

Original research

International teleproctoring in neurointerventional surgery and its potential impact on clinical trials in the era of COVID-19: legal and technical considerations

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ABSTRACT

Background Existing travel restrictions limit the mobility of proctors, significantly delaying clinical trials and the introduction of new neurointerventional devices. We aim to describe in detail technical and legal considerations regarding international teleproctoring, a tool that could waive the need for in-person supervision during procedures.

Methods International teleproctoring was chosen to provide remote supervision during the first three intracranial aneurysm treatments with a new flow diverter (currently subject of a clinical trial) in the US. Real-time, high-resolution transmission software streamed audiovisual data to a proctor located in Canada. The software allowed the transmission of images in a de-identified, HIPAA-compliant manner.

Results All three flow diverters were implanted as desired by operator and proctor and without complication. The proctor could swap between images from multiple sources and reported complete spatial and situational awareness, without any significant lag or delay in communication. Procedural times and radiologic dose were similar to those of uncomplicated, routine flow diversion cases at our institution.

Conclusions International teleproctoring was successfully implemented in our clinical practice. Its first use provided important insights for establishing this tool in our field. With no clear horizon for lifting the current travel restrictions, teleproctoring has the potential to remove the need for proctor presence in the angiography suite, thereby allowing the field to advance through the continuation of trials and the introduction of new devices in clinical practice. In order for this tool to be used safely and effectively, highly reliable connection and high-resolution equipment is necessary, and multiple legal nuances have to be considered.

INTRODUCTION

Physician proctoring is an established, fundamental component of the neuroendovascular field. The fast pace of technological advancements, both in terms of materials and imaging/operative technologies, requires a readily available proctoring network. Often, direct supervision by a physician who is already familiar with a new technology is required

by either the FDA or the sponsoring company before an operator can become a certified, independent user of a particular device.

Traditionally, proctoring entails the physical presence of the supervising physician in the operating room to provide direct and real-time technical guidance to the operator during the use of the new technology. In the neuroendovascular world, there is a small pool of expert providers with requisite in-depth knowledge of new devices, and the margin for error is small. As a result, proctoring physicians routinely need to travel nationally or internationally multiple times per year to facilitate this process. This is a time-consuming, costly, and carbon-intensive task. As a result, it scales poorly, potentially creating a bottleneck for widespread access to state-of-the-art patient care.

Since COVID-19 was declared a pandemic by the World Health Organization in March 2020,¹ virtually all countries in the world have instituted travel bans or mandatory quarantines in order to mitigate the diffusion of the novel coronavirus. Medical institutions and universities have either followed that example or applied even stricter standards, as their providers are considered essential personnel in dealing with patient care during the pandemic. This essentially brought to a complete halt any type of non-essential travel, including that related to procedural proctoring. In addition, hospitals have implemented strict policies to grant access to extra-institutional visitors. The reduction in mobility, along with the unprecedented economic and operational burden to health systems, resulted in the cancellation or postponement of elective cases worldwide. This has ultimately led to a delayed introduction of new technologies and clinical trial enrollment across medical specialties.²⁻⁴

In May 2020 the Department of Health and Human Services and the Centers for Medicare & Medicaid Services (CMS) published a Public Health Emergency (PHE) Interim Final Rule.⁵ In this rule, CMS revised the definition of direct supervision to allow it to be provided using real-time interactive audio and video technology for the duration of the PHE for the COVID-19 pandemic. CMS is proposing to continue to allow direct supervision to be provided using real-time interactive audio and



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video technology through December 31, 2021 and is currently seeking comment on this subject. We present the legal and technical challenges of teleproctoring in the setting of the first use of a new intracranial vascular implant in the US, currently the subject of a clinical trial.

