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Guest Editorials

The Value of Headache-Specific Recommendations During COVID-19

The coronavirus disease 2019 (COVID-19) pandemic has brought unprecedented levels of uncertainty for our entire population, and especially for clinical providers. As the disease is spreading from community to community, medical centers are scrambling to create procedures and policies to protect their patients, providers, faculty, and staff from potential infection, even from "asymptomatic carriers," while simultaneously working tirelessly to continue to provide care to all patients. On March 14, 2020, US Surgeon General Jerome Adams first recommended hospitals and health care systems should consider stopping elective procedures. Centers for Medicare and Medicaid Services followed with guidance on March 18, 2020 to limit "non-essential adult elective surgery and medical and surgical procedures, including all dental procedures" in an effort to (1) prevent further spread and (2) protect the resources of the health care systems currently caring for (or soon to be caring for) COVID-19 patients. As of April 1, 2020, 32 states have released statements addressing the issue of elective procedures during the ongoing COVID-19 outbreak.

Longstanding efforts to begin "telehealth medicine" have suddenly become a top priority to ensure patients' needs are still addressed without in-person visits that could un-necessarily place patients, providers, and staff at risk of exposure. Inadequate supplies of personal protective equipment (PPE), and uncertainty over PPE requirements, have led to additional concerns for in-person outpatient clinic appointments. Many questions have arisen as to the definition of "non-essential" and how to effectively manage patients through telehealth visits without in-person visits. Keeping patients from seeking emergency department evaluation is a top priority, which could increase the patient's chance of exposure to COVID and places additional strain on an already pressured system.

In this issue of Headache, Dr. Szperka and colleagues have created expert guidance for "Migraine Care in the Era of COVID-19."[1] This publication is extraordinarily helpful at this time of uncertainty. Providers can utilize this publication to help make effective decisions about treatment approaches for headache patients in the midst of the current COVID pandemic. Many providers have stopped conducting infusions for refractory or severe headaches, or clinic-based headache procedures, such as Onabotulinum toxin A or occipital nerve blocks. The authors provide a practical reference of alternative prevention strategies. For patients with status migrainosus or a severe or continuous pain cycle, the authors also recommend rescue treatment approaches and give specific dosing guidance. Status migrainosus is a commonly experienced manifestation that can lead to urgent attention, often-requiring provider communication, care in-between clinic visits, clinic-based infusions, and/or a trip to the ED or urgent care. There are few evidenced-based guidelines for management of this condition, making expert recommendations invaluable for this time of headache management. Although these current strategies are limited to the authors' experiences and those with whom they consulted, these strategies could form the

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basis of future evidenced-based guidelines for headache rescue treatment approaches. The newly published "manual" has a wide ability to help providers seeing headache in a multitude of settings including primary care physicians, neurologists, and headache specialists.

While many medical centers have already recommended all headache procedures pause, some centers are asking providers to give guidance on whether clinic visits or procedures for headache patients are "essential." Providers have been asked to give guidance on additional treatment options. This document serves to provide evidence that (1) effective outpatient treatment approaches are available and may be an effective alternative during this time and (2) many headache providers across the country are already effectively working to care for their patients without the increased risks of in-person visits.

This publication also serves as a demonstration of the value of an established network of committed providers working together for a common goal during "good times," that becomes invaluable during a crisis. The inspiration for this paper "grew out of conversations during a meeting of the American Headache Society (AHS) Practice Management Committee."[1] This group was remarkably poised to rapidly create and disseminate such a publication given their longstanding dedication to "Headache Practice Management." Given their expertise and depth of experience in caring for headache patients, the authors were able to call on their own professional experiences and those of their colleagues to suggest clinical treatment strategies. Further insight was gained from an established online network of female U.S. and Canadian headache specialists, the Facebook group "Migraine Mavens." The pre-existing communication networks, the infrastructure support from a national organization, and the representation from providers across the country created an ideal environment ready and able to create such a meaningful document that addresses an important public health issue with rapid turnaround.

During COVID-19, treatments that may have been considered "too expensive" in the past for typical insurance coverage, if effective in preventing headache patients from going to the Emergency department (ED), may now be dramatically less expensive than an ED visit and potential COVID-19 exposure. In addition, coverage of expensive migraine medications may be cost saving in the long-term with decreased disability and hospital care. The authors urge insurance companies to:

- Re-consider coverage for treatments that, prior to the COVID-19 pandemic, may have been considered "out-of-pocket" or "out-of-network"
- Eliminate prior authorizations, step therapy requirements, and limitations on simultaneous coverage for migraine therapies, as time-sensitive access to treatment is imperative for patients and removal of unnecessary administrative burdens for clinical staff is critical
- Eliminate or minimize migraine medication copays given the financial impact of COVID on patients

An additional recommendation for insurance companies would be the removal of a duration of time between ending Onabotulinum toxin A treatment and beginning CGRP treatment, as many insurance companies have had coverage policies in place that limit the ability to start a CGRP treatment until at least 4 months since the last Onabotulinum toxin A treatment. Such a policy significantly limits access to treatments when in-person Onabotulinum toxin A treatments are being avoided due to COVID.

