



PART 1

Avoiding Liability in Telemedicine: Licensure & Coverage

Telemedicine has exploded in scope with the COVID-19 pandemic and will leave a lasting imprint on how medicine is practiced, so it is essential for physicians to understand its basic principles and the specific rules that govern it during the pandemic.

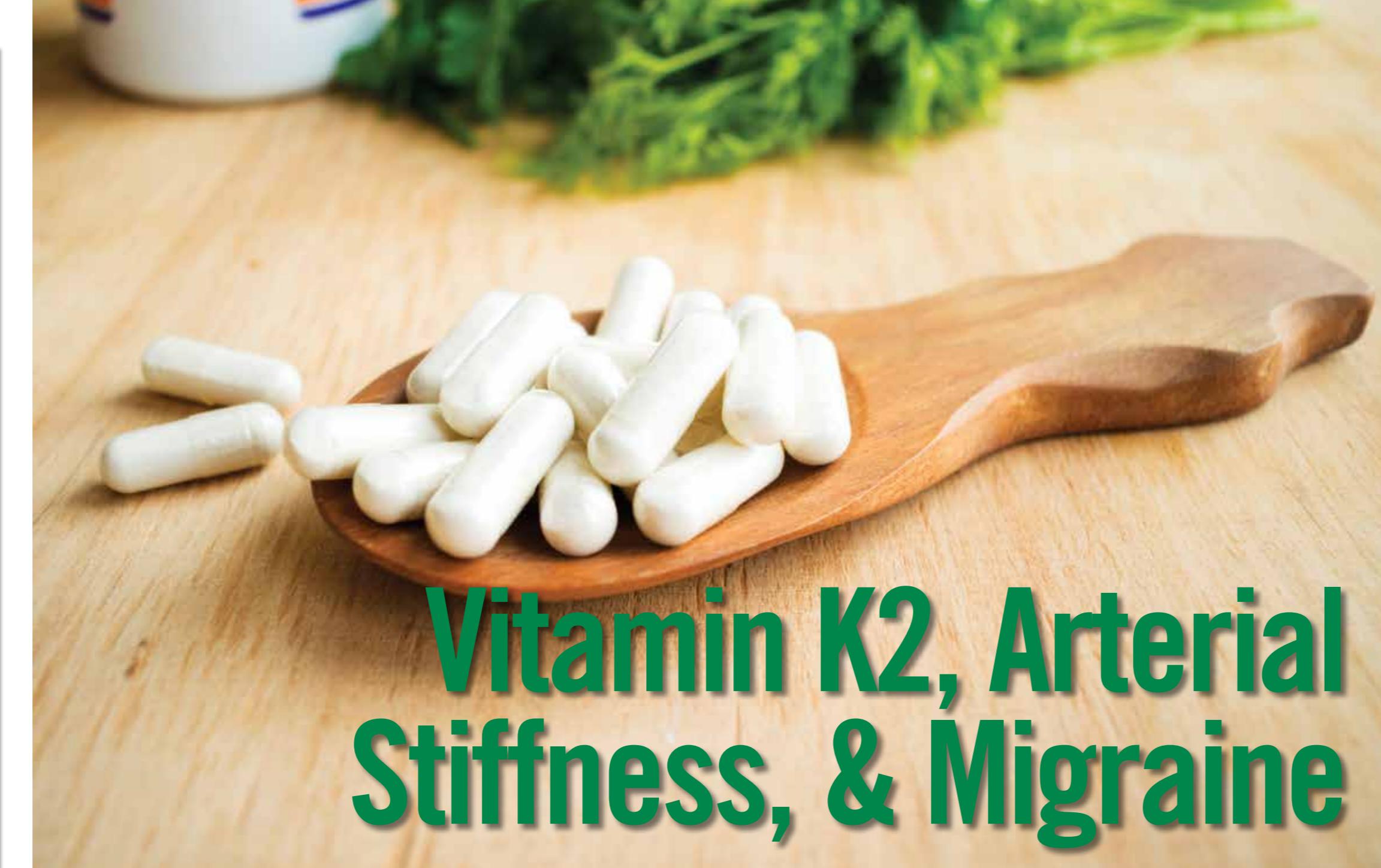
Normally, a patient's residence does not matter, because you see them in the state where you are licensed. However, when you as, for example, a doctor in Manhattan have a video visit with your patient at home just across the river in New Jersey, you are reaching into another state to practice and so your licensure status becomes of interest to that state. As a result of the COVID-19 crisis, states have extended licensure waivers. If you will be practicing telehealth with patients from states where you do not have a license, search fsmb.org for "states waiving licensure requirements" to make sure that is permissible.

