



PART 2 Medicolegal Issues During the COVID-19 Pandemic

This three-part series—Part 1 in the June issue covered patient confidentiality—reviews a few topics giving physicians concern during the COVID-19 pandemic.

Maintaining Office Safety

PATIENTS | You retain the right to refuse a patient who will not cooperate with requirements to wear a facemask. If they refuse and can be safely seen later, they should be given an appointment past the expected isolation period. However, you cannot summarily deny care to someone under active treatment without adequate notice to permit them to set up care elsewhere.

You should also keep the issue of constructive abandonment in mind. Actual termination from your practice because of how a patient conducted themselves is something to deal with when the isolation regimen has ended.

EMPLOYEES | The EEOC has specifically said that nothing in the ADA should be taken to interfere with employers following public health recommendations. As an employer under OSHA obligations to maintain a safe workplace and a physician with a fiduciary duty to safeguard the health of your patients, you may therefore take steps that you would normally be more limited in.

Current employees can be denied access to your premises if they place others at a significant risk. You can require that employees self-report any exposure, answer questions about symptoms, and be tested with sufficient medical basis. You can require temperature checks, should counsel employees to be mindful of how they feel generally and to immediately report any changes, and remind all that hygiene and PPE precautions apply fully. All employees should be required to engage in proper hygienic procedures. If an at-will employee is not cooperating with hygienic conduct, you may fire them immediately.

If an employee was exposed or has tested positive, you will need to inform co-workers, but ask for permission to reveal their identity. If they refuse, tell other employees without naming the source. Since a sudden absence at this time can be revealing, firmly instruct in writing that the employees who remain not discuss a co-worker's PHI. While an employee is on self-isolation, ask only the minimum information necessary to make a work-related determination of their safe return. You can also require that they provide a physician's note saying that they are fit to return.

This article was written by Dr. Medlaw, a physician and medical malpractice attorney.



REN: A Novel Approach to Migraine Treatment



Contributor
Alan M. Rapoport, MD
Clinical Professor
of Neurology
The David Geffen School
of Medicine at UCLA

Evidence suggests that pharmacologic agents often used to treat migraine may at times be ineffective, poorly tolerated, contraindicated, and—if used too frequently—can cause possible medication overuse headache, migraine chronification, and notable medical complications. A significant unmet need exists for effective and well-tolerated non-pharmacologic acute migraine therapy, according to Alan M. Rapoport, MD.

Studies have found external trigeminal nerve stimulation, non-invasive vagus nerve stimulation, and single-pulse transcranial magnetic stimulation to be safe and well-tolerated, non-invasive neuromodulation approaches. However, “they only work for up to 60% to 70% of patients,” says Dr. Rapoport, with efficacies that are at times inferior to those reported for migraine-specific pharmacologic treatments.

A Novel Approach

A novel alternative to pharmacologic and the above-mentioned non-invasive neuromodulation approaches to acute migraine treatment may be found in the use of remote electrical

neuromodulation (REN). With REN, the upper arm peripheral nerves are stimulated to induce conditioned pain modulation, which Dr. Rapoport and colleagues explain as “a descending endogenous analgesic mechanism caused by subthreshold conditioning stimulation that inhibits pain in remote body regions. REN presumably activates descending inhibition pathways that travel through the periaqueductal gray (PAG) and in the rostral ventromedial medulla (RVM) and involve the release of the neurotransmitters serotonin and noradrenalin; they inhibit incoming messages of pain in the trigeminal cervical complex (TCC) that occur during a migraine headache attack.”

A newly FDA-approved and available REN device (Nerivio; Theranica) is a wireless, wearable, battery-operated stimulation unit controlled by the patient through a smartphone app. Applied to the lateral upper arm for 45 minutes, the device mainly stimulates small skin nerves through a proprietary electrical signal comprising a modulated symmetrical biphasic square pulse with a modulated frequency of 100-120 Hz, pulse width of 400 μ s, and up to 40 mA output current (adjusted by the patient). In contrast with other neuromodulation treatments for migraine, the REN device uses upper arm

stimulation to produce global pain inhibition, allowing patients to continue with daily activities while it decreases migraine pain.

Data Thus Far

A pilot study, a pivotal study, and exploratory within-subject post hoc analyses thus far “show that the REN device works as well as existing treatments with almost no side effects,” says Dr. Rapoport. The pilot study found that treatment with the REN device helped achieve significantly reduced headache pain when compared with a sham device and had the greatest effects when applied within the first 20 minutes from migraine attack onset and used for 45 minutes.

The pivotal study found a statistically significant, clinically important benefit of REN when compared with sham treatment in adults randomized to either treatment for 4-6 weeks. “Pain freedom at 2 hours was 37%,” explains Dr. Rapoport (Figure). “Separate research shows this to be comparable with triptans. Pain relief at 2 hours was 67%, which is better than with many triptans.” Pain freedom and pain relief rates at 2 hours with the sham device were 18% and 39%, respectively. Most bothersome symptom relief rates at 2 hours were 46% for REN and 22% for sham.

