologies. We are living "the future of medicine," where regulations do not stifle innovation—they fuel it.

The U.S. Food and Drug Administration (FDA) has been at the forefront of ensuring safety and effectiveness of medical devices and technologies. The Center for Devices and Radiological Health (CDRH) within the FDA plays a pivotal role in this endeavor, especially when it comes to medical triage, diagnostic, and predictive technologies.

## Brief History and Summary: Emergence of AI and ML in Healthcare

Over recent years, the integration of artificial intelligence (AI) and machine learning (ML) in healthcare has been transformative. These technologies have shown significant promise in diagnostics, where vast amounts of medical data are analyzed to detect patterns, identify anomalies, and assist in disease diagnosis. AI-powered algorithms have been particularly effective in analyzing medical images, leading to early disease detection, improved workflow, communications, and improved patient outcomes. Moreover, ML algorithms have been instrumental in predicting disease progression and guiding treatment plans, offering a more personalized approach to medicine.

- YOY increase of AI/ML-enabled triage / diagnostic devices slowed in 2021 (15%) and 2022 (14%) after 39% increase in 2020 (compared to 2019)
  - Based on projected volume in 2023, increase of AI/ML-enabled devices (compared to 2022) is expected to reach 30+%

## Regulatory Landscape

The regulatory framework for these emerging technologies is still evolving. Historically, the FDA has considered health information technology (HIT) software as a medical device (SaMD). However, with advancements in AI/ML, there have been calls for the FDA to update its regulatory framework to better address the unique challenges posed by these technologies. The balance between promoting innovation, improving patient outcomes, and ensuring patient safety remains a central concern.

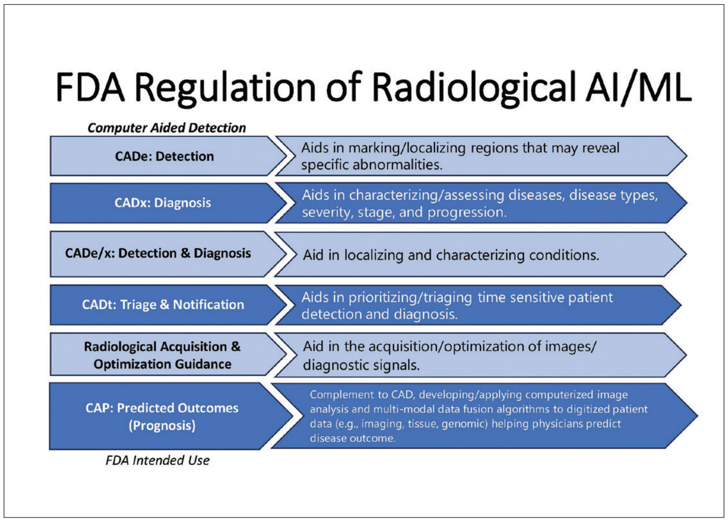
When regulators determine the essential outcomes for predictive algorithms, they must also consider some algorithms, especially those relying on subjective clinician data or outcomes linked to healthcare access, might inherently disadvantage specific patient groups. Such biases in algorithm outputs could reinforce existing prejudices and potentially harm patients. Beyond assessing efficacy, it's crucial to evaluate the effects of these algorithmic interventions on care quality for groups vulnerable to such biases.

## Focus on Precision Medicine

The concept of precision medicine, often referred to as personalized medicine, aims to provide tailored medical decisions, treatments, and products tailored to the individual patient. Advances in omics-based in vitro measurements, quantitative imaging biomarkers, AI/ML, generative AI, and electronic health records have been central to this shift. Government initiatives, such as the Precision Medicine Initiative (PMI) launched in 2015, have further propelled research in this domain. From a regulatory approval standpoint, predictive algorithms (prognostication) take much longer to pass through the regulatory process due to required retrospective studies to determine a hypothesis and a prospective study to prove hypothesis. Sample sizes need to be clinically significant and from diverse populations.

## Regulatory Framework

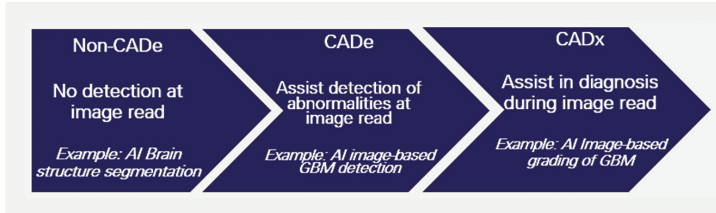
Healthcare's Computer-Aided Devices (CAD) may utilize AI/ML technologies, yet they serve distinct roles and offer unique functionalities. As the FDA greenlights a growing number of AI/ML-driven applications in healthcare, especially within medical imaging, new guidelines are being introduced to enhance the integration and application of these tools in clinical procedures. The FDA classified certain radiological image analyzers and related software:




- **CAP** – Computer-Aided Predicted Outcomes (Prognosis) complement to CAD, developing/applying computerized image analysis and multi-modal data fusion algorithms to digitized patient data (e.g., imaging, tissue, genomic) helping physicians predict disease outcome.
- **CADe** – Computer-Aided detection (CADe) aids in marking/ localizing regions that may reveal specific abnormalities.
- **CADx** – Computer-Aided diagnosis (CADx) aids in characterizing/ assessing diseases, disease types, severity, stage, and progression.
- **CADe/x** – Computer-Aided detection/diagnosis (CADe/x) – aid in localizing and characterizing conditions
- **CADt** – Computer-Aided Triage (CADt) – Aids in prioritizing/ triaging time sensitive patient detection and diagnosis
- **CADa/o** – Computer-Aided acquisition/optimization – aid in the acquisition/optimization of images/diagnostic signals.

