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INSIDE

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COVID-19 Exposed America's Healthcare Faultlines. What Now?

If there was any doubt the American healthcare system was riddled with inequities, the COVID-19 pandemic has erased that thinking. Communities of color, low-income populations, and other disadvantaged groups have been much more likely to suffer the consequences of COVID-19, yet quality of care has been harder to access in the neighborhoods where these populations often reside.

These inequities are hardly news to ED providers who have served as a safety net for such individuals for years. However, the pandemic exposed disparities in such broad relief that they can no longer be ignored. The issue of corrective action was high on the agenda at the Institute for Healthcare Improvement's (IHI) annual forum, which took place virtually in December.

Health system leaders agreed they must act on several fronts to make quality healthcare more accessible to disadvantaged populations. They shared multiple ideas on how clinical and operational players can work together to address this problem.

In his keynote address, IHI President and CEO **Kedar Mate**, MD, said healthcare leaders must consider how they will respond differently against future threats.

"The challenges laid bare by this virus are significant: Isolation and discoordination of both individuals and systems, inequities at local and global scales, and false choices between our prosperity and our health," he said.

How might health systems respond? Mate suggested clinical leaders and policymakers consider targeted universalism, a concept first described by University of California, Berkeley law professor john a. powell, JD. The term means society can achieve objectives by using focused tactics that aim to provide an advantage to those who have been systematically disadvantaged.[1] *(Editor's Note: Professor powell does not capitalize his name: http://bit.ly/2NHJZS5.)*

The idea, according to Mate, is that when one provides an advantage to marginalized or excluded groups, and then build from there, one can create a system that delivers benefits to all. As examples, Mate noted seat belts were designed to protect children, but have now saved the lives of thousands of adults and children. Further, smoking laws, which were designed to protect flight attendants and then restaurant

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and bar workers, have reduced tobacco consumption significantly.

Mate wrapped his address around the construct of "curb cuts," small off-ramps in the curbs that make it easier for wheelchair-users to traverse streets. Mate noted curb cuts are now widely implemented across the country, delivering benefits to not only disabled persons but also women with strollers, delivery personnel, travelers with suitcases, and many others.

These innovations run counter to the belief that when one provides an advantage to one group, it hurts the rest, and that such an advantage is unfair to others, according to Mate. "In fact, by focusing on the most marginalized and excluded, we just might create a system that is, in fact, better for all of us," he observed.

However, Mate acknowledged this must happen in a society that has become increasingly polarized, a reality that obscures the value of cooperation at a time when that is precisely what is needed. "It has reduced decision-making to 'either-or' constructs where someone has to lose instead of seeing the opportunity that might be present in both, and solutions where multiple parties can benefit," he explained. "Equity, and specifically health equity, is defined as when all people have the opportunity to achieve their full health potential, and no one is disadvantaged from achieving this potential because of their social position."

Consider Five Essential Steps

How does targeted universalism point to a way forward for healthcare? First, organizations must understand where they are in terms of equity. Several years ago, IHI decided to do just that, taking a closer look at some of the organization's most successful quality improvement (QI) initiatives focused on patient safety in a variety of clinical areas, including maternal health, tuberculosis, and cancer care.

Judging by the outcomes data, all the QI projects were successful, but IHI wanted to know which patient lives were improved and whether disparities were maintained or widened.

"For most of these projects, we hadn't collected the required demographic data that would have allowed us to even know the answer. For those projects where we did [have the data], the disparities remained unchanged," Mate noted.

Consequently, IHI investigators decided to study those organizations that had made good progress in alleviating identified disparities. The results of this endeavor showed these systems had taken five steps:

- They made equity a strategic priority.
- They dedicated resources to collect the right data, and leveraged their quality departments to focus on inequity.
- They endeavored to understand contributing non-medical social factors affecting specific clinical gaps.
- They spoke about racism and voiced a desire to overcome its lasting effects.
- They built relationships with community partners, realizing a push for equity required cooperation.

Since then, IHI has established a collaborative, Pursuing Equity, which is based on using the findings as a "theory of action" to improve health equity.[2] The collaborative includes several U.S. health systems, along with some in other countries, and the results have been eye-opening, according to Mate.

For example, he noted one Midwest health system found that among patients in its behavioral health (BH) units, patients who spoke English as a second language (ESL) recorded a length of stay (LOS) twice as long as that of English speakers.