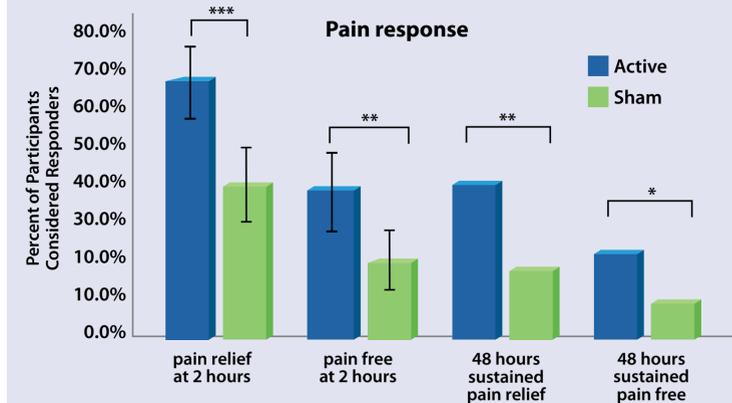
Exploratory within-subject post hoc analyses were performed on a subgroup of pivotal study participants who treated at least 1 attack with the active REN device and reported pain intensity at 2 hours posttreatment. “Each patient used usual care for 1 month before entering the double-blind study,” notes Dr. Rapoport. “Upon comparing their response to REN with that of any usual care, REN was found to be more effective. When compared with migraine-specific medications only, REN treatment was found to be just as effective.”

Looking Ahead

Trials are underway to study REN in more severe chronic migraine, with encouraging early results, according to Dr. Rapoport. “Future studies may also assess REN as a treatment for cluster headache, medication overuse headache, migraine with vertigo, and menstrual-related migraine,” he adds, “as well as for preventive treatment of migraine. For now, REN is a promising new treatment for patients with migraine.”

Figure Efficacy of Remote Electrical Neuromodulation

The figure below depicts pain response at 2- and 48-hours post-treatment. The error bars represent 95% confidence intervals.



***P < .001, **P < .005, *P < .05 (adapted with permission from Yarnitsky, et al.)

Source: Adapted from: Yarnitsky, et al. *Neurology*.

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Telemedicine Fatigue & the Stress of Remote Care

The first thing I heard from my team after starting fulltime telehealth was the exhaustion that seemed to set in at the end of the day. I have noticed this myself. After 8 hours of back-to-back virtual engagement with parents, I found myself with a kind of telemedicine fatigue that's hard to describe.

There are a few potential explanations for this almost consistent report among my colleagues who had transitioned to a full telehealth practice. I'm going to continue to dig deeper into this, but I suspect that it represents a couple of things.

Often, there are inconsistencies in connection, lighting, front-facing lens hygiene, and video quality that require a kind of on-the-fly compensation. And there are the parents who want to hold their phone at arm's length during a 30-minute consult, creating a simulated earthquake experience.

The most obvious potential contributor to this fatigue is the simple stress of transition. Adjusting to a completely different workflow is impossibly challenging, especially for health professionals who have been conducting analog care for most of their career. And on both ends of the encounter is the new “literacy” of engagement by live video connection. For example, the basic error of watching the screen display rather than the seeing-eye camera leads to a classic disjunctive virtual gaze that is subtly jarring and strangely distracting.

But the source of telemedicine fatigue goes beyond professional adjustment and correction of technical glitches.



I've identified that the emotional stress of subtly strained connection is a huge contributor to the exhaustion I feel. A video connection negates the subtleties of connection that are critical to my assessment of a parent and child. Identifying and exploring these subtleties is central to the care of chronically ill children and their families. It feels like I'm working hard to pick up on non-verbal cues that may be difficult to identify or simply out of the frame of view. The simultaneous observation of a mother and child in the same frame presents its own challenges in a home environment. I call this the “drive by” telemedicine assessment, as the child zips in and out of the field of view grabbing toys, running for snacks, etc.

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Light Colors & Effects On Migraine



Contributor
Arnold Wilkins, DPhil
Emeritus Professor
Department of Psychology
University of Essex
UK

Research suggests that patients with migraine have an increased sensitivity or intolerance to light, particularly flicker from sources like LED lighting and computer backlights. “Often, this photophobia can be reduced with tinted glasses, but the color that suits one patient might not suit the next,” explains Arnold Wilkins, DPhil. With the assistance of new color-testing technology, Dr. Wilkins and colleagues sought to understand light color preferences in patients with migraine.

The researchers conducted three studies—two published in *Vision* and one in *Headache*—comparing patients who had migraine with aura, without aura, and controls without migraine to better understand the differences in light color preferences. Using the Intuitive Colorimeter—an inexpensive instrument designed by Dr. Wilkins that allows patients to choose the tint that is most beneficial for them quickly and efficiently—the investigators were able to assess participants as they chose comfortable reading light. Once a comfortable color was chosen, the hue and saturation were refined to find the best color for each participant.

Participants without migraine chose light and color they would regularly experience in everyday life, whether natural daylight or artificial. The colors could all be categorized as blue, yellow, or white. Conversely, participants with migraine with aura chose strongly saturated colors, which could not be classified as natural daylight colors. “This was the case in all three studies with different samples of patients and two different investigators,” adds Dr. Wilkins. Once participants had chosen their preferred color, hue, and saturation, they were given lenses that provided that particular tint when worn in normal lighting and asked to complete various visual tasks with and without the lenses. Participants with aura increased word search speed by almost 50% with the lenses.

“Few practices in the US have the Intuitive Colorimeter used in our studies,” says Dr. Wilkins, “but I think it would benefit ophthalmologists to have this instrument in their offices.” There is preliminary evidence that various light tints may be helpful in the care of several neurological disorders (eg, autism, Tourette's) that, like migraine, are co-morbid with epilepsy and in which the brain may be hyper-excitable. Dr. Wilkins notes the need for additional research to further evaluate if tinted lenses may be beneficial in such patient populations.

COVID-19

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