CADe, CADx, CADt, incorporate AI/ML and are continually undergoing post-market improvement. Understanding the evaluation and approval process of improved products is important. All CAD systems integrate AI/ML and are gaining traction due to their potential to enhance diagnostic precision, improve patient outcomes, and streamline clinical workflows. Given the innovative nature of AI/ML-enhanced CAD tools, regulatory bodies such as the U.S. Food and Drug Administration (FDA), Pharmaceuticals and Medical Device Agency (PMDA), and European Medicines Agency (EMA) are exploring suitable regulatory frameworks. Examples of CAD and descriptions:

Navigating the intricacies of AI/ML-enhanced CAD regulations presents two primary hurdles: (1) intricate task of defining role as a medical device and (2) lack of unified agreement on regulatory




structure for regular post-market updates. While the FDA and CDRH stand at the forefront of regulating AI/ML-based CAD, there's still significant ambiguity surrounding the assessment methods for post-market enhancements. The evaluation techniques for CAD devices can be segmented into two categories: standalone software testing and reader study testing. Standalone software testing (SA) pertains to AI's performance assessment using historically gathered test data. Reader study testing (RT) gauges synergy between AI and medical professionals concerning diagnostic or detection precision. SA offers the benefit of being time- and cost-efficient than RT since it eliminates the need to enlist readers for performance assessment. However, limitations lie in its inability to assess real-world clinical performance, user-friendliness, and the influence of AI assistance. RT, conversely, can be conducted both prospectively and retrospectively, utilizing previously amassed images.

## Classes of medical devices and SaMD

The FDA classifies medical devices into three categories based on risk level they pose and the regulatory controls necessary to provide reasonable assurance of safety and effectiveness. As the class numbers increase, regulatory control and scrutiny becomes more stringent.

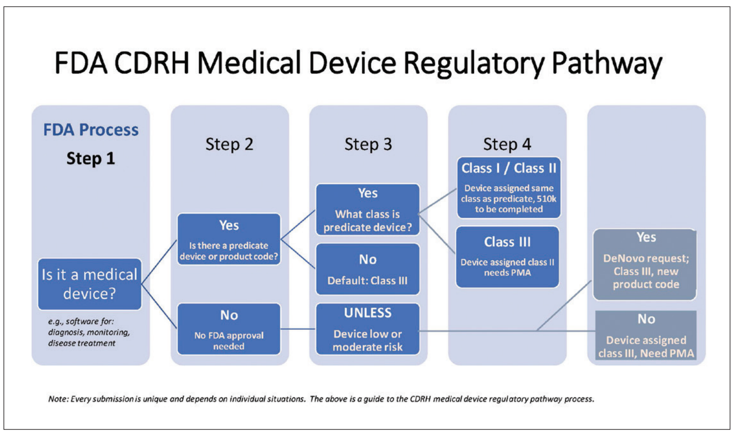
### FDA Classes of Medical Devices

| Class | Risk | Controls | Submission |
|---|---|---|---|
| I | Lowest | General | - Exempt *<br>- 510(k) |
| II | Moderate | General and Special (if available) | - Exempt *<br>- 510(k) |
| III | Highest | General and PMA | - PMA |

**More common submission requirement of this Class*

- **Class I Devices:** Low risk, devices pose minimal potential harm to the user. Most Class I devices are exempt from the premarket notification regulations. Examples: Bandages, hand-held surgical instruments.

- **Class II Devices:** Moderate risk, devices require more stringent regulatory controls, providing reasonable assurance of device's safety and effectiveness. Most Class II devices require a premarket notification, 510(k) submission, to demonstrate device substantially equivalent to a legally marketed device. Examples: Infusion pumps, blood pressure cuffs.
- **Class III Devices:** High risk, most rigorously regulated devices, usually support or sustain human life, preventing impairment of human health, or present potential unreasonable risk of illness or injury. Class III devices typically require premarket approval (PMA), which involves a thorough review by the FDA to ensure their safety and effectiveness. Examples: Implantable pacemakers, replacement heart valves.




The FDA CDRH (decision tree) regulatory pathway (example pathway above) consists of potential processes depending on individual situations. See below, a brief overview of illustrative FDA/ CDRH medical device (SaMD) regulatory approval pathway and submission study protocol:

1. Classify device
2. Select appropriate pre-market submission pathway
   - If device requires full PMA, etc., prepare appropriate application
3. Send submission to FDA
4. Register creation and list device
5. Post-approval, post market surveillance, follow-up

Before market release, studies typically evaluate the performance of standalone models using data gathered from human participants in a retrospective manner. These studies don't intervene or interact with subjects, and they do not influence clinical results. Such retrospective, non-intrusive, and non-interactive studies are deemed suitable for the following:

- Assessing standalone model's performance offers a statistical foundation for device's efficacy, giving clinical proof that backs its intended and suggested uses.
- Data from recent retrospective studies are anticipated to mirror data collected in a prospective manner.
- Studies with retrospective, non-intrusive, non-interactive design pose minimal threat to patients. To clarify study's approach, study methods include any alterations in study's execution or anticipated analyses.

Navigating the intricate landscape of medical technologies, the FDA's CDRH stands as a beacon, ensuring innovations in triage, diagnostic, and predictive tools meet the highest standards of safety and effectiveness. As the digital age ushers in groundbreaking AI/ML-driven solutions, the CDRH has been proactive, evolving its regulatory frameworks to match the pace of technological advancements. From early detection of diseases to predicting patient outcomes, these technologies hold immense promise. With great potential comes great responsibility. The CDRH's guidelines serve as a roadmap, guiding innovators while safeguarding patient interests, ensuring the future of medical technology remains both revolutionary and reliable.

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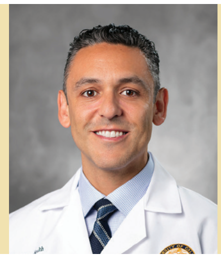

Joseph Osorio, MD, PhD

# Impact of the AiBLE Platform on Patient Care

The field of spine surgery has been moving in a direction of improving the highly variable outcomes that have plagued our field's reputation since the beginning of spinal instrumented fusions. Predictive analytics and big data solutions have been introduced to provide a pre-operative strategy to allow surgeons to plan and execute a pre-determined surgical solution determined from standing radiographic alignment parameters.