"Having made that observation, the system provided simultaneous language translation services, a targeted strategy, and reduced the LOS difference by 82% between the two populations," Mate reported. "Not only did the ESL speakers have a shorter hospital stay, but the intervention increased the overall capacity of the BH units in the system, which had the universal effect of benefitting all patients in the community."

In another health system, ED patients presenting with symptoms of stroke recorded a median time-to-clot-busting-thrombolytic-therapy of 33 minutes. However, when the same ED stratified its data by race, investigators found that time for a white patient was 29 minutes and the time for a Black patient was 48 minutes. "This observation shocked the ED leadership of the system," Mate said. "Within days of getting this information, they analyzed their core processes and had begun improvement activities with their clinicians."

Within a month, the disparity observed between white and Black patients had disappeared. Further, investigators also found the overall time, including all patients, from presentation to treatment with clot-busting drugs, declined from 33 minutes to 28 minutes.

The IHI, in conjunction with the John A. Hartford Foundation, the American Hospital Association, and the Catholic Health Association of the United States, has promoted a series of evidence-based practices to deliver better care for seniors.[3] "It turns out that while age-friendly healthcare was built and targeted to benefit older adults, it has had the beneficial side effect of helping all patients receive better care," Mate said.

EXECUTIVE SUMMARY

The COVID-19 pandemic has exposed the gaping inequities in healthcare access and quality. Healthcare leaders and policymakers are working to correct these problems. They are reaching out to underserved communities to better understand their needs and concerns.

- A possible solution is targeted universalism, a concept that involves using specific tactics to provide an advantage to those who have been systematically disadvantaged, and then build from there to achieve universal goals.
- The Institute for Healthcare Improvement has identified five essential steps: collect the right data, identify non-medical social factors that affect clinical care gaps, nurture open discussion about racism and its effects, and form relationships with community partners.
- Healthcare leaders stress it is not just racial or ethnic disparities that make a difference, but geographic disparities, too — the rural/urban divide.
- Experts warn failure to address recognized challenges among disadvantaged groups may lead to bigger problems.

Establish Goals

To address healthcare inequities, Mate advised leaders to establish universal goals, understanding that some groups have more ground to make up than others.

Second, identify a clinical measure that is important to the organization. For example, an ED might want to study time-to-thrombolytic-treatment for stroke patients, while an obstetrician might want to look at cesarean rates. "Stratify your data by race, ethnicity, and language," Mate noted. "You will learn something for sure ... and it may invite opportunities to make improvements."

Finally, to achieve progress, healthcare professionals must take care of themselves and colleagues. "We will need not only the PPE [personal protective equipment] we wear to physically shield us from this virus, but we need the psychological PPE that can safeguard our minds and souls as we work to save as many lives as we can," Mate said.

Mate warned that under the concept of targeted universalism, failure to address recognized challenges among disadvantaged groups can lead to bigger problems.

"In healthcare, ignoring the disadvantaged and the systems that perpetuate those disadvantages will lead to complications, not only in the health of individuals but in the health of entire nations," he said. "We are living this now with COVID-19."

Apply New Tools, Data

In a separate discussion at the IHI forum, **Amy Compton-Phillips**, MD, noted that while she still cannot provide great answers on how to improve health equity, her system is applying new data sources and tools to understanding what needs to be fixed.

At Renton, WA-based Providence St. Joseph Health, investigators studied the health outcomes of people who were admitted to the hospital, and found no relationship between ethnicity or race and health outcomes.

"The outcomes really were dependent on [what a patient's] health status was coming in and how sick they were," said Compton-Phillips, executive vice president and chief clinical officer for Providence. "There was less of an equity effect once [a patient] was in the hospital."

However, equity effects are much more noticeable in the community. As a result, Providence is looking much more upstream with the use of tools such as the Social Vulnerability Index (SVI), an instrument that considers 15 social factors, using statistical data collected by the U.S. Census Bureau, to gauge how much support specific areas might need in the face of an emergency such as a disease outbreak.[4]

With information from the SVI, the health system can study whether it has appropriate resources in place, such as enough COVID-19 testing sites, to ensure residents can access the care they need. However, Compton-Phillips noted a robust effort also must involve researching how people eat, their exercise levels, and what kinds of discrimination or elevated stress levels they may experience. "It requires us to work beyond healthcare's borders to a much broader community, and there is no place like now to start," she said.

Compton-Phillips expressed additional concerns about the so-called rural/urban divide. She noted downtown Seattle can may seem like a different country compared to rural areas served by a community access hospital or clinics. "It is not just racial inequities but geographic disparities that make a real difference," she observed.

