

Recommendations for the Resumption of Elective Neurointerventional Procedures during the COVID-19 Pandemic

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ABSTRACT

The COVID-19 pandemic has required temporary reallocation of healthcare resources in order to care for patients and to protect healthcare providers. Initially, non-emergent neurointerventional procedures were deferred to protect patients and healthcare workers, and to conserve resources. As the pandemic has become more manageable by local health systems, and some elective conditions have become more urgent, resuming non-emergent procedures has increasingly become a priority. The goal of this paper is to discuss relevant and practical elements of 'reopening' non-emergent neurointerventional services in the setting of a pandemic. Through an evaluation of key principles, a roadmap for managing neurointerventional cases during a pandemic is provided.

Background

The zoonotic novel β -coronavirus was identified in the human population in late 2019, and spread rapidly throughout the world. Labeled as the Coronavirus Disease 2019 (COVID-19) by the World Health Organization (WHO), infection induced by the virus reached pandemic proportions by early March 2020. The United States Centers for Disease Control and Prevention and the WHO have recommended aggressive measures to prevent viral transmission, including precautions such as personal protective equipment (PPE), handwashing, and social distancing, as well as self-quarantine for those with suspected or proven infections. In mid-March, U.S. hospitals adopted protocols to cease all elective, non-urgent procedures and clinic visits, as requested by the U.S. Surgeon General¹, supported by state government orders, and recommended by from major physician organizations including the American College of Surgeons (ACS) and American Society of Anesthesiologists.^{2 3} The goals of limiting non-essential healthcare have been to protect vulnerable patients and healthcare workers from unnecessary COVID-19 exposure, as well as to conserve resources. Resource conservation aims at preserving personal protective equipment (PPE), hospital and intensive care unit (ICU) beds, ventilators, and other medical equipment and supplies for the anticipated volume of COVID-19 patients with urgent and emergent medical needs.⁴

Despite the importance of these public health efforts and social distancing measures to control COVID-19 transmission, elective medical care and surgical procedures cannot be postponed indefinitely, and eventually many non-urgent conditions progress to urgent ones requiring treatment. Preparation and timelines for

resumption of elective procedures may vary at individual hospitals, based on multiple factors including geographic region, the local and regional incidence of COVID-19, available workforce, and supply-chain resources. As regional governments gradually re-open businesses, healthcare organizations must develop thoughtful action plans for the safe and efficient re-integration of elective procedures to address these needs. The purpose of this document is to provide guidance during the COVID-19 pandemic on the resumption of elective neurointerventional procedures which minimizes the risk of transmission of infection to patients, families, and healthcare providers while enabling healthcare organizations to provide optimal care to all the patients they serve. Indeed, while the initial outbreak of COVID-19 may be decreasing, there is a clear need for discussion and establishment of safe practices for stratifying workflows whenever regional and institutional resources are strained. Our goal is to provide a workable framework for this and future pandemics that affect the care of neurointerventional patients.

Timing of Resumption of Elective Cases

When resuming elective neurointerventional radiology (NIR) cases, institutions should follow local, regional, and state regulations, and should consider the following principles:

1. *HOSPITAL RESOURCES:*

The medical center must maintain adequate resources to safely and effectively diagnose and treat its current population of COVID-19-positive patients and persons under investigation, as well as anticipate an incremental volume of new cases without

resorting to a “crisis mode” of care.^{5 6} Consistent monitoring and tracking of resources will be essential, including hospital-ICU bed capacity and supply of ventilators, oxygen tanks, sedatives/anesthetics, critical medications, PPE, and key personnel for each stage of the procedure. Advanced plans and protocols for inter-patient cleaning of NIR suites, and workflow if COVID-19 positive and negative patients share sequential access to the same space will preserve resources and minimize delays.

The resumption of elective procedures should be based upon a graduated approach that accounts for the total capacity of the healthcare system to accommodate pandemic needs with a reserve of resources. Fortunately, most elective patients require shorter lengths of stay and lower intensity of care than the average COVID-19 patient requiring hospitalization. This difference should be considered, as it may allow flexibility to respond to new waves of COVID-19 inpatients.