Bear in mind that these modifications are related to the current pandemic. Do not assume that a waiver will continue past the end of the crisis, and make sure you meet all requirements that may re-establish if you want to continue to offer remote visits to your out-of-state patients, or you could face charges of practicing without a license.

The advent of the pandemic originally provoked a retreat by insurers, many of whom wanted to exclude COVID-related issues, but that was essentially a brief reaction, and virtual care coverage is now an expanding and competitive market. However, again, beware that while these changes are significantly the result of carriers seeing an expanding opportunity even after the pandemic ends, they are currently backed up by laws that offer considerable immunity from suits for those involved in COVID-19 care. That rates may rise later when such immunization is lifted should be assumed.

If you are getting coverage to do telemedicine, remember that it is not just about malpractice. You will need adequate coverage for technical issues and for privacy breaches. If you have free coverage of some \$50,000 for cyber issues on your current policy, make sure to increase it to at least \$1 million, because any breach can be costly and telemedicine is inherently more risky being entirely in the vulnerable electronic realm.

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



Vitamin K2, Arterial Stiffness, & Migraine



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With migraine as the fifth highest cause of years lost due to disability according to the WHO, approximately 38% of patients with migraine requiring preventative therapy but only 3% to 13% using it, and the limited effectiveness and significant adverse effects of currently available treatments—none of which are migraine-specific—a better understanding of disease pathophysiology

to help guide future research on migraine management is needed, explains Sola Aoun Bahous, MD, PhD, MHPE.

"Several mechanisms have been suggested to explain the condition and its linkage to other comorbidities, including generalized anxiety disorders, restless legs syndrome, chronic pain syndromes, and more serious cardiovascular diseases," adds Dr. Aoun Bahous, "but studies have failed to explain with certainty the increased cardiovascular risk and reasons behind

augmented large arterial stiffness in patients with migraine. Vitamin K2 (menaquinone) is a fat-soluble vitamin that serves as an essential cofactor in the activation of matrix Gla protein (MGP) in the vascular smooth muscle cell, with Vitamin K deficiency resulting in impaired MGP carboxylation and, subsequently, an increased calcification effect. Circulating concentrations of dephosphorylated uncarboxylated MGP (dp-ucMGP) have been shown to be indicative of vitamin K deficiency and associated with the extent of vascular calcification, arterial stiffness, and development of cardiovascular events in specific populations."

Exploring the Associations

For a study published in *Headache*, Dr. Aoun Bahous and colleagues hypothesized that patients with migraine have higher arterial stiffness and lower vitamin K2 levels than those without migraine, with a possible association between the two markers. The study team obtained health information from adults (89% women, mean age of 31.9 years) with migraine who were not on prophylactic therapy or any recent abortive ther-

apy and without cardiovascular disease, hypertension, diabetes mellitus, Raynaud's phenomenon, active cancer, or vasoactive drug use and age- and sex-matched healthy (without migraine) controls, all from a single outpatient clinic. "We performed physical examination, in addition to measurements of plasma dp-ucMGP (indicator of vitamin K2 status) and carotid-femoral pulse wave velocity (cfPWV), a measure of central (aortic) arterial stiffness and the gold standard non-invasive and reproducible technique for arterial stiffness measurement," adds Dr. Aoun Bahous.