The response to the pandemic has shown that one way to address geographic disparities is to more fully leverage telemedicine. Compton-Phillips noted that is how Providence assisted New York City during the pandemic's early days.

"We couldn't send physicians out to [New York], but we could do tele-ICU to help. We could do that across state lines because of the relaxation of the rules," she explained. "We can start matching need to where capacity exists, the 'moving knowledge, not people' concept."

Michael Dowling, president and CEO of New York-based Northwell Health, indicated his organization is working closely with 11 underserved communities as part of a long-term improvement project. Dowling noted an issue of focus right now in these areas is vaccine hesitancy. "Some of these communities are going to have a lot of skepticism toward the [COVID-19] vaccine or any vaccine," he said. "There are historic reasons for that."

Going forward, Dowling suggests healthcare organizations must move outside their normal practices to address longstanding inequities. "You've got to work with housing, you've got to work with empowerment," Dowling offered. "It is not just [about] delivering medical care itself. A job is the best healthcare antidote that you can actually find ... and as we hire people, that is a focus of ours. You have to broaden the definition of what health is." ■

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Leaders Plot How They Will Leverage the Lessons of COVID-19

While healthcare leaders continue to battle a global pandemic, many also are plotting how they will use the lessons of this emergency to make their health systems better. Several shared their ideas during IHI's annual forum in December.

Already, there is much more focus on the importance of caregiver well-being and how to sustain clinicians through extended emergencies, observed **Amy Compton-Phillips**, MD, executive vice president and chief clinical officer for Providence St. Joseph Health. "We have had mass shootings and we have had wildfires ... so we have had a lot of experience in dealing with calamity, but we haven't had experience in dealing with a calamity that goes on for a year and half," she observed. "We are figuring out how we sustain the people who are sustaining the patients and

sustaining our communities so that we can continue to be resilient into the future."

Frontline clinicians are exhausted. Still, after passing through two COVID-19 waves (so far), Compton-Phillips sees resilience. "I think that attitude is really what has been sustaining [clinical staff] through this current wave ... they know that because they have done it before, they can do it again," she said.

There also is renewed appreciation for the value of peer support, noted **James Mountford**, BM, BCh, MPH, director of National Improvement Strategy for the National Health Service in the United Kingdom. "When you look at some of the literature from military situations ... having escalating support is important. Probably the thing that makes the biggest difference to the most number of people is a little bit of time to just talk to peers on the principle that a problem shared is a problem halved," he explained.

The speed with which clinicians can innovate and improve has been eye-opening for both leaders and staff, according to Compton-Phillips. "The inpatient mortality rate [for COVID-19 patients] has gone from 25% down to the single digits, which is amazing. That is rapid improvement. It is a testament to the fact that when we focus on [an issue], admit that we don't know something, and put in the tools to measure and improve, it makes a huge difference," she noted. "I do think that now that we have done this, and we have done it in a broad way, we can actually leverage those skills in moving forward."

To fully reap the rewards of innovation, **Michael Dowling**, president and CEO of Northwell Health, stated there needs to be changes regarding regulations and compliance. "Innovation blossoms during a crisis, and it is no different this time," he said. "We have been able to do things during COVID that we dream of doing in non-COVID times."

For instance, when regulations were eased in New York when COVID-19 cases peaked there last spring, easing regulations enabled Northwell to respond quickly. "I remember sitting in meetings where [we] had to, overnight, create a couple hundred beds," Dowling recalled. "[We] just let people go do and figure it out, break the rules."

People pushed the envelope and did not worry too much about who was going to be upset. Dowling stressed this attitude must continue. "I am afraid when this is all over, government especially will go back and put all of the constraints back on again," he lamented.

Too often, government bureaucracy has been disassociated with what is happening on the frontlines, according to Dowling. "We need good people to go into government that have real-life experience on the ground," he said. "We should be encouraging young people to go in and help reform that side of [healthcare] as well."

Considering the acceleration of technology like telemedicine and remote work, leaders will have to reimagine how they deliver care. "It is going to be forced upon us rather than us initiating it because the world has changed as a result of COVID," Dowling said. "It will never go back to the same way." ■

Tools Keep Tabs on Patients Remotely, Predicting Outcomes and Conserving Resources

In the early days of the pandemic, some patients with COVID-19 were deteriorating a few days after their initial contact with a physician in the ED.

