

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.

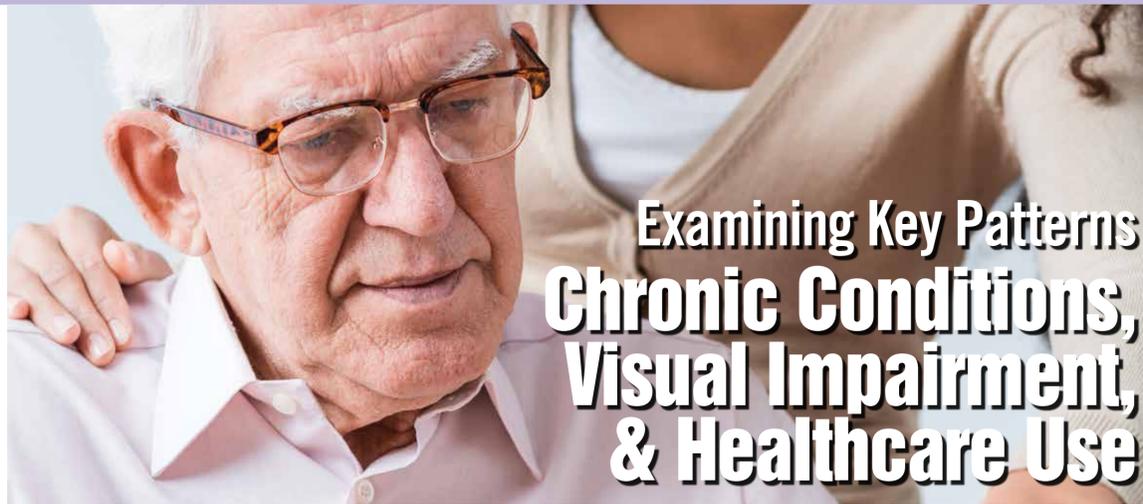
The standard during this waiver is one of good faith. If PHI is intercepted during transmission but the practitioner followed the OCR's guidance, there will be no penalty. Note, however, that states often have stricter regulations, and the federal waiver does not affect these.

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.



Examining Key Patterns Chronic Conditions, Visual Impairment, & Healthcare Use



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A study has identified several distinct groups of chronic condition patterns that appear to have increased risks of visual impairment and healthcare use. These data may lead to the development of targeted interventions for improving the coordination of care and perhaps preventing visual impairment.

The number of older adults in the United States living with multimorbidity—defined as the co-occurrence of at least 2 chronic conditions—has increased rapidly over the past few decades. "Visual impairment often co-occurs with other chronic conditions, such as diabetes, hypertension, and respiratory problems," says D. Diane Zheng, PhD. "Visual impairment is among the most disabling chronic conditions and has various psychological and functional consequences, including social isolation, poor well-being, functional decline, and frailty. The combination of multiple conditions and visual impairment can have disabling effects in older adults."

A Deeper Look

In previous studies, research on multimorbidity has focused on a patient's cumulative number of conditions rather than qualitative combinations of these conditions. Latent class analysis (LCA) is a statistical approach in which individuals are grouped into distinct homogeneous subgroups based on their pattern of response across several observed variables. LCA ensures that individuals within a group are more similar than those between groups.

Studies applying LCA to investigate patterns of chronic conditions and its association with visual impairment are lacking. A study published by Dr. Zheng and colleagues, published in *JAMA Ophthalmology*, addressed this unmet need by applying the LCA approach to identify patterns of multimorbidity with visual impairment and healthcare use. Using data from the National Health Interview Survey on nearly 388,000 US adults, the authors classified patients into subgroups using LCA, with different combinations of self-reported chronic conditions. They then assessed the relationships between chronic condition grouping and the rate of self-reported visual impairment, emergency department (ED) visits, and hospitalizations in the previous 12 months.