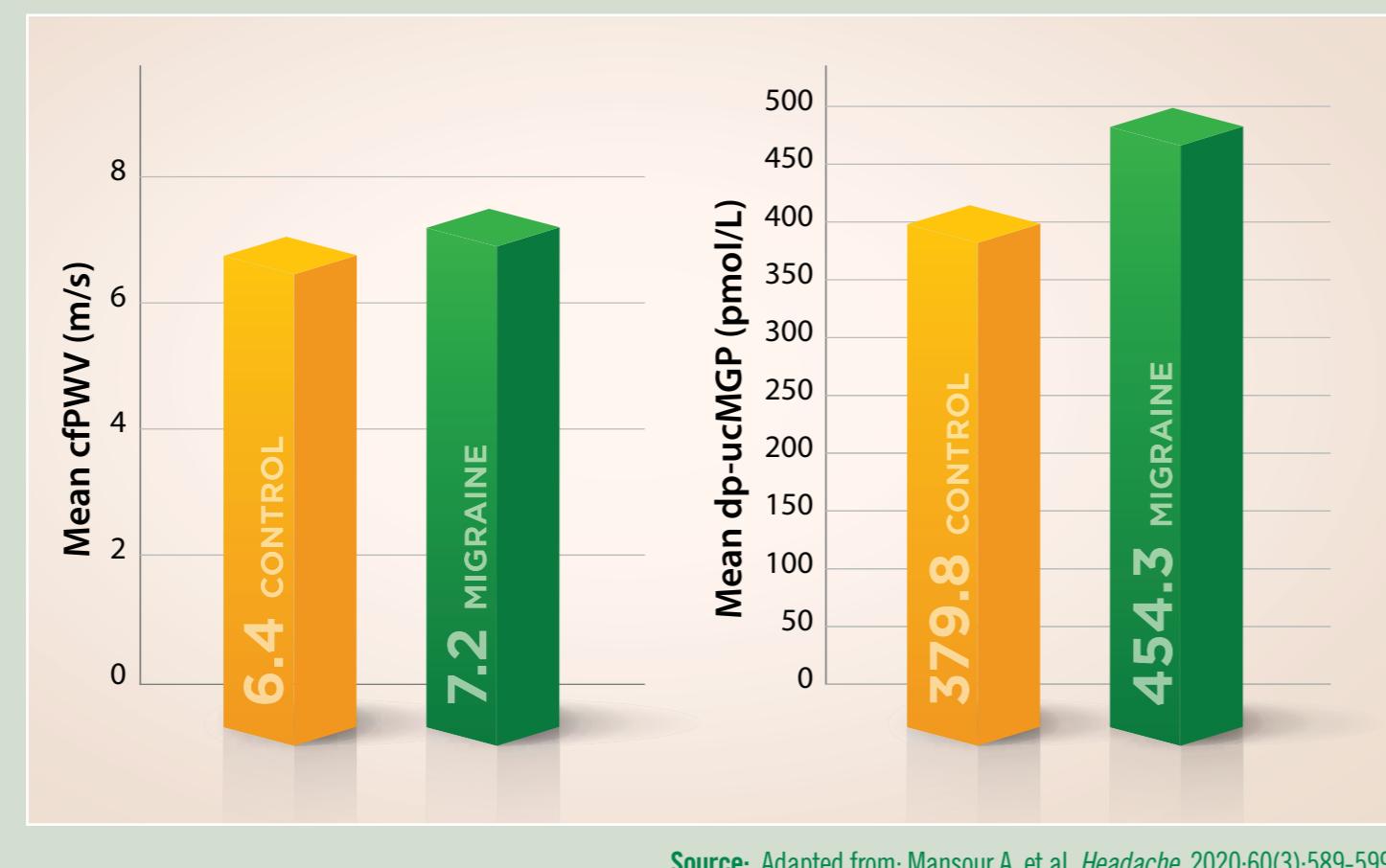
When compared with controls, patients with migraine had significantly higher arterial stiffness and increased levels of serum dp-ucMGP, reflecting vitamin K2 deficiency (Figure). "Although cfPWV was increased in patients with migraine when compared with controls, irrespective of aura status, this increase was independently associated with higher plasma dp-ucMGP levels only in the migraine with aura group after controlling for other variables," Dr. Aoun Bahous explains. "In particular, there was a cfPWV increase of approximately 0.18 m/s for every 100 pmol/L increase in dp-ucMGP. These results concur with prior research findings that the presence of aura amplifies cardiovascular risk when compared with both patients with migraine without aura and controls."

Looking Ahead

Dr. Aoun Bahous notes the need to direct the focus of research in the field of migraine headache toward examining the effect of vitamin K2 supplementation on migraine frequency, arterial stiffness, and cardiovascular outcome in patients with migraine. "Our study presents a plausible hypothesis that vitamin K2 deficiency in patients with migraine with aura may contribute to the increased cardiovascular risk observed in this patient population," she says. "Furthermore, patients with migraine in general have more vitamin K2 deficiency than their matched controls. Whether supplementation with vitamin K2 confers cardiovascular protection or reduces migraine episodes remains to be explored; nonetheless, discussing this potential relationship with patients with migraine may guide their dietary habits toward improving vitamin K2 status." ■

Figure Comparing Patients With Migraine & Controls

The figure depicts differences in mean carotid-femoral pulse wave velocity (cfPWV) and dephosphorylated-uncarboxylated matrix-Gla-protein (dp-ucMGP) between controls and patients with migraine with aura.