METHODS

Three patients with wide-necked intracranial aneurysms of the supraclinoid internal carotid artery were selected for endovascular treatment with the Surpass Evolve flow diverter (Stryker, Kalamazoo, MI, USA), which recently received FDA approval. Since the product had not been used in the US for patient treatment, a physician in Canada (where the implant is approved) with the most experience of implanting these devices was selected as proctor. Due to current international travel restrictions, the safest alternative was to perform the procedures using teleproctoring. After careful review of applicable information transmission security, access controls, privacy measures, and consent, the hospital's Office of General Counsel and the Office of Compliance & Privacy formally approved the decision to use remote supervision, given the extenuating circumstances. The manufacturer also agreed to this approach. The patients were provided with information about the procedure and signed consent forms specifically generated for teleproctoring purposes with the help of legal counsel.

The MedPresence virtual medical presence platform (Olympus, Center Valley, PA), which had previously been installed in the neuroangiography suite for intra-institutional teaching purposes, was chosen to securely broadcast clinical content between the treating hospital and the proctor. The system allows real-time sharing of high-resolution audiovisual data from clinical sources and room-context cameras with a remote receiver. Image sources are connected by the manufacturer to a workstation installed in the control room that allows team members to control streamed content and third parties' participation in the session at all times. Data is transmitted to the receivers through a company-specific cloud-based system with a fully encrypted, HIPAA compliant end-to-end security architecture. HIPAA safeguards are in place and the method of broadcast does not collect, transmit, or store patients' electronic protected health information (PHI). Third parties (both the proctor and the company support team) are required to follow a multistep authentication in order to access the live stream. The intended viewers receive an email with a unique, session-specific, machine-generated and time-limited security code that, along with a link in their invitation, allows them to join a web-based virtual procedure room. This virtual environment can be accessed via any internet-capable smart device, regardless of location, and does not require specific software on the viewer's side. The selection of image source, camera angles, and field-of-view magnifications are managed by the treating team through the MedPresence workstation and cannot be modified by the viewers. The proctor and the operator communicate via headsets included in the MedPresence setup. If present, environmental speakers present in the suite allow the entire neurointerventional team to communicate with the proctor and hear his recommendations.

In compliance with the legal counsel request, and to further protect patient anonymity, all images are anonymized and assigned a unique numerical identifier that is completely unrelated to any actual PHI.

In our case, radiologic images were streamed directly from the biplanar neuroangiographic equipment (Azurion, Philips Medical, Best, NL) and its post-processing workstation. Three pan-tilt cameras pre-mounted on the ceiling would allow

simultaneous visualization of the operators from different angles and with high-resolution zoom capability.

The MedPresence system, as well as the workflows required to facilitate the proctoring, were extensively tested for quality and stability in the days before the procedure and rehearsed with the on-site assistance of specialists from the imaging manufacturer. On the day before the procedure, the cases were discussed between the main operator, who had extensive experience in the use of flow diverting stents, his colleagues, and the support staff who would participate in the operation. Each member was assigned a precise role, and one technologist, who had been trained on the streaming software by the company, was exclusively assigned to management image transmission for the entire day from the neuroangiography control room to ensure that the proctor was viewing the correct images and that they did not contain PHI. The proctor had been contacted by the company and was instructed how to log in to the session following the invitation. The system does not require the physical presence of company's specialists and can be fully operated by an appropriately trained neurointerventional technologist. Since this was the first use of this technology for clinical teleproctoring, in order to ensure maximum patient safety and operational efficiency, a company engineer was remotely connected on the day of the procedure in case technical support was needed.

RESULTS

On the day of the procedure, the proctor was connected with the angio suite using the MedPresence image platform once the guiding catheter had been positioned within the target vessel. In order to have complete situational and spatial awareness, the proctor requested simultaneous access to real-time fluoroscopy and road map imaging, as well as to a live video feed of the operator's hands and of the operative table (figure 1).

All three interventions were successfully performed with uninterrupted step-by-step guidance. The flow diverters were implanted as desired by the operator and proctor. The proctor reported image quality equivalent to that he would expect in the neuroangiography suite. He was able to see the implant on fluoroscopic images without difficulty, and there were no interruptions or delays in audio-visual communication. Average procedural fluoroscopic time was 21 min (range: 20.5–21.5 min) and the average Air Kerma radiation dose was 1269 mGy (range 1095–1545 mGy). These values are similar to those of our institutional non-complicated neurointerventional flow diversion procedures. The patients were discharged home the day after the procedure at baseline clinical status.