The AiBLE platform is an integrated solution by Medtronic that includes artificial intelligence through alignment planning with custom patient-specific rods, Mazor robotic guidance, stereotactic navigation, and intraoperative imaging with the O-arm that includes 3-D and 2-D images with the capability to perform intraoperative alignment assessments. These capabilities in isolation can provide the surgeon with a better understanding of pre-operative alignment (UNiD Hub), pre-procedure planning (Mazor and UNiD) and machine learning tools for the surgeon who seeks to expand the execution of an operative solution beyond just the time of surgery. The platform has individual components that now interface with one another allowing for patient-specific rod planning to exist within the robotics platform, and this is translated to the operating room for intraoperative surgical execution. This platform modernizes spine surgery to the standard of our current era with artificial intelligence (AI).

Surgeon providers and companies are seeking to develop pathways for more reproducible patient outcomes that keep up with the times of leveraging data to improve the execution of spinal instrumented operations. The initial frontier into data and AI came through the patient-specific rods, and now the AiBLE platform has created an integrated solution that not only incorporates data driven, patient-specific implants, but also works towards integrating this technology across all aspects of the Medtronic platform. Surgeons can now create custom rods in advance to align with screw planning pre-operatively. All of this is integrated within stereotactic navigation, creating an environment focused on executing a pre-operative plan, and moving away from our prior era of 'figuring it out on the fly.'

Our field has had a tremendous emphasis on global alignment, distribution of lordosis, and thoughtful assessment of whether invasive osteotomies (pedicle subtraction osteotomies) are required to execute a desired operative realignment. The AiBLE platform works within the pre-operative planning phase, utilizing a smartphone application to create greater efficiency.

## Preoperative Planning

It is known that only a portion of spine surgeons evaluate alignment prior to surgery regardless of the invasiveness of a procedure. Additionally, having a consistent set of alignment parameters captured for all patients is time consuming to measure, and via the UNiD Hub, the AiBLE platform provides these values for the surgeon. Additionally, working via engineers and machine learning software, operative solutions are streamlined to an individual surgeon practice to provide desired consistency in rod material, rod diameter, and corrective strategies. For the cases in which surgeons are between various operative strategies, different alignment plans can be generated with radiographic representations and numerical alignment parameters that correspond to these plans; this allows the surgeon to select their desired plan. Surgeons can also use Mazor planning for screw trajectories that allow more accurate rod length planning when using the patient-specific rod planning and robotics planning software together.

## Intraoperative Execution

The intraoperative component of the AiBLE platform allows for pre-determined implants (custom rods and screw sizes) to be utilized for surgery, leading to greater efficiency for the surgeon and operative technicians assisting on cases. The various components of the AiBLE system (rod planning, screw size and positioning, intraoperative reconciliation, and interbody selection and execution) can be tailored to a surgeon's desired preference.

### *UNiD*

There are different aspects of having a pre-contoured rod that can be beneficial when utilized during surgery. The pre-bent patient-specific UNiD rods can be used as an intraoperative template along the dorsal surface of the bone elements to evaluate pre-planned goals during surgery. Additionally, the O-arm 2-D image can be coupled with the UNiD plan target values to assess the regional correction alignment after rod placement during surgery. This allows the surgeon to make changes during surgery to meet their desired outcome. These capabilities allow very specific goals to be targeted both regionally, and segmentally, to not only achieve alignment goals when a realignment is desired, but also to maintain a satisfactory alignment when no significant change is planned.

### *Mazor*

The robotic platform has continued to evolve with the most recent editions allowing for UNiD rod integration within the Mazor planning platform. The registration using the pre-operative CT scan allows for screw planning and registration that can be maintained even after interbody placement has been performed. This is particularly unique given that the registration is performed on individual spinal segments being captured. With the addition of burr cutting capabilities, surgeons can now perform facet decortication using the Mazor to provide streamline fusion techniques for minimally invasive procedures. All these techniques are coupled with the stealth navigation integration that provide additional feedback to the surgeon for a continuous understanding of depth and location to implant placement.

### *O-Arm*

The O-arm has been a long-term component of the Medtronic portfolio, but now with the 2-D imaging capabilities, a long film x-ray can be captured and used during surgery with the ability to annotate and measure images during an operation. This latest annotation feature can be used as an intra-operative x-ray alignment assessment tool that can provide the surgeon a platform for validating their pre-surgical AI driven alignment targets. This intra-operative assessment can provide a real-time evaluation of sagittal and coronal alignment through annotation tools that include the ability to measure Cobb angles and a 90-degree digital annotation tool.

## Postoperative Analysis

The ability to follow cases over time, which include radiographic outcomes, is a critical component to the impact AiBLE has on patient outcomes and a surgeon practice. It allows the surgeon utilizing the UNiD-Hub to gain insight into their radiographic outcomes on either a specific case, or an aggregate of their executed cases that have follow-up imaging within the UNiD-Hub.

Surgeons can not only create a dataset that can be used to gain an understanding of their successes and failures to alignment strategies, but they can be objective about what they would like to assess. If a surgeon has sufficient data, and they have had technique-driven changes within their practice, this platform provides a streamlined interface that allows the surgeon to compare their own surgical strategy. Additionally, it allows the pre-operative planning to be tailored to their individual capabilities—not solely based on their perceived abilities, but the objective outcomes that are generated can then be used for planning future cases. This component of pre-operative plans tailored to the surgeons outcomes (capabilities), adds the element of 'surgeon-specific' to the AiBLE platform.

Surgeons adopting these newer technology interfaces may have hesitations around the preconceived amount of input the planning requires and the time commitment involved, but the reality is once a surgeon has completed several cases, the engineers, the analytics, and the interoperative team can easily execute a deliverable that is reproducible without significant time commitment from the surgeon.

