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MEDLAW

PART 3

Medicolegal Issues During the COVID-19 Pandemic

This three-part series—Part 1 covered patient confidentiality and Part 2 covered maintaining office safety—reviews a few topics giving physicians concern during the COVID-19 pandemic.

Malpractice Liability

This is primarily a concern for retired doctors who are answering the call to come back to assist overwhelmed hospitals, but who no longer have malpractice coverage. The first thing to check is whether the state has an exemption from liability for COVID-19 care, whether there is an emergency worker statute that either immunizes or indemnifies the doctor, or whether the hospital will be providing indemnification.

A Good Samaritan law cannot, however, be relied upon. These cover care outside of medical facilities that is rendered to individuals to whom the practitioner does not owe a duty. Even a hospital that is low on resources or overcrowded is still a hospital, and if you are working as physician, you will have a duty to all patients under your care and for whom you are on-call.

The most essential issue in limiting liability, though, is self-assessment. In a setting in which your skills may not be as good as those of a specialist but you can still be of benefit to the patient, an informed consenting discussion with the patient about any limitations can be adequate, but modern critical care and its technology are not roles that you can step into if, say, you have been in private practice as a neurologist for the last 30 years, there is no on-the-spot training that can compensate for that, and the patients are in no position to select their caregivers.

In this regard, also bear in mind that even immunity laws do not cover gross negligence, which would be acting so recklessly that it shows a disregard for patient safety. Accepting to intubate a patient when the last time that you tried to do so was as a supervised intern would be such conduct, however well-intentioned you are, and would remove you from the law's protection.

It is therefore up to you, if you do re-enter to help, to specify what you can and cannot do… and it is very likely that they will be glad to have you in the ER or clinic using your skills well.

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

Nonnutritive Sweetener Use in Children

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Nonnutritive sweeteners (NNSs)—also known as non-caloric artificial sweeteners or high-intensity sweeteners—are common in food, beverages, condiments, and even gum. NNSs have been proposed for use among those aiming to lose weight and have been largely deemed as safe for use by the FDA. Given the ubiquity of these agents, the American Academy of Pediatrics published the policy statement "The Use of Nonnutritive Sweeteners in Children" to provide pediatricians and others who care for children with information regarding the steps taken to obtain approval for the use of NNSs in the general population, summarize existing data regarding the safety of NNS use, review what is known regarding the potential benefits and/or adverse effects of NNS use in youth, identify knowledge gaps (Table I), and propose talking points that can be used by pediatricians when discussing NNS use with families (Table II).

It should be noted that NNSs are 180 to 20,000 times sweeter than sugar and that most are approved for use as food additives within an accepted daily intake level that is difficult to quantify, given that manufacturers are not required to report the amount of NNS contained in products on food labels. Furthermore, while many assume that NNS use is associated with weight loss, studies suggest that NNS use alone (in the absence of other lifestyle adjustments) is unlikely to lead to substantial weight loss. In rare cases (eg, phenylketonuria), there are absolute contraindications to NNS use.

Pediatricians can make families aware of the limitations of what we know regarding the safety of NNSs, particularly in young children, and consider advocating for limiting the intake of both sugar-sweetened and NNS-containing beverages and foods. Ultimately, however, family members should be informed of the available evidence so that they can make the best decisions for themselves and for their family members.

Future studies with high-quality evidence that takes into consideration actual intake amounts of NNS are needed in order to truly understand the benefits and limitations of NNS agent use.

Table I Key Findings & Recommendations

1. Current FDA-approved nonnutritive sweeteners (NNSs) include saccharin, aspartame, acesulfame potassium, sucralose, neotame, stevia, and advantame. These agents are 180 to 20 000 times sweeter than sugar, potentially affecting preferences for sweet taste.
2. NNSs are designated either as food additives or as generally recognized as safe (GRAS); the long-term safety of NNSs in childhood has not been assessed in humans.
3. No advice can be provided on the use of NNS in children younger than 2 years old given the absence of data in this age group.
4. The number of consumer products containing NNSs has quadrupled over the past several years; manufacturers must list NNSs in the ingredient list but are not required to indicate the amount per serving.
5. When substituted for caloric-sweetened foods or beverages, NNSs can reduce weight gain or promote small amounts of weight loss (~1 kg) in children (and adults); however, data are limited, and use of NNSs in isolation is unlikely to lead to substantial weight loss.
6. Individuals affected by certain conditions (eg, obesity and type 1 or 2 diabetes mellitus) may benefit from the use of NNSs if substituted for caloric sweeteners. However, healthcare professionals should be aware that NNS use in isolation is unlikely to result in important weight loss, that observational studies show that NNS intake is associated with higher rates of metabolic syndrome and diabetes, and that a better understanding is needed about whether NNS use has a causal and harmful effect on metabolism and the risk of diabetes mediated through the gut microbiome or other as-yet-unidentified pathways.
7. To better inform the public about consumption of NNSs, the FDA should require products marketed in the United States to include labels that list the type and quantity of any NNS contained per serving of a product.
8. Funding should be allocated to encourage researchers to conduct high-quality research on the use of NNSs in childhood, focusing on age of exposure and taste preferences, neurodevelopment, and effect on the microbiome and its relevance to obesity, metabolic syndrome, and diabetes.
9. Healthcare professionals are encouraged to remain alert to new information and sensitive to patient and family preferences.
10. With the exception of aspartame and neotame in children with phenylketonuria, there are no absolute contraindications to use of NNSs by children.
11. Use of NNSs has been associated with a reduced presence of dental caries.