DISCUSSION

Since the beginning of the COVID-19 pandemic, there have been unprecedented limitations in the movement of people. Telemedicine approaches have helped to mitigate adverse effects of this by replacing or augmenting some previous routine clinical activities.^{6–9} Given the persistence of worldwide travel restrictions, teleproctoring for the introduction and supervision of the safe use of novel devices is becoming necessary.

Successful teleproctoring has been reported multiple times in the past 25 years across multiple surgical specialties, but mostly involving cases of laparoscopic surgery.^{10 11} Compared with surgeries that rely on direct visualization of relatively large structures through microscopes or fiber-optic cameras, image-guided interventions pose a unique set of challenges. The continuous interpretation of dynamic angiographic images of structures with limited visibility requires the proctor to have a real-time, high-definition visualization of the operator's view.

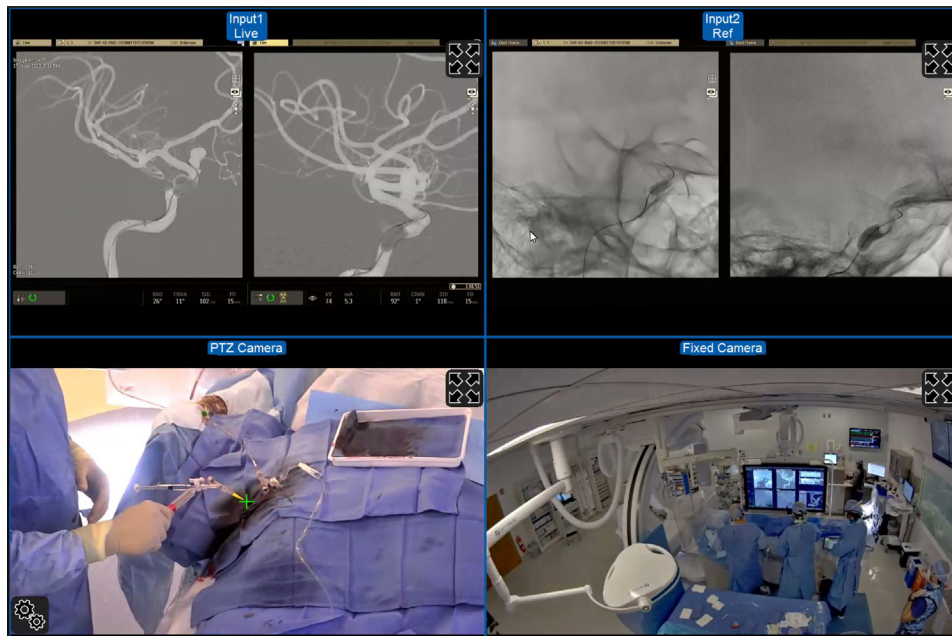


Figure 1 MedPresence proctor view during a Surpass Evolve flow diversion case. The views were configured remotely and included a live digitally subtracted roadmap (top left) and unsubtracting (top right) images in various planes. A pan-tilt-zoom camera (bottom left) provides a view of the operator's hands and equipment, and demonstrates the radial access. A fixed camera mounted to the ceiling provides an overview of activity in the room (bottom right).

In our experience, the elements that allow safe and effective long-distance remote supervision during a complex intracranial procedure are: careful technical planning of the procedure with well-defined process steps and clear roles and responsibilities assigned to all team members; a broadcasting system that guarantees a high-quality encrypted transfer of audiovisual data from multiple sources (fluoroscopy/Digital Subtraction Angiography and the operator's hands and surroundings) in order for the proctor to achieve complete spatial and situational awareness; and reliable bi-directional remote connectivity with negligible latency in order for the proctor's suggestions to be transmitted in real time. These aspects are particularly relevant when the primary operator may lack familiarity with new devices, given the low tolerance for errors that characterizes neurointerventional procedures.

