



**MEDLAW**

## PART 2 Avoiding Liability in Telemedicine: HIPAA & Informed Consent

That you are a responsible covered entity under HIPAA and a fiduciary for the privacy of your patients' PHI do not decrease with telemedicine. In fact, it is a setting in which you want to be very careful, particularly if working from home, where family will be present and habits may become lax. Your primary obligation is to make sure no unauthorized individual encounters PHI in any form.

However, the Office of Civil Rights (OCR) will waive penalties for HIPAA violations that would otherwise accrue due to this issue during the COVID-19 crisis. The intention is to open a telehealth option to practitioners who were not set up for such but who find themselves with patients in need of any telehealth diagnostic or treatment, even if not directly related to coronavirus.

The OCR extended permissible use to non-public-facing apps such as Skype, Google Hangouts video, and Zoom, that only allow intended parties to participate. A Business Associates Agreement is not required.

The standard during this waiver is one of good faith. If PHI is intercepted during transmission but the practitioner followed the OCR's guidance, there will be no penalty. Note, however, that states often have stricter regulations, and the federal waiver does not affect these.

Increased access also carries the important responsibility of informed consent. Many states specifically require that it be done and documented before engaging in a telehealth visit. In most such states, verbal consent is allowed, but consent must be obtained in writing in some. Regardless, the more certain the proof of consent, the better.

You should first inform the patient that this method is limited as compared with an in-person evaluation and is also potentially not secure. You should then get an affirmative consent to continue. If possible, build the consent form into the software so that the patient is required to assent before the virtual visit. If that is not possible, create a standardized e-mail with the consent and have the patient return it before you start. A verbal consent, if permissible, should be carefully documented.

You must apply all encryption and privacy modes available from your end. Increasing usable systems to ones that are inherently less secure is predicated on you doing what you can to minimize the risk of a breach, and it is this that the OCR will look to in determining a "good faith" use of the waiver. If a relative or friend or caregiver will be involved to help the patient with the televisit, make certain that you have a release that allows them access to PHI. Remember that the waiver on non-HIPAA compliant systems will only last during the emergency.

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



## Challenging Beta-Lactam Allergy Status



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The latest US census reports a 20% to 30% increase in the population older than 60, which is estimated to double by 2030. Investigations conducted with participants in this population have not kept up with its growth, resulting in a lack of currently available scientific evidence, explains Teodorikez Wilfox Jiménez Rodríguez, MD, MSc. Among the more than 95% of people reporting an allergy to beta-lactam (BL) antibiotics who have been shown to subsequently have good tolerance, elderly patients may do so due to initial false labeling of allergies, the spontaneous loss of sensitivity, or age-related decline in sensitization. This patient population may, thus, be unnecessarily treated with less appropriate antibiotics, causing more side effects and entailing increased health costs.

### An Allergological Study

Taking the above into consideration, Dr. Jiménez-Rodríguez and colleagues conducted an allergological study, published in the *Journal of Asthma and Allergy*, to assess whether patients aged 60 or older with allergy to BLs—some of whom had been previously confirmed—had lost sensitization and could tolerate these antibiotics. "We wanted to see if these patients could finally benefit from receiving first-line antibiotics with less toxic side-effects and less expense to the healthcare system," adds Dr. Jiménez-Rodríguez.

Study participants were 1) admitted in the participating services and either previously labeled as allergic to BLs or as having hypersensitivity reactions (HSRs) to BLs during a hospital stay or 2) had a history of HSRs to BLs and referred to an outpatient allergy clinic for evaluation. All of these patients were grouped by age into those aged 60-79 (group A) or 80 and older (group B). "Once we identified the patients, we completed a detailed medical history and skin tests with

immediate and delayed reading, quantification of total and BL-specific IgE," says Dr. Jiménez-Rodríguez. "Challenge tests were based on clinical history and skin test results and conducted to confirm or rule out the alleged allergy."