Key Findings

The study identified 5 classes of chronic condition patterns with main characteristics as: 1) a healthy group, 2) a hypertensive group, 3) a respiratory conditions group, 4) a heart conditions group, and 5) a severely impaired group. More than 70% of participants belonged to the healthy group, but the other groups had various degrees and patterns of multimorbidity. The hypertensive group had a high prevalence of hypertension; the respiratory conditions group had a high prevalence

of emphysema and asthma; and the heart disease group had a high prevalence of coronary heart disease and other cardiac diseases. The severely impaired group had a higher prevalence of most conditions when compared with the other groups.

"We found that individuals in all multimorbidity groups identified in our study had various increased risks of reporting visual impairment," Dr. Zheng says. "Even though these groups had different patterns of disease combinations, the risk of visual impairment was heightened in all groups," says Dr. Zheng. In an analysis adjusted for socioeconomic and health behavior factors, patients in the severely impaired group had the highest risk of visual impairment (Table). In addition to being more likely to report visual impairment, patients in all chronic condition groups used healthcare at a higher rate than the healthy group.

Of note, the study demonstrated that all multimorbidity groups had higher risks of using the ED and being hospitalized. The odds ratios for ED use and hospitalization were 9.39 and 10.80, respectively, for individuals in the severely impaired group. The severely impaired multimorbidity group was less educated, had lower income, and was less likely to be married. These socioeconomic factors may have contributed to their worse health.

Assessing Implications

"Our study highlights the important effect of visual impairment on a patient's general health," Dr. Zheng says. "The results are an important reminder that patients with multiple chronic conditions have elevated risks of visual impairment. Clinicians—including ophthalmologists and primary care physicians—would benefit from a heightened awareness of this relationship to coordinate healthcare in efforts to avert more severe consequences of multimorbidity, to prevent visual impairment, and to improve overall health."

According to the study team, the data may be used to help identify and target high-risk multimorbidity populations who are vulnerable to health disparities and use large amounts of healthcare resources. "Our data came from a national survey and were self-reported, but future research should examine if these associations remain true when measured objectively in a clinical setting," says Dr. Zheng.

Table Chronic Condition Latent Classes & Risk for Reporting Visual Impairment

The table below depicts odds ratios of reporting visual impairment for different chronic condition latent classes.*

Latent Class	Odds Ratio (95% CI)	P Value**
Healthy	1 [Reference]	-
Heart condition	3.19 (2.92-3.48)	<0.001
Hypertensive	3.28 (3.10-3.48)	<0.001
Respiratory condition	3.87 (3.56-4.20)	<0.001
Severely impaired	10.19 (9.20-11.28)	<0.001
Severely impaired vs respiratory condition	2.63 (2.33-2.98)	<0.001
Respiratory condition vs hypertensive	1.18 (1.08-1.28)	<0.001
Heart condition vs respiratory condition	0.82 (0.74-0.91)	<0.001
Severely impaired vs hypertensive	3.10 (2.81-3.41)	<0.001
Severely impaired vs heart condition	3.19 (2.79-3.65)	<0.001
Heart condition vs hypertensive	0.97 (0.89-1.06)	0.51

* Model controlled for age, sex, race, Hispanic ethnicity, educational level, marital status, health insurance, income, smoking status, alcohol consumption, and BMI status.

** P values are 2-sided.

Source: Adapted from: Zheng DD, et al. *JAMA Ophthalmol*. 2020;138(4):387-394.

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Refusing Telemedicine – Can Patients Opt-out of Remote Care?

With the sweeping rise of COVID-19, telemedicine has taken healthcare by storm. During the local surges, this served as a mandated way of maintaining safe distancing. But as things come back to a new normal and as we decide where telemedicine fits in to a clinic structure, it might be worth asking: should patients have the option for in-person care? Is refusing telemedicine in favor of being physically seen a choice patients should be able to make? As we begin to settle in to a fixed role for telemedicine in the post-COVID world, centers are beginning to shape processes around telehealth.