While hospitals in many locations have moved past the initial pandemic surge and slowly resumed routine clinical operations, movement restrictions are still largely in place 7 months after their initial enactment. Resurgence of the current pandemic is anticipated and there are increasing reports of rising numbers of infections.^{12,13} Due to the varied time course and local dynamics of the pandemic across the globe (or in certain cases, even within regions of the same country) and already recognizable second surges in some nations,¹⁴ it is very likely that in-person proctoring will not be logistically feasible at the necessary scale in the foreseeable future. This would unacceptably impact the advancement of our field and ultimately prevent or significantly delay the introduction of new devices for the benefit of our patients. The issue is particularly relevant in the context of patient enrollment in clinical trials, which is the main modality to validate the safety and effectiveness of new technology and require strict operator guidance during initial cases.¹⁵ In the US, due to strict FDA and NIH regulations, clinical trials with novel devices are often conducted after some preliminary experience has been gained in Europe, Canada, or Australia. Like in our

cases, in these instances international proctoring becomes the only option.

Thanks to recent advances in connectivity and communication technologies, the adoption of telehealth and virtual care has increased.¹⁶ Interdisciplinary clinical meetings as well as some aspects of research are now effectively carried out using a variety of different communication software and applications. Almost all major medical conferences have been successfully converted to virtual meetings by broadcasting a combined stream of live and pre-recorded material. While these technologies facilitate a variety of non-procedural medical activities, they are insufficient to allow safe teleproctoring during neuroendovascular surgeries, given the visual and technical complexity and the small margins of error that characterize these interventions. Remote and direct physician supervision in this field carries a unique set of technical challenges, such as the need for real-time, uninterrupted, bi-directional transmission of high-quality audiovisual communication with the proctor.

Waiving the need for the physical presence of the proctor could reduce the time delay to schedule a procedure. Furthermore, proctors would not be exposed to both infection risks related to air travel and radiation risk from being physically in the angiography suite. Teleproctoring could be cost effective for hospitals and sponsoring companies by saving expenses on travel, food, and lodging. Teleproctoring also has the potential to expand patient access to novel neurointerventional procedures and technologies, by enabling patients who might otherwise have had to travel further to receive state-of-the-art care at facilities closer to their homes.

The CMS has recognized the increasing role and importance of remote live supervision and permitted this mode of engagement to mitigate the current public health emergency while seeking feedback from the medical community to inform future decision making to permit this type of supervision long term (PHE). To date, the CMS has not promulgated specific regulations

addressing international teleproctoring. Therefore, until specified otherwise, it has to be assumed that the proctor has to follow and is subjected to the same laws that would be valid for in-person supervision. Clarification in this regard is needed in order to provide neurointerventionalists with a universally accepted legal framework.⁵

Results of a survey was conducted among neurointerventionalists from all five continents at the beginning of the COVID-19 pandemic showed that 33% of the respondents were in favor of 24/7 availability of remote physician supervision through live stream platforms. This technology was deemed particularly necessary for junior team members undergoing complex procedures without the possibility of supervision by senior partners either due to epidemic mitigation policies or to such members falling ill.¹⁷

Remote proctoring for neurointerventional procedures had been first investigated by Bechstein et al in 2019.¹⁸ The authors analyzed 36 thrombectomy procedures performed on an in vitro stroke model using vascular replica by non-subspecialty trained interventional radiologists either with on-site supervision or with teleproctoring. The study found that both supervision modalities led to comparable procedural times and outcomes, and thus concluded that remote proctoring was effective for thrombectomy procedures in a simulated environment.