Currently our publications support decrease rod fracture rates with patient-specific rods,[1] the ability to use machine learning to predict compensation of the uninstrumented spine and pelvic tilt,[2] and improved realignment for the degenerative spine patient using patient-specific rods.[3] Given that outcomes are best supported with long-term follow-up in spinal fusions, newer technologies often lag in the timing for publications to support evolving technologies, but the current evidence supports an emphasis on the expected improved patient outcomes. One proven deliverable is allowing the surgeon to plan and work towards executing a pre-planned and determined segmental and global realignment target. Furthermore, the collective outcomes captured allow for surgeons to evaluate their own outcomes, and the data platform can utilize machine learning to further improve the algorithms in a continuous cycle of improvement. It is hard to believe that patient care hasn't been already dramatically improved with the introduction of data and AI within our field of spine surgery, and it is expected that the future with big data will only continue to improve patient care.

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**Disclosure:**

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Ali Alawieh, MD PhD

Douglas Kondziolka, MD, MSc

# Navigating the Digital Era: The Integral Role of Surgical Videos in Neurosurgery Education and Practice

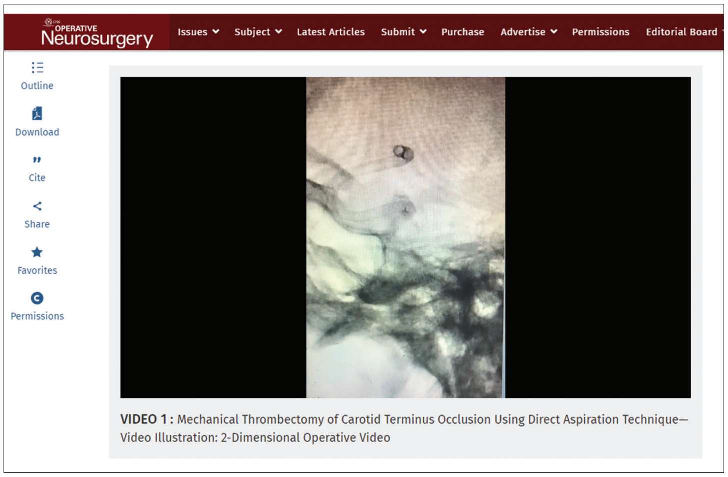
In the wake of the digital revolution over the past few decades, electronic learning has assumed a pivotal role in neurosurgical education across the world. Webinars, online lectures, anatomical illustrations, electronic/virtual simulators and operative videos have all become integral components of lifelong learning for neurosurgical trainees, junior practitioners, and more seasoned surgeons. Neurosurgical procedures epitomize the intimate relationship between patient outcomes and surgical expertise and craftsmanship in the operating room. These intricate skillsets are not merely transferable through traditional lectures and textbooks. Instead, recording, meticulous analysis, and dissemination of surgical videos have emerged as indispensable facets of neurosurgical training, research, collaboration, and the enduring legacy of the discipline, dating back to the pioneering microsurgical videos introduced by Professor Gazi Yasargil.

Several individual and society-driven initiatives persistently contribute to expanding video libraries, encompassing a wide spectrum of neurosurgical pathology. The Congress of Neurological Surgeons (CNS) created the journal *Operative Neurosurgery* to be the specialized publication of operative techniques, prominently featuring surgical videos. Remarkably, in less than a decade, *Operative Neurosurgery* has published nearly 1,000 operative videos, spanning the gamut of neurosurgical techniques, from microsurgical and endoscopic procedures to minimally invasive and endovascular interventions. A review of the past five years reveals that cranial cases constituted approximately two-thirds of the published videos, while spinal pathologies accounted for 30%, with the remaining 3% addressing peripheral nerve-related conditions. This vast repository of published videos includes all neurosurgical subspecialties, with a significant focus on open vascular cases (28%) and skull base tumors (23%), reflecting the intricate nature and limited prevalence of these specific pathologies.

Technological advancements have unleashed the potential of operative videos. Video acquisition technologies, such as high-definition (HD) cameras with enhanced resolution, frame rates, and low-light capabilities, have become the standard in neurosurgical operating rooms. These cameras provide a clear and detailed view of the surgical field, greatly enhancing intraoperative visualization of critical anatomical structures, which is subsequently captured in the recorded footage. Stereoscopic three-dimensional (3D) video technology is another routine addition for intraoperative recording, preserving depth perception to offer an accurate replica of the surgeon's field of view. Concurrently, software technologies have evolved to enable 3D reconstruction of case-specific anatomical details and the development of procedure-specific roadmaps, facilitating precise replication of documented procedures. Recently, *Operative Neurosurgery* has published several 360-degree virtual reality (360° VR) enhanced videos, providing viewers with a more immersive experience to capture intricate details of the published operation with high precision. These technologies have been seamlessly integrated into both microscopic and endoscopic cases, effectively transforming them into educational opportunities. Endovascular videos account for approximately 10% of published surgical videos in *Operative Neurosurgery*. The combination of live fluoroscopy imaging and room-mounted cameras focused on the operators' hand movements is currently used to document the procedural details of endovascular procedures, allowing for teaching and collaboration on individual cases. Several commercial systems are now available to facilitate the development of endovascular video libraries, as well as live and collaborative video broadcasting. Reviewing these recordings provides invaluable educational opportunities given the ability of the observer to pause and replay the videos focusing on different views (fluoroscopic views) or the operator's hand movements, which is not feasible in real life. Real-time video conferencing capabilities will become more prominent with new robotic approaches. Surgical videos have also been conducted on cadaveric specimens, further enriching the intraoperative learning experience to illustrates complex procedures and approaches.

The applications of surgical videos in neurosurgery are multifaceted. The primary objective remains enhancing the educational and training experiences of trainees and novice surgeons. After acquiring and mastering the fundamental neurosurgical skills in the operating room through routine procedures, trainees can observe experienced colleagues, learn techniques, and acquaint themselves with complex procedures. When adequately processed and annotated, surgical videos allow experienced colleagues to convey the significance of different operative maneuvers and common pitfalls during each case. For trainees at various stages of development, these video libraries facilitate the sharing of multi-institutional expertise without geographical constraints. Surgical videos serve as a comprehensive record of neurosurgical procedures that can be analyzed to evaluate surgical techniques, outcomes, and complications. This data contributes to the development of best practices and the refinement of surgical approaches. Surgical videos are critical for surgical innovations covering novel approaches, surgical tools, and technologies. These libraries also serve as a valuable resource for more senior surgeons, enabling them to explore novel technologies and tools in light of the rapid advancements within the neurosurgical industry, spanning areas such as microsurgery, endoscopy, endovascular procedures, spinal instrumentation, neuronavigation, among others. In his November 2023 editors' message, Dr. Michael Lawton discusses these elements within his own practice.