Source: Adapted from: Baker-Smith C, et al. *Pediatrics.* 2019;144(5):e20192765.

Table II Guidance for Pediatricians

Primary healthcare professionals should discuss with parents and patients (as appropriate) the available evidence regarding the benefits and harms of non-nutritive sweetener (NNS) use in children and adolescents. The American Academy of Pediatrics recommends that pediatricians discuss the following points with families.

1. NNSs are FDA approved for use in humans or are GRAS and, thereby, approved for use under the GRAS designation.
2. The GRAS designation is based on consumption of NNSs within an ADI level; it is not possible to measure an individual's daily intake of NNSs at this time.
3. Higher-quality data suggest that NNS use is associated with weight stabilization and/or weight loss in the short-term. Currently, there is a paucity of long-term data.
4. High-quality evidence, including meta-analysis and data from RCTs, suggests that there is no association between hyperactivity and NNS use in children.
5. There are limited data regarding the effect of NNS use on appetite change and taste preference.

Source: Adapted from: Baker-Smith C, et al. *Pediatrics.*

USPSTF: Primary Care Still the Place to Keep Kids Tobacco-Free

Primary care providers (PCPs) should continue to provide interventions to prevent school-aged children and adolescents from using tobacco products, including e-cigarettes, according to the U.S. Preventive Services Task Force (USPSTF). However, the effect of such behavioral interventions, such as education or brief counseling, offers a "moderate net benefit," wrote Douglas K. Owens, MD, MS, of Stanford University in California, and USPSTF members, leading to the task force's "B" grade recommendation with "moderate certainty." And in an "I" statement, the task force concluded that there is currently not enough evidence to get a handle on "the balance of benefits and harms of primary care-feasible interventions for the cessation of tobacco use among school-aged children and adolescents," they wrote in *JAMA*.

"This recommendation replaces the 2013 USPSTF recommendation on primary care interventions to prevent tobacco use in children and adolescents… New to the current recommendation is the inclusion of e-cigarettes as a tobacco product. Also new to the current recommendation is the I statement on insufficient evidence on interventions for cessation of tobacco use among this population. The USPSTF is calling for more research to identify interventions (behavioral counseling or pharmacotherapy) to help children and adolescents who use tobacco to quit," Dr. Owens and colleagues said.

The task force highlighted that PCPs could deliver face-to-face counseling, telephone counseling, computer-based interventions, and print-based interventions, noting that print-based materials may be best suited for young children (age 7 to 10), while kids 10 and older could benefit more from in-person counseling, phone-, or computer-based interventions. "No medications are currently approved by the FDA for tobacco cessation in children and adolescents," the authors added.

The evidence report on which the updated guidelines are based highlighted "significant gaps [in evidence], such as the absence of large trials testing primary care-relevant interventions (behavioral counseling or medication) to promote youth tobacco use cessation and any intervention research addressing e-cigarette prevention or cessation in youth," noted Adam M. Leventhal, PhD, and co-authors in an accompanying editorial. "Given these gaps, it is uncertain that primary care interventions alone will reverse recent increases in youth e-cigarette use without new regulatory policies that restrict availability of tobacco products that attract youth," they stated.

The Importance of Out-of-Office BP in NHB Patients

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Research indicates that non-Hispanic black (NHB) patients, especially men, are at a greater risk of hypertension and hypertensive heart disease, and have worse outcomes and a higher risk of complications, when compared with patients with the same diagnosis in other ethnic groups. This is made all the more dangerous, Florian Rader, MD, MSc, explains, by higher rates of masked hypertension in NHB patients, with higher out-of-office blood pressure (BP) compared with clinic BP. Dr. Rader and colleagues conducted a study to better understand whether in-clinic or out-of-office BP measurements were more likely to be associated with left ventricular hypertrophy, a major manifestation of hypertensive heart disease.

For a study published in *Hypertension*, the research team assessed data on more than 2,000 NHB and white patients aged 30-64 to determine the association of in-office and out-of-office BP measurements with left ventricular hypertrophy through cardiac MRI. Participants underwent standard clinic and out-of-office (in-home) BP and left ventricular mass index by cardiac MRI assessment.

Out-of-office BP measurement was found to be a stronger indicator of left ventricular hypertrophy (odds ratio per 10 mm Hg, 1.48; 1.34–1.64 for out-of-office systolic BP and 1.15 [1.04–1.28] for clinic systolic BP; 1.71 [1.43–2.05] for out-of-office diastolic BP, and 1.03 [0.86–1.24] for clinic diastolic BP). "The implications here are that lowering out-of-office BP may be a much more important treatment target compared with the usual treatment target of clinic-measured BP," says Dr. Rader. Other independent indicators of hypertrophy included NHB race/ethnicity, treatment status, and lower left ventricular ejection fraction.

"Our research suggests that reliance on office BP measurement alone may be a missed opportunity to reduce cardiovascular complications, especially in high-risk NHB hypertensives," emphasizes Dr. Rader. "It also supports hypertension management programs that focus on hypertension diagnosis and treatment in the community, outside the doctor's office."

Dr. Rader believes, "A large randomized outcomes trial that focuses on BP reduction at participants' homes compared with BP reductions in the clinic would definitively show whether this approach reduces hypertension-related complications and whether such an approach is more effective in reducing cardiac muscle mass."