The same group has reported the use of inter-hospital teleproctoring at the national level for three implants of WEBs (Microvention, Tustin, CA). The operators were already appropriately experienced with the device but elected to obtain additional assistance by a remote supervising physician. The proctoring physician reported full perception of the procedural environment and a high level of situational awareness, despite an unstable connection during the first case.¹⁹

Two other groups have reported successful experiences of teleproctoring for procedures requiring extra-institutional guidance in the context of COVID-19 travel restrictions. Isaak et al reported successful teleproctoring for percutaneous ultrasound-guided hemodialysis arteriovenous fistula creation in four patients.²⁰ The interaction with the proctor was constant throughout the procedures, and due to his guidance, the procedural strategy was changed in two cases. The team experienced interruption of communications in one instance for a duration shorter than 5 min, with no clinical consequences. Goel et al reported successful teleproctoring for an urgent mitral valve replacement through an innovative valve-in-valve technique that had never been used at their institution and would normally require on-site proctoring.²¹ The operators used a robot-mounted camera system that allowed bidirectional image streaming between Texas and Georgia through a user interface that enabled the proctor to move a robot to areas of the room where he thought his assistance was needed, as well as switch views between live in-room camera, fluoroscopy, and ultrasound video streams. The authors recognize the potential of teleproctoring, particularly in medical subspecialties where physician experts need to be trained in highly technical and demanding but rarely performed procedures. In their opinion, the keys to successful teleproctoring are extensive preoperative discussion of the cases and significant clinical experience, both on the performing team and proctor sides.

Accounting for differences between regulations for each institution and jurisdiction, the routine implementation of teleproctoring will need to address specific legal and technical challenges:

1. Potential need for remote supervision will need to be included in procedural consents and in FDA/trial guidelines.

2. The need for constant transmission of patient images from one hospital to another and from one country to another will require software manufacturers to use data transfer and encryption algorithms compliant with HIPAA Privacy and Security Rules, GDPR, and other country-specific privacy regulations.
3. The costs of high resolution video equipment and dedicated software might make this solution unfeasible for institutions with limited resources, particularly if installation of ceiling-mounted cameras in the angiography suite is preferred in order to provide the most accurate situational and spatial information to the viewer. In both their reports, Bechstein et al employed wide-angle pan-tilt cameras mounted on a tripod.^{18,19} This obviated the need for room modification and allowed the treating team to move the environmental cameras according to the proctor's preference. Similarly, the robot-mounted camera used by Goel et al did not require the installation of ceiling cameras.²¹
4. Image quality and transmission stability also depend on the proctor's viewing system and internet connection.
5. Some systems do not allow active participation of the proctor in choosing image sources or moving cameras in the operating room. This might require an increase in size of the treating team as, in order to maximize personnel concentration and efficiency, one technologist should be dedicated to the management of the streaming platform in order to promptly direct the image source to the location in which the proctor believes their attention is needed.
6. Consent from team members whose identities are captured in the live broadcast might have to be obtained.
7. Confidentiality and data-sharing agreements, and even in some cases, business associate agreements between the entities and/or individuals participating in the live broadcast may be necessary to protect the rights and interests of all parties involved.
8. Hospitals will need a policy and procedure to establish acceptable use cases, team member roles, and responsibilities, and requirements for remote participants (proctors, technical personnel) to ensure confidentiality and patient privacy are protected at all times throughout the session.

Robotic and augmented reality technologies, whose use has recently been explored in the neuroendovascular field, could also have a potential role in teleproctoring.²²

In summary, if performed with appropriate equipment and by experienced operators, teleproctoring can be applied safely and effectively to real-world neurointerventional practice. The uncertain course of the current and potential future pandemics warrants consideration for, and resource investment in, this approach. This will help mitigate adverse effects on the development and widespread application of neuroendovascular technology, potentially also in remote areas or developing nations, though costs and logistics might not make it widely feasible in those contexts. Efforts should be made to determine how a streamlined integration of high-quality image broadcasting systems and robotics can open new pathways for physician training, assistance, and, ultimately, safer and more readily available delivery of patient care. A broad-based application of these very appealing technologies will eventually need to be regulated by the FDA and by the CMS.

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