The significance of surgical videos in neurosurgery cannot be overstated. Technological advances in video acquisition and 3D imaging have revolutionized the field, enhancing the precision and safety of procedures. These videos find application in education, training, research, and collaboration. We are so thankful to the video collections of Dr. Robert Spetzler and Dr. Ossama Al-Mefty, together with the efforts of Dr. Walter Jean who curated the current technical lessons series. As technology continues to evolve, surgical videos will remain a cornerstone of neurosurgical practice, contributing to improved patient outcomes and the advancement of the field. Nevertheless, there has been a proliferation of short surgical videos shared daily on social media platforms, showcasing both common and complex neurosurgical procedures. This surge presents certain challenges, including the absence of peer review, insufficient scientific representation of cases, and inadequate measures to safeguard patient privacy. In this era of pervasive social media and information overload, the presence of a specialized journal like *Operative Neurosurgery* dedicated to the publication of high-quality surgical videos becomes crucial. Such a platform can standardize the neurosurgical video library, ensure rigorous peer review, uphold patient privacy and protection, and create an educational resource that transcends institutional boundaries, thereby maximizing training and collaboration. Enhanced training and preparation before conducting real-life cases will naturally lead to improved patient outcomes at a global scale, rather than being confined to individual institutions.




"In less than a decade, Operative Neurosurgery has published nearly 1,000 operative videos."

DOUGLAS KONDZIOLKA, EDITOR-IN-CHIEF

# FOUNDATION UPDATE

## Dear Colleagues and Friends of the Foundation,

2023 was another impactful year for the CNS Foundation, and thanks to you, the momentum will continue through 2024 with no less than $600,000 funding 16 programs. The CNS Foundation has become established as neurosurgery's partner for a range of awards, including novel DEI programs, support of the specialty's only developer of clinical guidelines, a growing number of international observer- and visitorships, as well as the prestigious Getch/K12 award. It is because of you, our donors and corporate partners, that we can achieve the Foundation's goals through our array of programs.

We rely on your commitment and generosity in order to sustain these vital programs. If you have not yet made your first donation of the new year, I urge you to give today. Your gifts will help the CNS Foundation continue to grow these incredible opportunities in 2024 and beyond.

**Martina Stippler, MD**
Chair, The CNS Foundation

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## GUIDELINES

The CNS Foundation supports the CNS Guidelines initiative, leveraging your donations to maintain an exceptional infrastructure with impeccable methodology that is unique to the CNS.

The CNS is the only neurosurgical organization with the volunteer and staff resources to develop clinical guidelines, which it disseminates online and through the CNS+ app, increasing their accessibility and impact.

*"The CNS guidelines are a critical resource for all levels of neurosurgical practice. As an early career neurosurgeon studying for my oral boards, these guidelines are a trusted tool for testing my practical fund of knowledge. Having them at my fingertips on the CNS+ app is an added bonus!"*

– **Rima Rindler** / Sierra Neurosurgery Group

Clinical practice guidelines are essential in helping you confront the rapidly changing healthcare environment and improve your patient outcomes. Guidelines are also becoming more and more important to practitioners and institutions, as they support insurance reimbursement. Over the past decade, CNS's investment in guidelines for all subspecialties has been rewarded with demand for new guidelines increasing threefold. While a team of dedicated volunteer neurosurgeons conducts rigorous reviews and authors the guidelines, the cost of the resources needed for production continues to increase.

**The CNS Foundation Guidelines Initiative supports the CNS infrastructure in developing and disseminating high quality evidence-based guidelines. Donate today at https://foundation.cns.org/donate to help us continue this essential work.**

DONATE!

Donate today at ***https://foundation.cns.org/donate*** to help us continue our essential work in guidelines.

## PATHWAY TO NEUROSURGERY

With the support of the Foundation's Strategic Partners, Medtronic, Stryker, and MicroVention, the CNS Foundation will hold its fourth Pathway to Neurosurgery program at our CNS Annual Meeting in Houston. This annual event is dedicated to alleviating healthcare disparities by encouraging high school students from underrepresented groups or disadvantaged backgrounds to pursue a career in neurosurgery. High school students visit the annual meeting and take part in an immersive experience, including lectures from neurosurgeons, industry representatives, and other health care professionals. They also participate in a hands-on activity lab that gives them insight into a day in a neurosurgeon's life.

## INTERNATIONAL

Our International pillar brings about positive change and global impact through its observership program. Originating with the University of Miami Tumor Observership program in 2018, the Foundation observership and visitorship program invites neurosurgeons--often from low- and middle-income nations--to observe first-hand practices they can use to improve patient care in their home countries.

Mentors from the observership institutions graciously dedicate time and unwavering support to provide rich experiences for a growing body of international neurosurgeons. These leaders in the field lend their time and institutions to provide unparalleled opportunities for young neurosurgeons from throughout the world.

*"This culture helped me to combine both art and anatomy knowledge to follow Dr. Rhoton's philosophy and legacy: 'Make surgery more accurate, gentle and safe'."*

– **Muhammad Reza Arifianto, M.D.** / Neurosurgeon of National Brain Center, Jakarta, Indonesia / Stanford University Visitorship

*"With the knowledge, training, and connections I gained, I hope to advance neurosurgery in my country, improve access to surgical care, enhance surgical outcomes, and boost the research capacity and output for neurosurgery in Zambia."*

– **Arnold Bhebhe** / MGI/Harvard Global Studies Observership

## D E I PROGRAMS

The CNS Foundation's Diversity, Equity and Inclusivity (DEI) pillar directly addresses healthcare disparities with programs that encourage the development of inclusive and equitable practices in the specialty, ultimately leading to structural change.