Third Leading Cause of Death Revisited



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Ever since the publication of the infamous 2016 *BMJ* opinion piece by Makary claiming medical error should be considered the third leading cause of death in the US, the debate on the true incidence of deaths caused by medical error has been raging. Many, including me, felt the Makary estimate of 251,000 deaths per year from medical error was grossly inflated. For example, Makary extrapolated the number of deaths from three outdated studies with a total of just 35 deaths, and medical error was not well-defined.

A new paper in *BMJ Open Access* by investigators from the UK looked at 70 studies involving 337,025 patients mostly treated in general hospitals. Of that total, 47,148 suffered harm with 25,977 (55%) of harms judged as preventable.

The authors concluded "The pooled prevalence for preventable patient harm was 6% (95% confidence interval 5% to 7%). A pooled proportion of 12% (9% to 15%) of preventable patient harm was severe or led to death." I'll do the math; 12% of 6% is 0.72% or just over 2400 preventable severe harms and deaths.

A recent literature review on the website Healthy Debate Canada cited three papers estimating incidence of preventable deaths due to medical error ranged from less than 1% to 5.2% and said "This would correspond to 15,000-35,000 deaths per year in the US, an order of magnitude lower than the BMJ estimate."

Even one preventable death is too many. However, inflated figures like 251,000 deaths or even 440,000, as a 2013 paper claimed, undermine public confidence in medical care.

Some examples. The Canadian authors said calling medical error "the third leading cause of death" in the US enabled supporters of the NRA to say doctors are more harmful than guns. Naturopaths and alternative news sites warned about the dangers of our health system.

From Healthy Debate: "In-hospital deaths from medical error are a small subset of all medical errors, and non-fatal errors cause considerable harm to patients. Considering that most of health care occurs in the ambulatory setting, there is an even larger potential for error to cause harm outside of hospitals." Focusing too much on in-hospital deaths from error may direct attention away from other areas of quality improvement.

Medical error is not the third leading cause of death in the US. Will people stop saying it? I doubt it. ■

Meniere's Disease, Migraine & Phonophobia



Meniere's disease (MD) or idiopathic endolymphatic hydrops, is a debilitating disorder of the inner ear, characterized by a triad or tetrad of periodic true vertigo, wax and waning tinnitus, oscillatory progressive low-frequency hearing loss, and aural fullness. Similar to MD, migraine is characterized by headache attacks with symptoms that include nausea, vomiting, photophobia, osmophobia, and phonophobia. Despite epidemiologic studies suggesting associations between migraine and MD, few have investigated the frequency of phonophobia in patients with MD.

For a study published in *Acta Oto-Laryngologica*, Alia Saberi, MD, Fataneh Bakhshi, PhD, Tina Taherzadeh Amlashi, MD, Sepehr Tohidi, MD, and I evaluated the frequency of phonophobia in MD, as well as other migraine symptoms, among adults with definite MD and healthy sex- and age-matched controls. Participants provided demographic data and other clinical features, including age of vertigo onset; family history of migraine, MD, or episodic vertigo with or without auditory symptoms; signs of migraine (including headache, photophobia, phonophobia, osmophobia, and aura); and clinical manifestations of MD.

Among those with MD, the frequency of migraine headache was 16%, compared with only 5% in controls. A positive family history of migraine was seen in 63.7% of migraineous patients with MD, compared with 12.1% in others with MD. Positive family history of migraine was the only significant determinant of migraine presence in patients with MD. Phonophobia frequency in patients with MD was 88.4% overall, 54.5% in those with migraine, and 89.6% in those without migraine.

Among patients with MD, the higher frequency of phonophobia in those without migraine suggests it may be an independent symptom in MD. If we consider the acute attacks of MD as "labyrinthitis" spells, the presence of phonophobia in MD may be explainable. Due to other more significant, and perhaps more annoying symptoms—such as vertigo, roaring tinnitus, or hearing loss—many MD cases do not "declare" the presence of phonophobia. Hence, it may be important to add the fourth or fifth symptom of phonophobia to the remaining classic triad or tetrad of MD. ■

