

Take 3 – Practical Practice Pointers[®] May 6, 2019 Edition

FDA Safety Warning, Hepatitis A, Emotional Support Animals (ESA)

From the FDA – Safety Communication

1) New Boxed Warning for Insomnia Medications

On April 30th, the FDA released a new boxed warning advising that rare but serious injuries have happened with certain common prescription insomnia medicines because of sleep behaviors, including sleepwalking, sleep driving, and engaging in other activities while not fully awake. These complex sleep behaviors have also resulted in deaths. These behaviors appear to be more common with eszopiclone (Lunesta), zaleplon (Sonata), and zolpidem (Ambien, Ambien CR, Edluar, Intermezzo, Zolpimist) than other prescription medicines used for sleep.

In addition to the boxed warning, the FDA is also requiring a *Contraindication*, their strongest warning, to avoid use in patients who have previously experienced an episode of complex sleep behavior with eszopiclone, zaleplon, and zolpidem.

Specifically, health care professionals should be aware of the following:

- Complex sleep behaviors, in which patients engage in activities while they are not fully awake have been reported with eszopiclone, zaleplon, and zolpidem.
- These events can occur with just one dose of these medicines as well as after a longer duration of treatment.
- Eszopiclone, zaleplon, and zolpidem are contraindicated in patients who report an episode of complex sleep behavior after taking these insomnia medicines.
- Tell patients to discontinue their insomnia medicine if they experience an episode of complex sleep behavior even if it did not result in a serious injury.
- When starting patients on any of these medications, start with the lowest possible dose and follow prescribing guidance.
- Encourage patients to read the medication guide every time they fill their eszopiclone, zaleplon, or zolpidem prescriptions, and remind them not to combine them with other insomnia medicines, anxiolytics, opioids, alcohol, or other CNS depressants (including sedating antihistamines).
- Previous safety information surrounding these medications include: risk of next-morning impairment with zolpidem; lower recommended doses for zolpidem; and risk of next-morning impairment with eszopiclone resulting in a lowered recommended dose.

My Comment:

This warning caused me to take pause. I follow a fair number of patients who insist they cannot sleep without one of these medications (despite sleep hygiene, etc.) and who report good sleep with them. Getting them off these medications can also be a real challenge. My encouragement is to think carefully before starting anyone on them, educate regarding sleep hygiene (which I'm confident many of these patients don't follow) and consider a sleep medicine consultation for patients who feel they need to take these chronically. At the least, make sure they are aware of these possible side effects and instruct them (and document) that they should stop them immediately if they

have any of these side-effects. And don't assume they need to be on these in perpetuity by revisiting alternatives regularly.

Reference:

FDA Safety Communication – April 30, 2019. [Link](#)

From the CDC and the Virginia Department of Health (VDH)

2) Hepatitis A Virus (HAV) Infection Health Alert

The CDC recently released a Health Alert Network (HAN) Advisory indicating that multiple states have experienced HAV outbreaks, primarily among people who use drugs and people experiencing homelessness. Since these outbreaks were first identified in 2016, more than 15,000 cases and 8,500 hospitalizations (57% of cases) have been reported in the US.

Between January 1, 2019 and April 19, 2019, Virginia has reported 44 cases of HAV, a 132% increase compared to the same time period in 2018. This increase indicates that the Commonwealth is now experiencing the effects of this nationwide outbreak, and action is needed to prevent the continued spread of HAV.

Virginia's local health districts are working with community partners to increase vaccination efforts, with specific focus on persons at high risk of acquiring HAV infection or developing serious complications from infection. HAV is highly transmissible from person-to-person. The best way to prevent infection is through vaccination with the hepatitis A vaccine. The CDC has reported that one dose of single-antigen hepatitis A vaccine has been shown to control HAV outbreaks and provides up to 95% seroprotection in healthy individuals for up to 11 years. Pre-vaccination serologic testing is not required and vaccination should not be postponed if vaccination history cannot be obtained or records are unavailable.

The following groups are at highest risk for acquiring HAV infection or developing serious complications from HAV infection in these outbreaks and should be offered the hepatitis A vaccine:

- People who use drugs (injection or non-injection)
- People experiencing homelessness
- Men who have sex with men (MSM)
- People who are, or were recently, incarcerated
- People with chronic liver disease, including cirrhosis, hepatitis B, or hepatitis C

The CDC recommends healthcare clinicians do the following:

- Screen patients for risk factors (e.g., drug use, homelessness, incarceration, MSM, and chronic liver disease).
- Recommend and administer hepatitis A vaccine to at-risk patients, regardless of the original presenting complaint or the type of clinical facility. In particular, the emergency department may be an individual's only interaction with the healthcare system and is an important opportunity for prevention. If you do not stock the hepatitis A vaccine, refer patients to a local pharmacy or health department.
- Record immunizations in the state immunization information system (registry).
- Consider hepatitis A as a diagnosis in anyone with jaundice or clinically compatible symptoms.