Thanks to our Strategic Partners, Medtronic and Stryker, the Foundation has awarded support for four types of programs. The Diversity, Equity, and Inclusion Scholar awardees examine the causes of health care disparities in neurosurgery and propose methods to address them. The Innovative Pilot Projects in Diversity, Equity, and Inclusion awards fund an active study to implement, test and report results of an intervention hypothesized to correct a known health care disparit(ies) and/or improve diversity in the neurosurgery workforce. The Impact Award recognizes a neurosurgeon for their outstanding DEI and community engagement work to share best practices in addressing equity and inclusion. In conjunction with the CNS Annual Meeting, three DEI Abstract Awards are given to authors demonstrating outstanding research on diversity, equity, and inclusion impacting neurosurgery workforce or patient care.

*The DEI Scholar award has allowed me to investigate an important problem impacting the patients I care for. I commend the CNS Foundation for investing in this type of important work.*

– **Jacob Greenberg** / DEI Scholar

The Future Women Leaders in Neurosurgery scholarship is awarded to both domestic and international early-career neurosurgeons. This program funds training for female neurosurgeons seeking leadership roles or who recently stepped into such roles. International awardees attend courses of their own choice and attend the CNS Annual Meeting. Domestic awardees can participate in the CNS Leadership Institute program.

*The course was exceptionally well-organized, and the lecturers were fantastic. The course helped me build on my interpersonal and communication skills, and the exercises helped me identify personal strengths and weaknesses-*

**– Tracy Flanders / Future Women Leader Scholarship award winne**

## THE CLINICAL SCIENTIST CAREER DEVELOPMENT PILLAR INCLUDES TWO MAJOR AWARDS.

For the past two years, the CV Section has partnered with the Foundation to offer the CV/CNSF Young Investigator Award. Each of the awardees (two per year) receives $150,000 over three years. The Young Investigators award provides these early-career neurosurgeons with valuable recognition, networking opportunities, and support for their research endeavors in the specialty

Since 2015, the CNS Foundation has funded the prestigious FNIH K12 program thanks to donations from the CNS of up to $200,000 per year. Early-career investigators who are transitioning into independent research careers receive support for two years in a matching arrangement between the CNSF and the FNIH.

## SECTIONS

Since 2017, the Foundation has received $1,350,000 in donations from the Sections, matched with a $1,000,000 donation by the CNS. These donations have funded the largest guidelines project in CNS history (Perioperative Spine), four $150,000 CV Young Investigator Awards, Trauma visitorships, and portions of the Getch/K12 award (CV Section). These donations and endeavors demonstrate the Sections' shared mission to improve worldwide patient health by supporting innovative programs that allow neurosurgeons to collaborate globally. We look forward to further collaborations with our Joint Section partners.

**Donate Today to Support the CNS Foundation programs in 2024 and beyond!**

# INSIDE THE CNS

# Washington Committee Report

**Russell R. Lonser, MD**
Chair, Washington Committee

## New Medicare Physician Payment Reform Legislation Released

House Doc Caucus leaders Reps. **Greg Murphy**, MD, (R-N.C.); **Brad Wenstrup**, DPM, (R-Ohio) and **Michael Burgess**, MD, (R-Texas) recently released the Provider Reimbursement Stability Act discussion draft, which would reform the Medicare Physician Fee Schedule's budget neutrality requirements. The draft reflects the work of the American Medical Association's (AMA) Medicare Reform Workgroup — of which the CNS and AANS are members — and would help stabilize physician payments by improving how the Centers for Medicare & Medicaid Services (CMS) calculates the budget neutrality adjustment. On Oct. 18, the legislation was discussed during a House Committee on Energy and Commerce hearing titled "What's the Prognosis?: Examining Medicare Proposals to Improve Patient Access to Care & Minimize Red Tape for Doctors."

Earlier this year, Reps. **Raul Ruiz,** MD, (D-Calif.); **Larry Bucshon, MD, (R-Ind.); Ami Bera**, MD, (D-Calif.) and **Mariannette Miller-Meeks**, MD, (R-Iowa) introduced the Strengthening Medicare for Patients and Providers Act (H.R. 2474), which would put in place an annual physician payment update starting in 2024 based on the Medicare economic index (MEI). The MEI reflects increases in physician practice costs and would reverse a downward spiral of Medicare physician payments, which have failed to keep pace **with inflation, jeopardizing the viability of physician practices and patients' timely access to care.** Additional information and resources are available at the AMA's Fix Medicare Now website.

## Contact Congress to Co-Sponsor Medicare Payment Reform Legislation

The Medicare physician payment system is broken, requiring Congress to intervene to prevent steep cuts year after year. One flaw is that Medicare payments do not automatically receive an annual inflationary update. Medicare physician pay has eroded by 26% over the last two decades relative to inflation, and temporary patches to the Medicare physician payment system are not sustainable year after year.

Click here **to go to neurosurgery's Advocacy Action Center to contact Congress to co-sponsor the Strengthening Medicare for Patients and Providers Act** (H.R. 2474), which would implement an annual Medicare physician payment update based on the MEI. A sample message, which can be personalized, is provided.

## House Committee Advances Prior Authorization Legislation

On July 26, the House Ways and Means Committee advanced legislation — the Health Care Transparency Act (H.R. 4822) — to reform prior authorization in the Medicare Advantage (MA) program. The bill included the neurosurgery-backed Improving Seniors' Timely Access to Care Act (H.R. 3173 in the 117th Congress). Before consideration, the CNS and the AANS joined the Regulatory Relief Coalition in sending a letter to committee leaders. If adopted, the bill will establish an electronic prior authorization program that requires MA plans to provide real-time approval of routinely approved services.

In applauding the committee for taking this action, Washington Committee chair **Russell R. Lonser,** MD, stated:

> The rampant overuse of prior authorization continues to cause inappropriate delays and denials of medical treatments that our seniors need, and we appreciate the ongoing efforts of the Ways and Means Committee to advance reforms that enjoy broad bipartisan support in the House and Senate. Patients can ill afford to wait any longer for policymakers to hold Medicare Advantage plans accountable, and America's neurosurgeons urge Congress to get this legislation across the finish line this year.