"For a lot of respiratory illnesses like the flu or colds, we generally expect those illnesses to get better when patients leave the ED. Because this particular viral illness was defying our typical expectations for how viral respiratory illnesses behave, we were trying to figure out if there were any risk factors [to explain] why patients might return," explains **Austin Kilaru**, MD, MSHP, an emergency physician and researcher at the Perelman School of Medicine at the University of Pennsylvania.

Consequently, Kilaru and colleagues examined the outcomes of about 1,400 patients with COVID-19 who were treated and discharged from the ED between March and May 2020. Investigators found 5% returned to the ED within 72 hours of their initial visit and required admission. Another 3.5% required hospital admission within a week of their initial ED visit.

Additionally, the researchers found (perhaps not surprisingly) age was a significant risk factor. "Patients who were older than 60 compared to younger patients between the ages of 18 and 39, had three times the probability of coming to the hospital within 72 hours vs. 2.5% [in the younger patients]," Kilaru reports.

Other risk factors associated with a return visit to the ED included low blood oxygen levels (a pulse oximetry

reading less than 95%), an abnormal X-ray, or a fever upon presentation to the ED. Each factor was associated with double the probability of a return visit to the ED within 72 hours.

"We also looked at patients who came back [to the ED] within seven days. For that group, we found additional risk factors [for a return visit to the ED] were obesity as well as having hypertension as a comorbid illness," Kilaru says.

Monitor Patients

Knowing which COVID-19 patients may need closer monitoring is helpful, but carrying out such a task when staff resources are strained is tough. To address this issue, the University of Pennsylvania Center for Health Care Innovation developed COVID Watch, an automated text messaging approach that checks in with patients twice a day. The tool escalates concerning cases to a team of telemedicine clinicians who are available to respond 24/7. If a patient reports any deterioration in his or her ability to breathe or other worsening symptoms, that case will go to a clinician who will follow up with the patient quickly. The clinician can refer the patient to the ED, if necessary, or arrange for further assessments or care, as needed.

Clinicians in the ED greatly appreciate COVID Watch because they know their patients will be followed once they leave the ED. Patients seem to appreciate the monitoring, too. "The goal of the program is to make sure patients are feeling better, but also to make sure that our outpatient colleagues aren't overwhelmed with calls or concerns so we can all be more efficient," Kilaru says.

Further, there now is an additional program for COVID-19 patients who meet higher-risk criteria. These patients will receive both the automated text messages through COVID Watch and a pulse oximeter upon discharge from the ED. "We collect ... their pulse oximeter readings, and are able to again escalate [patients with] increasing hypoxia to a pool of nurses and a physician. If necessary, we are able to bring patients back to the hospital," Kilaru explains.

These tools help prevent patients from becoming so sick that no one can help them.

"We want patients to come back if they are starting to get sicker," Kilaru adds. "We have better therapeutics, and we can put those patients on oxygen."

Tally the Benefits

COVID Watch is available to a broad patient pool. "Anybody who interacts with our health system, whether they are in the hospital setting or outpatient setting, can be enrolled in this program," says Kilaru, adding there is no cost to the patients or their insurance companies. "This program significantly benefits our health system in terms of triage and capacity as well as patient satisfaction, but this is not a profit-seeking enterprise."

Of the first 3,000 patients invited to participate in COVID Watch, researchers found 83% were managed through the tool without escalating to a clinician for follow-up.[1] They also found 78% of patients who were offered the program accepted enrollment and remained engaged for a mean of about 12 days. Further, about half of participants asked to extend their involvement with the 14-day COVID Watch monitoring period to 21 days.

About 2% of participating patients were escalated to a nurse every day. Of all the patients who escalated to a nurse during the study period (396), 83 patients were advised to go to the ED. An additional 26 patients were

EXECUTIVE SUMMARY

Hospitals are looking to new approaches that can help them manage COVID-19-related capacity challenges without adversely affecting patient care. Researchers developed an automated text messaging approach that can monitor patients who have been discharged from the ED. Other investigators have leveraged artificial intelligence to train an algorithm to help emergency clinicians better predict outcomes and manage resources.

