

What's Your Compliance IQ?

Volume 3

Issue 4

April, 2020



HIPAA News

Using COVID-19 patient data for research creates privacy concerns. Creating a patient registry through pooling data bring a variety of privacy and security concerns. For instance, any cloud provider must be assessed for security controls mapped to regulations.

Data collected will be high velocity, often changing or expanding by the hour. The absence of a national privacy law setting a floor on how personally identifiable information could be shared or consumers protected against misuse or unauthorized disclosures underscores the hurdles present.

The huge increases in virtual medical visits are expected to continue after the pandemic. During this crisis, these services are available in all settings, including patient homes. HHS has also waived po-

tential HIPAA violations serving patients through widely available communication apps like Face Time or Skype. The question now is how to sustain telehealth services once the crisis is over.

On site medical visits will still be needed, but telehealth and remote monitoring will need to become part of the "new normal" urge some healthcare leaders.

Location tracking has been around for some time. Google, Facebook, and other tech companies have been talking to the U.S. government about ways to use location tracking data from smartphones and online software applications to combat the spread of COVID-19.

Data could be used by Public Health officials to spot outbreaks and predict how it might spread.

There is a question about whether privacy can be maintained while tracking disease. It is suggested maps be built with aggregated and anonymized data that people opt to share.

Labs are handling more tests than in normal times, so there is more patient data stored, processed, and transmitted. Cybercriminals see this as an opportunity to steal for financial gain. Also, IT departments are focusing on the support needs of a remote workforce.

A CA genetic testing laboratory reported an email hacking incident that may have exposed the medical information of nearly 233,000 individuals. Genetic information is especially sensitive because it is unique to the person and cannot be de-identified and is linked forever to one person.

Compliance News

A Marrero Physician Assistant has entered into a settlement agreement with the U.S. Attorney's office for allegedly accepting illegal payments in return for recommending and prescribing compounded drugs produced by OK Compounding, LLC. He will pay \$620, 500.

In the wake of digitization, healthcare infrastructure has become a chaotic web of disparate systems & applications. The average health system is running 18 different EMR vendors across the entire provider network.

Gaps or errors in patient identity management can have serious patient consequences. Forty percent of U.S. providers have reported an adverse event in the last 2 years as the result of a patient matching is-

sue. Patient safety and coordination of care issues can often be traced back to patient identity management.

The Verified Innovative Testing in American Laboratories Act of 2020 (VITAL Act) has been introduced in the Senate to provide a new pathway to make tests quickly and widely available during public health emergencies. Supporters believe CLIA needs to be updated by removing LDTs from FDA oversight during a public health emergency. The act would do 4 things:

- Clarify Public Health Service Act that governs all aspects of LDTs including during a PHE
- Require CMS to have public hearing to solicit recommendations for CLIA updates w/in 90 days of enactment.
- Require HHS Secretary to report

this to Congress w/in 180 days of enactment

- Express the sense of Congress LDTs should adhere to Personnel requirements under the Public Health Service act and work with the federal government to ensure accuracy and quality of tests and availability of testing during a PHE.

Both Google & Apple promise to add new capabilities to their operating systems to help with contact tracing; both refuse to accede to demands from some countries to allow centralized storage about users who adopt their apps. According to security experts, a decentralized storage will avoid unchecked surveillance and minimize data breach risks. These apps will augment manual tracking.

Safety

OSHA has received thousands of COVID-19-related complaints across the U.S. Complaints involved multiple industries and ranged from PPE shortages to lack of space to enable social distancing to being forced to work with visibly ill associates.

The CDC has a spreadsheet for facilities to use to calculate the burn rate of PPE. It can be found on this CDC website link: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/burn-calculator.html>

Cytology labs should follow the following guidelines when working with patient with or potential-

ly infected with COVID-19:

- Use universal precautions since specimens can contain viable virus
- Take special precautions when specimen prep requires steps that can lead to aerosols—minimize formation of aerosols or droplets & any such procedure should be performed under a Class II Biosafety Cabinet

If rapid onsite evaluations are involved (ROSE), must wear appropriate PPE to include N95 masks and eye protection.

- Virus is inactivated by gamma irradiation & formalin. When handling specimens fixed with

PreserveCyt, CytoLyt, or Sure-Path should be handled with gloves since it is not known if these destroy the virus.

- Good microbiology general safety procedures.

Masks being worn during the pandemic to protect others from you are not considered PPE by OSHA. If homemade masks are used, they should be washed daily & some hospitals allow staff to take these home to wash. Paper masks can be worn for a shift unless they become wet or moist.

A hazardous waste vendor or an educated laboratory staff member may move chemical waste to a facility site.

Miscellaneous

In past public health emergencies like now, the FDA has relied on its EUA pathway to bring new tests to market rapidly. In each case in the past, the initial EUA either went to the CDC or the Department of Defense typically within a week of the declaration. It was the same this time with the first EUA for a CDC test.

Several obstacles encountered resulted in a position pivot allowing high complex CLIA labs to devel-

op and start using validated tests even before completion of the EUA process following guidelines provided. This strategy was expanded then to commercial manufacturers. While not without risk, the strategy worked.

COVID-19 transformed the world in a short period of time. Regaining control will also entail the continued ability of antibiotics to stay on top of pathogens. Bacterial superinfections are often what make pandemics so

deadly. During the 2009 H1N1 flu pandemic, there was a warning that the spike in antibiotic use would lead to more resistant bacterial infections. The same is now happening but on a vaster scale and at a time when the antibiotic pipeline is almost empty.

Healthcare CFOs indicate a likelihood to accelerate the use of automation tools and also expect an increased demand for associate protections over the next month. Some see telework continuing for a while.

Fun Spot



Answer to last month's puzzle: HOT—you can catch a cold!

April Puzzle:
How do you make the number 7 an even number w/o addition, subtraction, multiplication, or division?

Trivia:

- April was named after Aphrodite, the Greek goddess of Love. It was spelled Aprilis which means "to open."
- Glitter was accidentally invented in New Jersey when a man crushed a plastic bottle.

- Hitler's nephew earned a Purple Heart for the Allies in WWII.
- "Radar" is an acronym for "radio detection and ranging".
- Armadillos are bulletproof.
- Abraham Lincoln was a licensed bartender.
- In a flat landscape at night, the human eye can see a small candle flame 1.6 miles away.
- The average person's body gives off enough heat in 30 minutes to boil a gallon of water.
- You can survive longer without food than without sleep.