2. COVID-19 SCREENING:

All patients scheduled for elective procedures should undergo clinical screening for COVID-19 prior to their procedure. Screening typically consists of a direct measurement of a patient’s temperature (preferably using non-contact means), and questions regarding the presence of a new or changing cough, shortness of breath, fever, chills, repeated shaking with chills, muscle pain, headache, sore throat, new loss of taste or smell, known exposure to a COVID-positive individual, and recent history of any temperature > 100.4° F. If the temperature is greater than 100.4° F, further investigation is warranted to determine whether to proceed. Organizations may also require COVID-19 laboratory diagnostic testing for elective procedures, especially for

patients at increased risk for the disease (e.g., those living in a long-term care facility) and those requiring general anesthesia or at high risk for intubation. If a patient screens positive, testing for COVID-19 prior to a procedure or postponing a procedure is advised. Depending on hospital policy and test availability, in some regions asymptomatic patients will also be tested. Patients who are suspected or confirmed to have COVID-19 should reschedule their elective procedure. Urgent procedures would move forward with appropriate PPE. More protocolized risk stratification rubrics may be warranted, depending on the institution and its resource capacity. Healthcare providers and workers should also be screened on a routine basis, as per their organizational policies and governmental guidelines.⁷ Clinical areas should be restricted to essential personnel only, and staff turnover and traffic within the procedural suite during cases should be minimized.

The resumption of elective cases will significantly increase the demand for COVID-19 tests. The healthcare organization should have the capacity to perform COVID-19 testing on patients in the perioperative or inpatient setting, as well as testing of hospital employees to ensure the protection of patients and staff.⁸ Organizations must define when and where patients will undergo COVID-19 testing in advance of a procedure, and by which test methodology. After a patient is screened or tested, social distancing is recommended until the time of the procedure. Ideally, initial screening and any necessary testing should be completed prior to entry into the hospital to minimize exposure to other patients, healthcare workers, and the facility itself. Elective procedures may be suspended if an organization's testing capabilities fall below the levels necessary to maintain adequate reserves.

3. ACCESS FOR FAMILY MEMBERS:

The benefits of family members and close friends to provide support and comfort, and assist with decision-making for patients undergoing procedures, is well recognized. The healthcare system or organization should have protocols in place for a limited number of family members to have access to the hospital, which balances these important needs against the risks of acquiring and transmitting infection and the need to conserve PPE resources. Any family members allowed into the facility for elective procedures should undergo appropriate screening per standard hospital protocol, and should wear face coverings as per local guidance. Hospitals should be able to provide adequate waiting room space for appropriate social distancing.

4. REGULATORY

Resumption of elective NIR procedures should be aligned with other clinical services and healthcare system governing bodies, as well as with local, regional, and state guidelines. Initially, during the early phase of the pandemic, the idea was promulgated that a “sustained decrease in measures of COVID-19 incidence for at least 14 days should be considered before transitioning to provide surgical services for patients without immediately life- or limb-threatening conditions ^{9.}⁸ ¹⁰ This has been more recently challenged, as the incidence of disease may reflect the volume of testing more than it reflects the burden of disease in the community, and published numbers may have little correlation with the likelihood of a resurgence that threatens the availability of hospitals’ resources. Instead, the number of available ICU beds and

ventilators is likely be a superior indicator of a hospital's preparedness and capacity for elective cases during this pandemic.^{8 10} Governmental regulation is expected to continue to evolve over time to reflect the burden on the healthcare system, rather than overall COVID-19 case rates, informing public health policy and hospital regulatory guidelines.^{5 6}

Prioritization of Elective Procedures

The COVID-19 pandemic consists of multiple local and regional outbreaks across the country, each with its own dynamics, disease burden, and resource setting. As hospitals adapt their daily operations to the pandemic, it is recommended that individual practices develop their own system of prioritization for performance of non-emergency procedures, taking into account the risk to a patient in delaying an interventional procedure. Such a protocol should be transparent across clinical service lines and focused on comparative patient risk assessment. This facilitates an open discussion among services that may need to share resources such as PPE, anesthesia teams, ventilators, operating rooms/interventional suites, inpatient/ICU beds, and blood products. The Centers for Medicare and Medicaid Services (CMS), the ACS, and other groups have advocated a tiered system that stratifies patients according to the medical risk of their condition.^{10 11} **Table 1** shows a sample rubric for triaging patients in need of neurointerventional procedures. Guides such as this are not intended to be exhaustive lists nor requirements that replace a physician's judgement about a patient's individual circumstances, but they may promote transparency and consistency of care, help communicate expectations, and serve as a model for assessing the relative severity and

complexity of patients' conditions. As the number of patients requiring hospitalization and the availability of local resources fluctuate, the most elective (Tier 1) cases may have to be delayed until conditions improve. Frequent communication with hospital administration and other clinical services for status updates on available resources is recommended to facilitate scheduling of an elective case. It is also essential to continuously update the roster of upcoming cases, and have the flexibility to shift a patient to a new tier if that patient's clinical status changes.

