

[MEDLAW]

PART 2

Avoiding Liability in Telemedicine: HIPAA & Informed Consent

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.

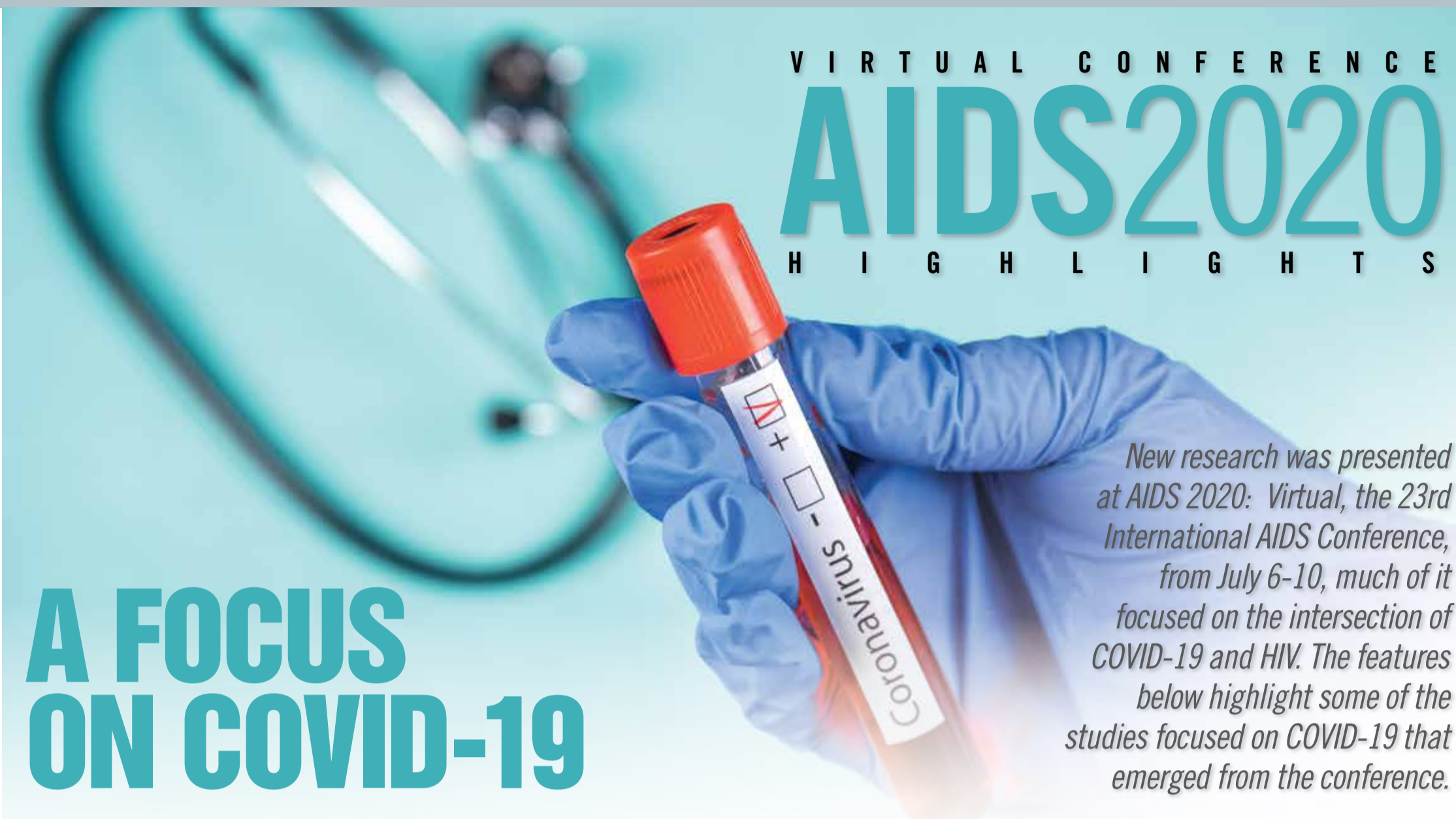
The standard during this waiver is one of good faith. If PHI is intercepted during transmission but the practitioner followed the OCR's guidance, there will be no penalty. Note, however, that states often have stricter regulations, and the federal waiver does not affect these.

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.