### Exposure-Based Modification

Based on the results of skin and drug challenge testing, the researchers confirmed a final diagnosis of allergy to BL in 27.0% of group A and 5.4% of group B. Upon multivariable analysis adjusted for sex, atopy, allergy to other drugs, and specific IgE to amoxicilloyl, younger age was found to be an independent risk factor for allergy to BL.

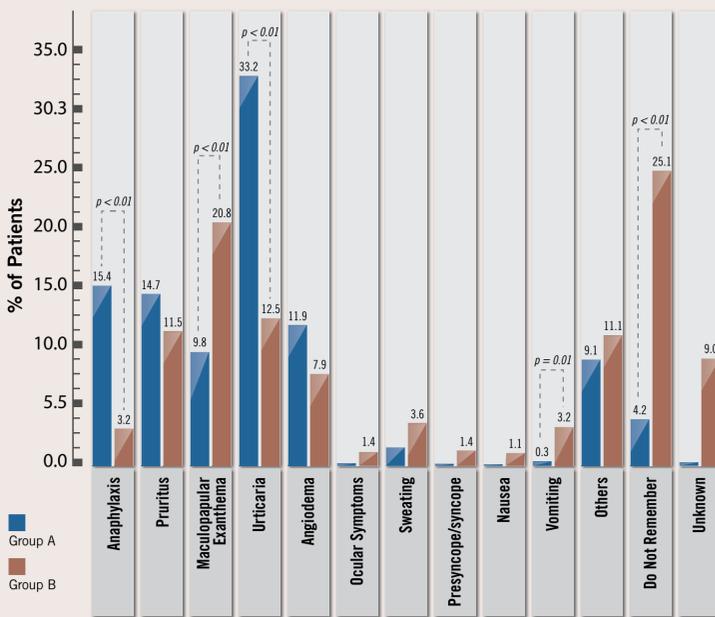
"The culprit drugs for the initial reactions were different and showed changes in consumption patterns," says Dr. Jiménez-Rodríguez, "since the youngest (group A) were sensitized to frequently used antibiotics like amoxicillin, ampicillin, amoxicillin/clavulanic, and cephalosporins, whereas the older patients (group B) were sensitized mostly to benzylpenicillin, showing that allergy is modified according to exposure." He notes, however, that immunosenescence could be a possible explanation for the decrease in allergies in group B, adding that additional research is needed to "clarify the mechanisms involved in the production of specific IgE at this age and its clinical significance."

### Valid, Safe & Necessary

Dr. Jiménez-Rodríguez stresses the significance of anaphylaxis as a clinical manifestation of the initial hypersensitivity reactions seen in participants, particularly among group A, due to its severity and the implicit deadly risk (Figure). "Anaphylaxis is related to the culprit drug, and in the case of beta-lactam drugs, it is more frequently triggered by the specific side chains of these agents, so it was logically more common in group A," he adds. "However, the skin was the organ most frequently involved in reactions, mainly in the form of hives in group A and maculopapular rash in group B. Unsurprisingly, the older the participants were, the greater their limitation to remember the symptoms of their HSRs, supporting previous findings in which it is established that the medical history alone is not enough to establish an allergological diagnosis; hence, the importance of referring patients for an allergological study, even before antibiotics are needed. The allergological study is valid, safe, and must be performed by an allergist before requiring antibiotics, because discarding BL allergy allows patients to be treated better, with safer antibiotics, and with less impact on the healthcare costs." ■

**Figure Clinical Manifestations of Initial Hypersensitivity Reactions**

The figure shows the symptoms of hypersensitivity reactions based on which the diagnosis of beta-lactam allergy was established. Cutaneous symptoms were the most frequent in both groups, while anaphylaxis was more frequent in group A (aged 60-79). The majority of patients who did not remember symptoms were in group B (aged ≥80).



Source: Adapted from: Jimenez-Rodríguez T, et al. *J Asthma Allergy*. 2019;12:421-435.

MEDPAGE TODAY'S

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## To Wear a Mask Is to Be Brave. To Trust Your Doctors Is to Be Brave

By Abubakr Chaudhry, MD

The pandemic is a lie. I will not wear someone else's fear. This is all fake news. It is remarkable to see these statements littered across the news and social media. Individuals with a fairly decent level of understanding and intelligence pandering to these ideas just go to show how strong anti-science culture has become.