- COVID Watch is a text-messaging tool that checks on patients twice a day, only escalating patients to a live clinician when their conditions warrant.
- Emergency clinicians report it is easy to enroll patients in COVID Watch during discharge, a process that won broad approval from emergency staff.
- Patients deemed at higher risk also may receive pulse oximeters upon discharge so their blood oxygen readings can be monitored remotely.
- At Mount Sinai, investigators have trained an algorithm to enable frontline clinicians to better predict which COVID-19 patients require more aggressive monitoring or treatment, using results from routine bloodwork, blood pressure readings, and a chest X-ray to produce a severity score.

in the ED or admitted to the hospital by the time a COVID Watch nurse responded.[1]

More data should be forthcoming soon. Funding from the Patient-Centered Outcomes Research Institute is enabling investigators to rigorously study outcomes from patients enrolled in the COVID Watch program. "We are essentially comparing patients enrolled in the program to patients not enrolled, and examining outcomes for 30 days after getting symptoms from COVID-19 and getting tested," Kilaru observes. "That study is actively going on right now."

Researchers also are analyzing the benefits of providing higher-risk patients with pulse oximeters to determine if this approach enables clinicians to identify worsening symptoms faster, and whether earlier detection can help patients recover without returning to the hospital.

Prioritize Ease of Use

COVID Watch does not require a smartphone. Most patients own some kind of cellphone that allows them to participate. Kilaru says a goal of the program is to cut the number of check-in phone calls staff have to make "so that we are only responding to patients who are worsening or reporting some kind of concern rather than calling every patient every day. The use of these automated programs reduces the amount of human power needed."

Another plus is the ease with which emergency clinicians can enroll patients, essentially with one click in the electronic medical record during discharge. "We had to have a system that was essentially very easy to implement in the ED," Kilaru says. "We purposefully didn't want it to take an hour to get someone into the program."

Further, investigators note that automated text messaging backed up by clinician support carries potential beyond the monitoring of COVID-19 patients. Researchers at the University of Pennsylvania have produced a similar approach for patients with COPD, and they are in the process of developing programs for patients with other chronic conditions, such as congestive heart failure and hypertension.

Leverage AI

Another way to better manage available resources is to develop a tool that can provide frontline providers with keener insight on which patients who present to the ED with mild symptoms from COVID-19 are at the highest risk for requiring intubation or succumbing to the illness within 30 days. Researchers at the Icahn School of Medicine in the Mount Sinai Health System in New York City created an artificial intelligence-driven algorithm they say can deliver such insight based on routine test data and a chest X-ray. This is information emergency physicians generally have at hand.

Fred Kwon, PhD, a researcher in biomedical sciences at Icahn, says this algorithm differs from other predictive tools. "There are algorithms that use only imaging data or that only use the clinical data from EMRs. What our algorithm does is combine [both sets of data] together similar to would a clinician would do," he explains.

Further, Kwon notes most other prognostic algorithms only take information from patients who have been admitted or have undergone more advanced imaging tests, such as a CT scan. "You only need to take information that is obtained within days, if not hours, of patients coming to the ED to get an idea of the potential severity so that you can triage the patient and make sure appropriate resources are allocated," he says.

To develop the algorithm, researchers used data from 338 patients ages 21 to 50 years with COVID-19 who presented to EDs in the Mount Sinai Health System between March 10 and March 26, 2020. The data included chest X-rays, basic blood work (including a

metabolic panel and complete blood count), and blood pressure readings. Researchers applied the algorithm to adult patients of all age groups.

Researchers reported the algorithm offers 82% sensitivity in predicting intubation and death within 30 days of initial arrival to the hospital, producing a severity score clinicians can use to plan care. For instance, a patient with a higher severity score likely would be placed under close observation and perhaps given more aggressive or rapid treatment.

However, Kwon acknowledges these results are based on a patient population served by EDs within the Mount Sinai Health System. While this cohort was diverse, other investigators are collaborating with 20 different hospitals around the globe to train a more generalizable algorithm with data from more than 60,000 patients.

"Our algorithm can be readily adapted to be used in patients not just positive for COVID-19, but hopefully in the future, other acute respiratory syndromes and other respiratory illnesses," Kwon says. "Pneumonia and acute respiratory distress syndrome — those are the big ones." ■

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Streamlined Lyme Disease Guidelines for Frontline Providers

Recognizing potential cases of Lyme disease can be tricky, particularly for frontline providers who are not accustomed to seeing patients present with the tick-borne illness. But understanding the peculiarities of this disease has grown increasingly important in recent years. The incidence of Lyme disease has spread rapidly into regions beyond the traditional areas of the Mid-Atlantic and upper Midwest where the ailment is most common.