VIRTUAL CONFERENCE
AIDS2020
H I G H L I G H T S

New research was presented at AIDS 2020: Virtual, the 23rd International AIDS Conference, from July 6-10, much of it focused on the intersection of COVID-19 and HIV. The features below highlight some of the studies focused on COVID-19 that emerged from the conference.

A FOCUS ON COVID-19

COVID-19 & HIV Susceptibility in LGBTI+ Communities

With evidence suggesting that COVID-19 and the public health response to it have exacerbated prevailing inequalities and the hypothesis that their combination may worsen economic circumstances of lesbian, gay, bisexual, transgender, intersex and other sexuality, sex and gender diverse (LGBTI+) people—including a possible increase in HIV exposure—researchers conducted a cross-sectional online survey that was broadcasted online among LGBTI+ social networks. Among 13,562 LGBTI+ participants from 138 countries/territories, approximately 91% were partly or entirely confined. Among the 26% of participants with HIV who had experienced interrupted or restricted access to refills of ART medication, 55% had 1 month's stock

supply or less of ART available. Loss of employment was expected by 47% of those currently working, and 12.6% had already lost it. Among the 45% of respondents facing economic difficulty, 73% could not meet basic needs and 37% had to skip or reduce the size of meals. Overall, 1% of respondents (n = 1,532) were pushed into engaging in sex work by the pandemic, among whom COVID-19 reduced the capacity to negotiate safe sex practices—more condomless relations (3%), taking more risks (7%)—and thus increasing HIV exposure. The pandemic also reduced access to safe injection equipment for the 36% who inject drugs and limited access to opioid substitution therapy for the 26% of those who needed it. ■

The Immunologic Impact of COVID-19 in PLWHIV

Because data on the immunologic impact of COVID-19 co-infection in people living with HIV (PLWHIV) are limited, researchers conducted a retrospective study of clinical and immunologic outcomes of COVID-19 in 93 PLWHIV presenting to five New York City emergency departments who tested positive for COVID-19. At presentation, PLWHIV with COVID-19 demonstrated significant lymphopenia and decreased CD4 cell counts. Inflammatory marker levels were commonly elevated. Serum cytokine profiles during acute COVID-19 were characterized by elevated interleukin (IL)-6, IL-8, and TNF-alpha, but not IL-1b. Among those hospitalized with COVID-19, 22.2% died, 66.7% recovered, and 11.1% remained hospitalized at

the time of the analysis. When compared with those who recovered, those who died had significantly lower nadir absolute lymphocyte counts during COVID-19. Peak inflammatory markers, including C-reactive protein, IL-6, and fibrinogen were significantly higher in those who died. Those who died also had non-significant trends toward IL-8 and TNF-alpha elevations. A greater proportion in the recovered group was on a regimen containing tenofovir, but the difference was not statistically significant. "Our findings indicate that a subset of [PLWHIV] are capable of mounting profound inflammatory responses that have been noted to correlate with poor outcomes in people without HIV," write the study authors. ■

COVID-19 & HIV Service Interruption in MSM

Researchers have hypothesized that the range of population-based measures meant to stem the spread of COVID-19 infection and reduce related morbidity and mortality may be associated with disruptions to other health services, including for men who have sex with men (MSM) who are at risk for or living with HIV. To assess the relationship between intensity and breadth of COVID-19 mitigation strategies and interruptions to HIV prevention and treatment services for MSM, they collected data from a COVID-19 disparities survey implemented by the gay social networking app Hornet between April 16 and May 4, 2020. Each of eight countries received a 0-100 score based on the number and strictness of nine indicators related to school and workplace closures and travel bans. Participants had a mean age of 36, included

13% who were living with HIV, and lived in countries with a mean stringency score of 70.5, ranging from 29.4 in Taiwan to 89.4 in France. For each indicator of prevention, increasing stringency of response was associated with decreased access to services. Every 1-point increase in stringency was associated with a 4% reduction in odds of access to in-person testing and a 3% reduction in odds of access to self-testing, PrEP, and condoms. Health insurance—government (adjusted odds ratio [aOR], 4.86) or private (aOR, 4.47)—was independently associated with access to ART. "Innovative strategies, like mobile-service delivery or telehealth, may be needed to minimize the service interruptions from these types of government responses on MSM communities and ensure continuity of care," write the study authors. ■