This publication is a reference for providers' use in justifying to insurance companies the value of certain treatment approaches, helpful when dealing with prior authorizations and other insurance processes for treatment coverage. Many insurance companies have already changed policies about treatment coverage during COVID-19, so providers should also be aware that treatments previously not covered, may now be covered, and pre-pandemic insurance coverage plans should not dictate prescribing patterns during COVID.

This manuscript may also serve as a model for other specialties and subspecialties who may need to gather consensus or recommendations for disease-specific treatment options to continue providing excellent care during COVID-19. Given the rapid progression and spread of COVID, many hospitals have converted to providing care for "COVID-only" patients. Millions of Americans with other medical problems continue to need care during this time, and having a systematic approach is especially helpful to guide providers to effective management plans.

The manuscript has a few limitations, which may have been addressed with a longer review process. However, the rapid turnaround of this publication is justified given the current crisis and immediate merit the recommendations provide, removing any questions as to the value of its swift dissemination. For example, the article lays out exact dosing of medications, which provides concrete informative instructions for providers, but does not offer pediatric considerations or weight-based medication dosing.

The recommendations for acute treatments begin with the 2015 AHS Guidelines for acute management a migraine, and describes nonsteroidal anti-inflammatory drugs, triptans, and anti-emetics as options. This brief statement is followed by in-depth paragraph-long discussions of newly approved Food and Drug Administration (FDA) treatments. For example, in bold, described next, are the gepants class, lasmiditan, and neuromodulation devices. Gepants are an exciting class of medications for those in the headache world as they are a new class of acute treatment approaches and may provide alternatives to those who have otherwise "failed everything," however the data supporting their benefit has been questioned as to whether their effects are clinically meaningful.[2] Given the restrictions in travel, "shelter in place" provisions, and social distancing recommendations, this may be an excellent time for patients and providers to gain experience with treatments that many were previously hesitant to use due to potential or unknown side effects or long-term risks. For example, lasmiditan has an 8-hour driving limitation. Devices also offer hope as a newly approved non-drug treatment approach. However, as the authors clearly point out, these devices typically require out-of-pocket payments and may not be ideal as patients may be suffering real financial crisis during COVID. Highlighting gepants, lasmiditan, and devices with such prominence gives the appearance that they should be considered first-line treatment approaches, when older treatments may be just as useful without the unknown long-term risks and costs associated with treatments only recently made available to the public.

In the preventive treatment section, a reference is made to prior prophylactic guidelines, without any specifications or even a table referencing or naming such medications, while an entire paragraph is devoted to the new calcitonin gene-related peptide (CGRP) class of preventives. The authors do an excellent job of addressing the potential risks of cardiac prophylactic medications during COVID, and the recommendation to avoid steroid treatment for those with COVID, but fail to point out unknown potential interactions of COVID with the new CGRP medications.

The authors acknowledged that the pandemic may be especially challenging for migraine patients, with the significant increase in stressors, anxiety, and changes in daily routines, all of which may serve a headache triggers. The authors omitted to include evidenced-based non-drug strategies that may be especially powerful at this time of stress. For example, relaxation strategies or mindfulness[3] may help target the tremendous stress and anxiety of the pandemic. Other effective integrative approaches such as supplements[4] can be obtained through online stores, particularly beneficial in avoiding COVID exposure.

As previously described, this paper effectively argues that insurance companies need to make adjustments during this time for treatment coverage. However, prescribing expensive medications or treatments that are often not covered (such as recently approved FDA medications or devices) may result in patients, providers, and/or staff spending precious time dealing with insurance coverage issues when urgency in care is essential.

Given the targeted approach of this manuscript, additional issues important for headache care during COVID that were not discussed in this manuscript could be addressed with future papers. The authors recognized this point of the evolving pandemic, and offered to work to "update the manuscript as the need arises".[1] Future discussions could include:

- When or if in-person outpatient urgent headache care visits are needed during COVID-19, especially since the timeline to resolution of the pandemic is uncertain.
- How to address referrals for new onset headache, when the symptom of headache may be a manifestation of COVID itself, as headache may be an early symptom of COVID prior to cough/fever.
    - Are patients with pre-existing headache conditions more prone to have headache be an early manifestation of COVID, and should COVID be

a consideration if a patient with stable headaches has a "sudden worsening" of their headache syndrome?

- Are there new headache conditions that are unique to COVID, such as ones that have nerve involvement? (eg, Trigeminal Neuralgia).

Many of these discussions are becoming more apparent as the pandemic evolves, and likely more issues and questions will arise as the pandemic progresses, all worthy of further investigation.

In summary, this publication is an extraordinary effort by a group of dedicated headache specialists with unique expertise in Headache Management with "real-world" strategies during this pandemic. This will help headache providers continue to provide excellent care without the risks involved with in-person visits during COVID-19. It is helpful at both the provider level, with specific and concrete recommendations for acute, preventive, and bridge treatment approaches, and at the administrative level, as it provides recommendations that can help inform decision making regarding the ability to provide care in the absence of in-person visits that could potentially avoid unnecessary and potentially dangerous ED visits. This paper also serves as a model for other providers to consider – as recommendations for disease-specific treatment options during COVID will enable patients to continue to receive non-COVID care during this pandemic. This paper could also help inform the development of future evidenced-based guidelines. The limitations described are minimal compared to the benefit of the rapid turnaround of this manuscript at this time of crisis.

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