Three assumptions that we make about patients and virtual encounters give shape to our policies:

ASSUMPTION OF APPROVAL

We assume that telemedicine is what patients prefer. The belief that patients prefer to be cared for in the context of their home isn't always the case. There may be sensitive issues or a hidden agenda that doesn't show well across a screen.

ASSUMPTION OF EQUIVALENCE

We assume that telemedicine is as good as in-person care. There is a bias to try to assess virtually some conditions that may best be assessed in real life. But, sometimes, medicine needs to be inconvenient.

ASSUMPTION OF CAPACITY

We assume the patient is able to participate in a virtual visit. Some families lack Internet access and equipment to complete a telemedicine visit. Tech insecurity is a bigger issue than thought initially when we started doing telemedicine.



There are many reasons why a patient may prefer an in-person visit. Our assumptions about the magic of telemedicine are not always right. While we should work to accommodate the preferences of the patient, patients need to understand that there are conditions and circumstances where an in-person visit is not necessary. And patients should be offered the right of refusing telemedicine.

Will our telemedicine policies pull us back to an imbalanced doctor-patient relationship? After the COVID dust falls, we need to create more structure that respects the interests and will of the patient. Telemedicine is a moving target. What works or doesn't work today may have a very different solution or experience a year from now. Flexibility and rapid reiteration of our processes will be critical to successful adjustment and growth.

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In Case You Missed It

Bifocal Contact Lenses May Slow Children's Myopia Progression

Among children with myopia, treatment with high add power multifocal contact lenses reduces the rate of myopia progression over 3 years compared with medium add power multifocal and single-vision contact lenses, according to a study published in *JAMA*. Researchers randomly assigned 294 consecutive eligible children (aged 7-11) with spherical component myopia to wear high add power (+2.5 D; 98 children), medium add power (+1.5 D; 98 children), or single-vision (98 children) contact lenses. Adjusted 3-year myopia progression was -0.60 D for high add power, -0.89 D for medium add power, and -1.05 D for single-vision contact lenses, with differences in progression of 0.46 D for high add power versus single-vision contact lenses, 0.30 D for high add versus medium add power contact lenses, and 0.16 D for medium add power versus single-vision contact lenses. Of the four secondary end points, there were no statistically significant differences between the groups for three of the end points. Three-year adjusted mean eye growth was 0.42 mm for high add power, 0.58 mm for medium add power, and 0.66 mm for single-vision contact lenses, with differences in eye growth of -0.23 mm for high add power versus single-vision contact lenses, -0.16 mm for high add versus medium add power contact lenses, and -0.07 mm for medium add power versus single-vision contact lenses. "Further research is needed to understand the clinical importance of the observed differences," the authors write.

Pupil Area May Help Indicate Prognosis in Heart Failure

Pupil area is an independent predictor of all-cause mortality and readmission due to heart failure, according to a study published in the *European Journal of Heart Failure*. Study investigators examined whether pupil area can be used as a prognostic indicator in 870 consecutive hospitalized patients with heart failure (mean age, 67.0 years; 37.0% women). During a median follow-up of 1.9 years, 131 patients died and 328 patients were readmitted because of heart failure. Pupil area was shown to be independently associated with all-cause mortality (hazard ratio [HR], 0.72) and readmission due to heart failure (HR, 0.82) after adjustment for preexisting prognostic factors, including the Seattle Heart Failure Score (SHFS). The area under the receiver operating characteristic curve was significantly increased for all-cause mortality (0.69 versus 0.72, respectively) with the addition of pupil area to the SHFS. "Pupil area can be obtained rapidly, easily, and noninvasively. Our study indicates that it could be used in daily clinical practice to predict prognosis in patients with heart failure, including those who also have atrial fibrillation," a co-author said in a statement. "Patients with a small pupil area (eg, less than 16.6 mm²) could be prioritized for cardiac rehabilitation with physical activity, which has been reported to improve autonomic function."

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