On January 19, the first American would test positive for the novel coronavirus. By early February, the hysteria would start to set in and social media would start increasing speculative reporting. By late February, the stress and arguments about who should take responsibility began to boil over. Then there was the increase in fear among healthcare exposure rates, conflicting case fatality reports, and frustrations with the CDC on the flip-flopping in guidelines.

We became tired of the complaining, fear, and misinformation, so we decided to pen a guideline for our hospital. Georgia went on lockdown April 3. Throughout March and April, the world seemed to trust us as the scientific community to lead them through this crisis.

By April, we saw our algorithms were working, and we had some of the best outcomes in the state. People were adhering to the guidelines by staying home. Businesses had shut down, the spread was contained, and we could see the light at the end of the proverbial tunnel. Then, on April 24—with 892 deaths and 22,147 infected in GA—the lockdown restrictions were eased in our state. We were one of the last to close but the first to reopen. We knew the world needed to open; we just didn't know our world would open like this. I remember wondering why we couldn't mandate masks, contact tracing, and social distancing when we reopened. The virus became political.

When I started writing this, I was upset at a social media comment I read from a friend that read, "This pandemic is a joke, I will not wear a mask because I will not wear their fear." Now, I see that he was afraid and uninformed. People, in general, are still afraid, if not of the virus, then of loneliness, poverty, or even subjugation. When people exhibit these fears, and if their voices are loud, the politicians must bend to their will. If our politicians are afraid and their voices alleviate our fears, then we bend to *their* will. My point is, it is OK to be afraid. I am a pulmonary and critical care doctor, my wife is a pediatric intensivist, we have a small child, and we are afraid. But to wear a mask is to be brave. To social distance is to be brave. To trust your doctors is to be brave. To those with doubts, know that you are correct in your feeling that the system is broken. I don't know how to fix it, but I know that it has to be done soon. Help us get through this so we can build a better world: a world built from understanding, not from fear.

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## Addressing HF-Exacerbating Medications



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Evidence suggests that while significant focus has been placed on ensuring that patients with heart failure (HF) are prescribed medications like beta-blockers and other neurohormonal antagonists that have been shown to improve outcomes, little attention has been paid to discontinuing medications that can worsen HF. For a study published in *JACC: Heart Failure*, Parag Goyal, MD, MSc, FACC, and colleagues sought to better understand the prevalence of harmful medication use in the setting of HF-related hospitalization.

The study team examined a cohort of older adults hospitalized for HF from 380 unique hospitals across the United States, identifying medications taken at admission and prescribed at discharge, cross-referencing these lists with the 2016 American Heart Association (AHA) Scientific Statement on 70 medications that can exacerbate HF and analyzing the data to determine predictors for harmful prescribing practice.

"Medications that can worsen HF are commonly used in older adults with HF," says Dr. Goyal. Indeed, the study showed that nearly half of patients hospitalized for HF were on HF-exacerbating medications at the time of hospital admission, with 18% experiencing a decrease in the number of these medications by hospital discharge, 19% remaining on the same number, and 12% experiencing an increase. Upon multivariable logistic regression analysis, diabetes (odds ratio [OR], 1.80) and small hospital size (OR, 1.93) were the strongest, independently associated determinants of harmful prescribing practices.

"Despite possibly contributing to the hospitalization, these potentially harmful medications are often continued even upon hospital discharge," adds Dr. Goyal. "When older adults with HF are hospitalized, it is critical to perform a thorough review of all medications and to consider eliminating medications that could possibly worsen HF. To achieve this, it is important to increase awareness about how common potentially harmful medication use is, and for physicians to become increasingly familiar with which medications may be harmful. It is equally important for clinicians to also incorporate their own judgement and patient preferences when deciding whether to discontinue a medication that may be harmful in HF, since many of the agents listed on the 2016 AHA Scientific Statement may be first-line treatments for common HF comorbidities, like diabetes and COPD." ■



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