- Rapidly report all persons diagnosed with hepatitis A to the health department to ensure timely case investigation and follow-up of contacts.

My Comment:

In many ways, Hepatitis A is the “forgotten” hepatitis, as it doesn’t get as much press as its B and C relatives. While the total numbers are still relatively low, the greater than 50% hospitalization rate is notable. The Virginia Department of Health has established an HAV webpage with resources for you and your patients (see references below). If you have any additional questions, please contact the Division of Immunization at 804-864-8055 or your local health department.

Reference:

- CDC Health Alert: Widespread Outbreaks of Hepatitis A among People Who Use Drugs and People Experiencing Homelessness. March 25, 2019. [Link](#)
- VDH – Hepatitis A in Virginia: [Link](#)

A Question From a Colleague Reprise

3) Emotional Support Animals (ESA)

Question:

“I’ve had a number of patient’s bring forms asking for my ‘authorization’ for an emotional support animal (ESA). These have almost always been for their housing situation, be it an apartment complex or a college dorm which usually has a ‘no pets’ policy. Do you have any suggestions for how best to deal with this?”

Answer:

This is a wonderful and timely question, given the publicity that ESAs have had, particularly with regard to air travel, housing, and dorm life. There is a difference between “Service Animals” (SA) and “Emotional Support Animals” (ESA). A service animal is defined in the Americans with Disabilities Act (ADA) as a dog that is specifically trained to help a disabled patient cope with a particular disability (PTSD, diabetes, visually impaired, memory impairment). Disability is defined in the Americans With Disabilities Act as “a physical or mental impairment that substantially limits one or more major life activities.”

An ESA, by contrast, can be any animal that provides comfort and support to its owner through companionship. While ESAs are not defined by the ADA, they are recognized under the Fair Housing Act and the Air Carrier Access Act, and are considered a “reasonable accommodation” for a disability. Pursuant to the federal Fair Housing Act and Virginia law, housing facilities must allow service dogs *and* emotional support animals, if necessary for a person with a disability to have an equal opportunity to use and enjoy the home. To fall under this provision one must have a disability-related need for the animal. In other words, the animal must work, perform tasks or services, or alleviate the emotional effects of the disability in order to qualify. Virginia law specifically states that providing companionship, emotional support, well-being, or comfort does not qualify as performing work or tasks for a person with a disability.

If there is no history of a mental health diagnosis then the clinician can elect to conduct a screening and assessment and choose to sign the form or not. Even if there is a mental health diagnosis, this does not necessarily imply a “disability.” While there are

some patients who have been declared “disabled” due to their mental health diagnosis, that is not the case for most.

Additionally, the clinician should take steps to manage the patient’s expectations:

- Provide education that the results of an evaluation may not render a diagnosis to support their petition for an ESA letter and that a clinician’s letter does not turn an animal into a service animal.
- If the patient wishes to proceed, the clinician can conduct the appropriate testing or evaluation to make the diagnosis, if one can be made **OR** may elect instead to refer the patient to a mental health provider for assessment and/or treatment prior to signing the ESA form (or the MH provider can sign the form).

My Comment:

This topic was originally addressed in Take 3 in 2018, but has continued to come up, so I am reviewing it again.

Given the paucity of evidence regarding the efficacy of ESAs in augmenting human physical/mental health, this is an area in need of rigorous, empirical research. There is an entire industry that has been formed around providing these letters on the internet (Google “emotional support animal letter”). My recommendation is that you avoid getting involved in this process for ESAs and allow our mental health colleagues, who better understand the nuances of the laws, to handle it. However, knowing that some of you won’t be able to resist the pleas of your patients, don’t say you weren’t warned

References:

- Crossman M. Effects of Interactions With Animals On Human Psychological Distress. J Clin Psychol. 2017 Jul;73(7):761-784. [Link](#)
- Virginia Fair Housing Law – Informational Brochure: [Brochure](#)
- Gershen S. Letters for Emotional Support Animals. Tulane University. [Guide](#)

Feel free to forward Take 3 to your colleagues. Glad to add them to the distribution list.

Mark

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