On Oct. 17, the CNS and the AANS joined the Regulatory Relief Coalition in sending a letter thanking Reps. **Brett Guthrie** (R-Ky.) and **Anna Eshoo** (D-Calif.) for including the Seniors' Timely Access to Care Act at the recent House Committee on Energy and Commerce health care hearing.

## GOLD CARD Act Introduced in the House of Representatives

On July 27, Reps. **Michael Burgess**, MD, (R-Texas) and **Vicente Gonzalez** (D-Texas) introduced the Getting Over Lengthy Delays in Care As Required by Doctors (GOLD CARD) Act (H.R. 4968). This bipartisan bill would exempt providers from prior authorization requirements in the Medicare Advantage program for one year if at least 90% of prior authorization requests in the preceding year are approved. The CNS and the AANS endorsed the legislation.

Washington Committee chair **Russell R. Lonser,** MD, was featured in Rep. Burgess' press release:

> Our patients cannot afford to wait or jump through unnecessary hoops to get care for painful, debilitating and life-threatening neurologic conditions. The GOLD CARD Act is a commonsense approach to addressing the unnecessary burdens and delays caused by the widespread use of prior authorization, and America's neurosurgeons thank Reps. Burgess and Gonzalez for introducing legislation to expedite this process so our nation's seniors get timely access to care.

In reporting on the GOLD CARD Act, *Medical Economics* published an article that included Dr. Lonser's comments.

## Neurosurgery Leads Amicus Brief in Surprise Medical Billing Case

Under the No Surprises Act (NSA), physicians and insurers can use an independent dispute resolution process to resolve out-of-network payment disputes. The process was intended to keep patients out of the middle of these billing disputes. Unfortunately, the final rule implementing the law unfairly favors insurers. Continuing their advocacy to ensure that the Biden Administration implements the law as written and intended by Congress on Sept. 18, the CNS and the AANS spearheaded a physician-led amicus brief, along with the Physician Advocacy Institute in the Texas Medical Association's second lawsuit (TMA II) challenging elements of the NSA. The government has appealed the TMA II ruling, which favored physicians.

## CNS Advocacy Results in CMS Rescinding Edit for Decompression Add-on Codes

Due to CNS and AANS leadership and advocacy, CMS rescinded an incorrect National Correct Coding Initiative (NCCI) edit restricting the reporting of spinal fusion codes (Current Procedural Terminology (CPT®) codes 22630, 22632, 22633 and 22634) with decompression add-on codes (CPT codes 63052 and 63053). Unsatisfied with the agency's original plan, the CNS and the AANS led a coalition letter effort urging a swift resolution. Following an Aug. 24 meeting, which was joined by representatives from the American Academy of Orthopaedic Surgeons and North American Spine Society, CMS stated it would resolve the error by Oct. 1.

CMS has corrected the error, and neurosurgeons who have held claims may now submit them. For claims submitted before Oct. 1, CMS has instructed Medicare Administrative Contractors (MACs) to adjust denied claims manually. Manual adjustments are ongoing, and payments will be made for these claims.

## Neurosurgery Comments on Proposed 2024 Medicare Physician Fee Schedule

On Sept. 6, the CNS and the AANS submitted comments on the Calendar Year (CY) 2024 Medicare Physician Fee Schedule Proposed Rule. The neurosurgical groups expressed concerns about the 3.5% decrease in the CY 2024 conversion factor, primarily stemming from a new office visit add-on code (G2211) for complex services. In their letter, the CNS and the AANS urged CMS to:

- Halt implementation of the G2211 add-on code;
- Adjust the 10- and 90-day global codes to reflect increases in the value of post-operative evaluation and management services; and

- Accept the American Medical Association/Specialty Society Relative Value Scale Update Committee-recommended values for the total disc arthroplasty code (CPT code 22860).

The CNS and the AANS also commented on Medicare's Quality Payment Program issues. Among other things, the letter:

- Objected to the new Merit-Based Incentive Payment System Value Pathways framework;
- Requested that CMS maintain measure #128: Body Mass Index Screening so that it is available to specialists who otherwise have access to very few relevant measures; and
- Registered concerns about the flawed approach to cost measurement and the inclusion of surgeons in the newly developed Low Back Pain episode-based cost measure, which is aimed at evaluating non-operative, chronic care.

Responding to neurosurgery's ongoing advocacy, CMS proposed suspending the implementation of the Appropriate Use Criteria for Advanced Diagnostic Imaging Program due to unsurmountable operational challenges and a reassessment of the program's utility.

Besides their letter, the CNS and the AANS joined several coalition letters. Click here for a surgical coalition letter opposing the G2211 add-on code, here for the Alliance of Specialty Medicine letter and here for the Physician Clinical Registry Coalition letter.

For additional details about the proposed rule, click here for a summary of provisions of interest to neurosurgery and here for a CMS fact sheet.

## CNS Supports Medicare Coverage of Carotid Artery Stenting

On Aug. 4, the CNS, the AANS and the Joint Cerebrovascular Section sent a letter to CMS thanking the agency for releasing a Decision Memo on Carotid Artery Stenting (CAS) and encouraging CMS to expand the indications for CAS. Earlier this year, the neurosurgical groups wrote CMS urging the agency to revisit the indications for CAS. On Oct. 11, CMS issued a final decision memo consistent with organized neurosurgery's position. Specifically, the updated policy would:

- Expand coverage to individuals previously only eligible for coverage in clinical trials;
- Expand coverage to include standard surgical risk individuals by removing the limitation of coverage to only high surgical risk individuals;
- Remove facility standards and approval requirements;
- Add formal shared decision-making documentation with the individual prior to furnishing CAS; and
- Allow MACs discretion for all other coverage of percutaneous transluminal angioplasty of the carotid artery concurrent with stenting not otherwise addressed in the national coverage determinations.