Tier 3 (Emergent) cases should proceed regardless of hospital/resource utilization status regarding the pandemic. Recommendations for the management of emergent cases with COVID-19-suspected or unknown patients have been provided by the SNIS and ESMINT previously.^{4 12} Tier 2 (Urgent) cases should be delayed no longer than 30 days if possible, but institutional dedication of resources may shift needs, requiring continued communication about scheduling. Tier 1 (Elective) cases may be delayed as long as necessary, or until such time as risk of hospital acquired infection is low relative to resources and ability to care for patients. Finally, there may be situations where multi-specialty care is necessary on complex cases, and the coordination of services may impact timing and prioritization, beyond those expected by medical condition alone, in order to achieve the appropriate outcomes.

Ethics of Prioritization

We appreciate that the practice of neurointerventional care during the COVID-19 pandemic has significantly changed in ways that could never have been imagined, and our role in the allocation of scarce resources and the need to prioritize patients – even thrombectomy candidates - may lead to ethical challenges. Legally, practitioners should

follow recommendations from governmental bodies regarding local/regional scheduling of non-emergent cases. We recognize that the psychosocial and financial pressures facing patients while waiting for their elective procedures can be significant, especially for those who have lost close friends or family to COVID-19 and those who have lost, or are at risk of losing, their source of income and insurance. Furthermore, many patients have been on waiting lists, rescheduled multiple times over the course of the COVID-19 crisis, due to hospital constraints and other factors outside of their control. We recommend balancing factors related to fair consideration of a patient's circumstances and medical necessity. Psychosocial factors are also important; it is reasonable to consider that extreme hardship or waiting time in the queue for a procedure may break ties among patients with the equivalent medical acuity. We also endorse the American College of Radiology recommendation that healthcare institutions should try to anticipate patient needs, take steps to mitigate patient suffering, and communicate solutions to patients prior to arrival.¹³

Operational Logistics

An impartial hospital governing body or committee, consisting of representatives of hospital administration and all affected clinical service lines, may be necessary to adjudicate case priority status among physicians and specialties. Frequent, regularly scheduled meetings or huddles are recommended to facilitate communications about workflow and safety issues, patient concerns, and policy updates; this promotes close monitoring and management while conditions are rapidly changing. Frequent re-evaluation of the urgency of delayed cases in partnership with patients should be performed, as some cases initially deemed of lower urgency may become more urgent

in time; the tier to which a patient's case is initially assigned is not immutable, and may require modification for new symptoms or signs of impending deterioration. Maintaining block operating schedules may not be realistic until such time as the case backlog is reduced. Inpatient cohorting and social distancing requirements may also require new considerations for organization of staffing and workflow.

Specific Recommendations for Neurointerventional Procedures

Once the health system and applicable local, regional and state authorities have confirmed conditions and resources are adequate to resume elective cases, and once elective procedures have been prioritized, such procedures can be scheduled and performed. We suggest some recommendations to safeguard both patients and healthcare providers.¹⁴⁻¹⁸ **Figure 1** is a printable checklist that embodies the suggestions below.

1. Patients and family members should be educated regarding temporary pandemic-specific measures currently required for elective procedures as well as the additional risk, however minimal, that they could become infected during their hospital experience. They should be given the opportunity to delay the procedure if desired to minimize this inconvenience or discomfort. Pandemic-specific issues that may be discussed include new restrictions on visitors in the hospital, new screening and disease testing requirements, and expectation for patients to self-monitor temperatures. Policies should also address recommendations for self-isolation between the time of COVID testing (typically 48 to 96 hours before the procedure) and the morning of the procedure,

differences in patient flow and experience, the duration of post-procedural care for COVID-positive patients, and the possible need to cancel or reschedule a procedure in response to a positive COVID test result or resurgence of the pandemic in the hospital/community. The timing of this process may change based on the availability for rapid testing of the disease.

2. The procedural team should, at appropriate intervals, screen patients for risk factors, order pre-COVID testing on patients based upon any positive risk factors as well as based upon the anticipated need for certain forms of anesthesia or high flow rates of supplemental oxygen via mask or nasal cannula, which may be aerosol generating, need for observation in a non-isolation area such as pre or post-operative recovery, and consistent with the health-system's policies on pre-operative COVID testing.