The Impact of COVID-19 on PrEP Care

In order to describe the impact of COVID-19 on HIV pre-exposure prophylaxis (PrEP) care at a health center specializing in sexual healthcare, investigators extracted electronic healthcare data for patients with at least one active PrEP prescription from January-April 2020. The study team assessed trends in PrEP initiations and refill lapses, testing for gonorrhea/chlamydia (GC/CT) and HIV, and telehealth use. Among more than 3,500 participants with a mean age of about 37 who were 72.7% white, 13.6% Latinx, 92.1% cisgender men, and 12.9% publicly insured, PrEP initiations decreased 72.1% during the study period, from 122 to 34 per month. Refill lapses increased 278%, from 140 to 407 per month, while the number of PrEP patients decreased 17.9%. GC/CT and HIV tests each decreased by 85.1% (1,058/month to 158/month for GC/CT and 1,014/month to 151/month for HIV), while GC/CT test positivity rates increased slightly (12.3%-15.8%). Clinical encounters decreased 26.3% and transitioned from 0.0% to 97.7% telehealth. ■

Outcomes in Patients With COVID-19 by HIV Status

With data lacking on whether people living with HIV (PLWHIV) are at great risk for adverse outcomes due to COVID-19 than those without HIV—or if outcomes differ by CD4 count and viral suppression among PLWHIV—researchers conducted a retrospective cohort study of COVID-19+ patients admitted to a large tertiary academic health system between March 10 and May 11, 2020. Among 4,662 patients with a median age of 65, 1.7% were PLWHIV. Intubation occurred in 13% of PLWHIV and 14% of those without HIV. Among PLWHIV, 38% developed acute kidney injury, compared with 41% of those without HIV. In-hospital mortality rates were 18% among PLWHIV and 23% among those without HIV. Among both groups, hospital length of stay was 5 days (3-9) for those who were discharged. An exploratory analyses of PLWHIV who had CD4 counts available found that higher count was associated with intubation (adjusted odds ratio, 1.36 per 100 cells/μL). Zero viremic PLWHIV were intubated, compared with 18% of those with suppressed HIV. "Our preliminary findings regarding intubation among PLWHIV warrant further examination," write the study authors. ■

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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The Need for HIV-Specific Risk Scores of Subclinical Vascular Damage Progression

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Data indicate that people living with HIV (PLWHIV) have an increased risk of cardiovascular disease (CVD) when compared with the general population, with traditional CVD risk scores not accurately reflecting this risk. Non-invasive subclinical vascular damage (SVD) biomarkers are valid surrogates of CVD and have been suggested in prior research to be able to stratify CVD risk.

In a 3-year, single-operator study published in the *Journal of Acquired Immune Deficiency Syndrome*, we assessed whether four widely applied CVD risk scores (Framingham

[FRS], Atherosclerotic CVD, Data Collection on Adverse Effects of Anti-HIV Drugs Study, and Greek-specific European Society of Cardiology [ESC] risk scores) could detect the presence, incidence, and progression of arteriosclerosis, atheromatosis, and arterial hypertrophy in PLWHIV and uninfected individuals.

We prospectively examined (at baseline and 3-year follow up) 10 arterial sites, applying five non-invasive vascular biomarkers and measuring the four CVD risk scores at baseline. Our team found that in both PLWHIV and uninfected individuals, the CVD risk scores—apart from ESC—performed differently but reasonably well in identifying the presence of SVD. However, all scores failed to predict the incidence or progression of overall SVD. The most clinically useful biomarkers (carotid plaque/atheromatosis) revealed that only the FRS was able to stratify overall SVD progression in PLWHIV (11.0% of the low-risk group, 33.3% of the medium risk, and 0.0% of the high-risk).

Physicians should be aware of the increased CVD risk in PLWHIV, and thus, the importance of risk stratification for CVD and early initiation of preventative treatment as necessary in this patient population. As the current cardiovascular risk scores do not appear to fully recognize CVD risk seen in PLWHIV, vascular imaging should be incorporated in CVD risk stratification protocols. More accurate HIV-specific CVD risk models are also needed. Until these are developed, FRS appears to be the best available score to optimize treatment and CVD prevention in PLWHIV at medium CVD risk, as one-third of carotid atheromatosis progressed within 3 years. ■