## CNS Supports Proposed Breakthrough Device Coverage Policy

On Aug. 28, the CNS and the AANS submitted comments to the Centers for Medicare & Medicaid Services responding to a proposal to cover devices cleared under the Food and Drug Administration's (FDA) Breakthrough Device pathway. The neurosurgery groups expressed support for the new CMS coverage pathway, Transitional Coverage for Emerging Technologies, urging the agency to implement the program in a way that will safeguard high-quality and real-world evidence development for the technologies selected.

## Gabriella Miller Kids First Research Act 2.0 Legislation Approved by Senate Committee

On Sept. 21, the Senate Health, Education, Labor and Pensions Committee approved the Gabriella Miller Kids First Research Act 2.0 (S. 1624). Introduced by Sens. **Tim Kaine** (D-Va.) and **Jerry Moran** (R- Kan.), this legislation would expand the available funds to support research on pediatric diseases and disorders, including childhood cancer, at the National Institutes of Health (NIH). The CNS and the AANS previously sent letters of support to the Senate and House sponsors. On Aug. 25, the House Committee on Energy and Commerce approved the companion bill (H.R. 3391), which is awaiting action on the House floor.

## Follow the Washington Committee on Social Media

Never miss a post by subscribing today! The mission of *Neurosurgery Blog* is to investigate and report on how health care policy affects patients, physicians and medical practice and to illustrate how the art and science of neurosurgery encompass much more than brain surgery. We invite you to visit the blog, subscribe and connect with us on our various social media platforms. This will allow you to keep up with the many health policy activities happening in the nation's capital and beyond the Beltway.

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# IMAGES IN NEUROSURGERY

## A Combined Approach for C6-C7 Unilateral Perched Facet

A 41-year-old man presented with left arm weakness and tingling radiating down to his second and third digits after being struck by a vehicle. On physical examination, there were no visible deformities, but he had diminished triceps reflex and strength. CT demonstrated left C6-7 perched facet with fracture of the C7 facet and fractured fragment displaced into the C6-C7 foramen causing the C7 radiculopathy (**Figure 1**). MRI revealed no spinal cord compression or injury (**Figure 2**). A minimally invasive trans-tubular approach was performed, followed by a C6-7 ACDF. The inferior portion of the C6 lateral mass was drilled to expose the underlying fractured C7 superior articulating pillar. The fractured fragment was carefully removed with visualization of the underlying C7 nerve (**Figure 3**). Anterior cervical discectomy and fusion at C6-7 was performed to provide stabilization (**Figure 4**). Post-procedure patient had immediate resolution of C7 pain and parathesias. At two-week follow up, the patient had complete return of triceps strength. A combined posterior/anterior approach can help achieve decompression, while limiting muscle dissection and number of levels fused.

**Click here to view a complete writeup of this case on CNS Nexus**

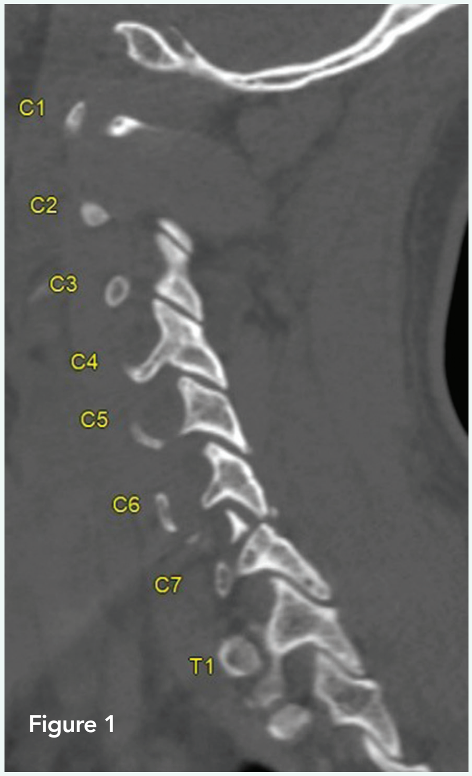


**Figure 1:** Sagittal CT showing fractured C7 SAP with fragment in the foramen.


**Figure 2:** Sagittal T2 sequence showing no significant traumatic compression or cord edema.

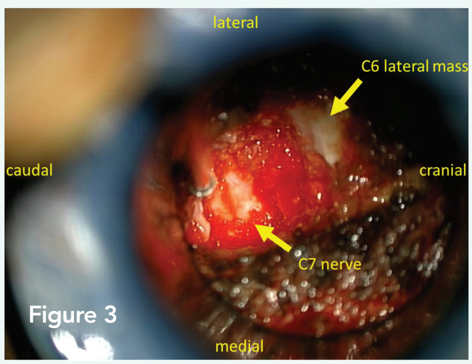


**Figure 3:** Posterior trans-tubular view after removal of fractured fragment with C7 nerve intact.

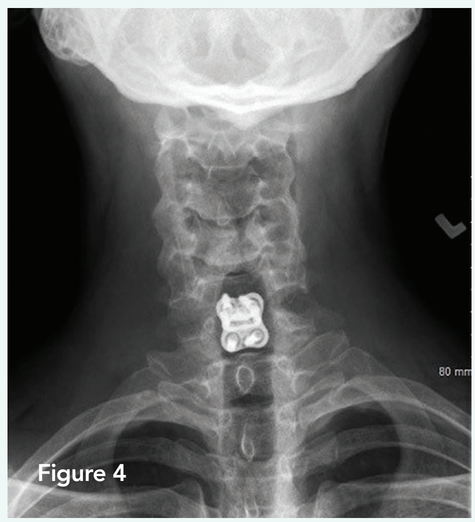


**Figure 4:** AP x-ray at 2 months post-operative visit.

*Submitted by: Salazar Jones MD[1], Pemla Jagtiani BS[2]*
*Affiliation: 1. Department of Neurosurgery, Mount Sinai, New York City, New York 2. School of Medicine, SUNY Downstate Health Sciences University, New York, NY.*

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*(Continued from page 7)*

## How Samsung Leverages Technology to Enhance Patient Care


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## How Samsung Leverages Technology to Enhance Patient Care


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