3. The procedural team should communicate results of any positive COVID testing to the patient, the OR/interventional angiography suite, anesthesia, recovery room, day surgery and/or post-procedural inpatient care units as indicated. Consensus should be reached whether to continue with the elective procedure on the COVID-positive patient, utilizing the hospital's COVID protocols, or whether to reschedule the procedure.

4. The procedural team should confirm post-procedural ICU/hospital bed space availability at time of scheduling and again the morning of the procedure. Confirmation of COVID status and availability of anticipated post-procedural bed should also be included in the standard pre-procedural time out.

5. Procedures should be performed with PPE as per the institution's standard protocols and COVID-19 policies, specific to COVID positive patients such as enhanced PPE, appropriate donning/doffing, and PPE protocol exiting and entering the interventional suite.

Conclusion

The COVID-19 pandemic has placed significant strain on healthcare institutions and their resources. Neurointerventional services are vital to patients and their communities. While the initial case spread curve may be flattening, the epidemic has exposed a need for developed protocols to handle neurointerventional practices in moments and environments where resources are strained. Safe and effective scheduling of non-emergent cases during a pandemic requires a coordinated and protocolized approach that balances the challenges of the pandemic with the needs of our patients requiring neurointerventional surgical care for serious diagnoses.

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TWM was the primary author and, as such, was the primary constructor of the initial text of the manuscript. He also led discussion on consensus regarding each issue. SAA, GRD, KMF, SWH, FAM, AP, and CMS all provided drafts and revisions of segments of the manuscript. They were heavily involved in the editing process. JFF, as senior author, was responsible for organizing the writing group, overseeing the outline construction, facilitating communication between the writing group and the Standards and Guidelines Committee, drafting and editing of the manuscript, the submission/proofing for publication.

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None of the authors have any competing interests related to this manuscript. Specific potential conflicts of interest are disclosed below.

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Dr. Fraser is an equity interest holder for Fawkes Biotechnology, LLC, an owner in Cerelux, LLC, and a consultant for Stream Biomedical, Medtronic, and Penumbra.

Dr. Hetts has research grants and contracts with NIH, Siemens Healthineers, Stryker Neurovascular, Microvention Terumo, Route 92 Medical, is a stockholder in ThrombX Medical, and a consultant for Imperative.

Dr. Schirmer receives research support from Penumbra, and is a shareholder in Neurotechnology Investors.

Dr. Duckwiler is a consultant (proctor) for Medtronic.

All other authors report no relevant conflicts of interest.

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TABLE 1. Tiered system for case designation.

Tier	Designation	Definition	Examples
1	Elective	No likelihood of medical harm from delay	<ol style="list-style-type: none"> 1. Direct puncture sclerotherapy 2. Angioplasty/stenting for asymptomatic carotid atherosclerotic disease 3. Low risk intracranial aneurysm/vascular malformation 4. Late (>2 year) follow-up angiography for stable treated cerebral aneurysm
2	Urgent	Possible or likely serious medical harm if delayed beyond 30 days	<ol style="list-style-type: none"> 1. High risk unruptured intracranial aneurysm 2. Unstable/ symptomatic atherosclerotic disease 3. Tumor or Infection requiring biopsy to guide management. 4. Tumor requiring preoperative angiography, balloon test occlusion, or embolization for surgical planning/treatment 5. Dural arteriovenous fistula with high-risk cortical venous drainage 6. Pain –Minimally Invasive Spinal Procedure[#]
3	Emergent	Serious medical harm possible if any delay	<ol style="list-style-type: none"> 1. Acute Ischemic Stroke / ELVO - mechanical thrombectomy 2. Acute intracranial hemorrhage (SAH/ICH/IVH/SDH) requiring diagnostic angiography and/or endovascular treatment of ruptured aneurysm/vascular malformation 3. New neurological deficit/symptoms related to neurovascular pathology requiring diagnostic angiography or endovascular treatment 4. Acute head and neck bleeding 5. Dural Venous Sinus Thrombosis - thrombectomy

[#] Immobility, reliance on narcotics, depression or suicidal ideation associated with chronic severe pain represent serious confounding medical/psychological issues that may render a case urgent, especially spinal pain procedures, vertebral augmentation, and minimally invasive spinal decompressive procedures.