Paul Auwaerter, MBA, MD, clinical director of the division of infectious diseases at Johns Hopkins Medicine, says Lyme disease has been reported in New England, southern Canada, parts of the Rust Belt and Midwest, and in parts of West Virginia and Virginia. "These are all new areas that 10 or 15 years ago did not have [Lyme disease] very commonly. People practicing in these areas need be aware [of possible cases]."

To that end, new guidelines sponsored by the Infectious Diseases Society of America, the American Academy of Neurology, and the American College of Rheumatology have been established to help providers with diagnosis and treatment decisions related to Lyme disease, along with coinfections involving Lyme disease and another tick-borne illness.[1]

Auwaerter, a co-author of the guidelines, says by focusing specifically on Lyme disease, the authors believed they could produce simpler recommendations than previous guidelines, which addressed multiple tick-borne illnesses. Auwaerter and colleagues also applied the GRADE approach (Grading

EXECUTIVE SUMMARY

With the peak period for Lyme disease approaching, new guidelines help clinicians understand when to consider the ailment in patients who present to the ED, how to properly diagnose a case, and how to treat.

- Recently, Lyme disease has spread into new regions, reaching as far south as the Shenandoah Mountains of Virginia, and north into regions of the upper Midwest and even southern Canada.
- Patients with Lyme disease often present with erythema migrans, often called a bull's-eye rash. About two-thirds will exhibit fever, headache, or systemic symptoms. Some present with neurologic symptoms like a facial nerve palsy or radiculitis, or with arthritis.
- Usually, a defined course of antibiotics is sufficient to microbiologically eradicate the bacteria that cause Lyme disease, but some patients report lingering symptoms.
- Doxycycline now is recommended for children younger than age 8 years diagnosed with Lyme disease. A modified two-tier algorithm for serology produces faster results than older methods.

of Recommendations Assessment, Development and Evaluation) so practitioners could assess the strength of each recommendation.

Recognize the Signs

Typically, patients with Lyme disease in North America present with erythema migrans, often called a bull's-eye rash. It is a tell-tale symptom, but one patients do not always recognize.

"About two-thirds of those people will have fever, headache, or systemic symptoms, but many times they are unaware of a tick bite or unaware that they have a rash," Auwaerter observes. "Those people might present with neurologic symptoms like a facial nerve palsy or radiculitis [pain that results from pressure on a spinal nerve], or they may present with arthritis."

Patients with Lyme disease who present to the ED may have aseptic meningitis or endocarditis.

"Any of those symptoms in someone who could have a potential tick exposure should prompt [clinicians] to think about tick-borne diseases," Auwaerter says. "Ask about whether there is a history that might suggest there is a compatible rash recently, if it is not present, or trigger consideration of ordering Lyme serology tests."

Auwaerter cautions there are some challenges with serology tests because they can be negative early in a Lyme infection. In fact, he says serology tests deliver negative results 60% to 70% of the time in the first week or two of a Lyme infection because it takes time for the immune system to respond.

"However, if someone has had symptoms for six weeks or longer, I think a negative Lyme serological test is sufficient and accurate to rule out concerns that the patient has Lyme disease," Auwaerter notes.

On top of serological testing complications, *Borrelia burgdorferi* or *Borrelia mayonii*, which cause Lyme disease, are difficult to culture. Clinicians usually identify the disease when they see signs or symptoms comparable to Lyme. The incidence of Lyme disease tends to peak in children between the ages of 5 and 8 years and in adults older than age 50 years. There are some differences in presentation between these age groups.

"Particularly in children under the age of 10, they may present with an arthritis that appears more like an affected joint, especially in the hip," Auwaerter says. "This is especially true in the New England area where there may be more erythrogenic strains of the *Borrelia* bacteria." Auwaerter adds clinicians often do not see the rash, neurologic complaints, or even carditis in young children, but these symptoms may be present in teenagers and in young adults. "Carditis might affect more people in older age groups, but it is the least common manifestation [of Lyme disease]," he says.

Consider Coinfections

After making a diagnosis, treat Lyme disease with a short course of antibiotics, generally doxycycline. "Usually, a defined course of antibiotics, generally between 10 to 28 days, depending on disease presentation, is sufficient to microbiologically eradicate the bacteria," Auwaerter explains.

Following antibiotic treatment, Auwaerter notes there are some patients who seem to experience lingering symptoms, a condition sometimes referred to as post-treatment Lyme disease syndrome. "This particular circumstance, which usually [involves symptoms of] pain and fatigue, does not [typically] respond to additional antibiotic therapy, and it is generally not advocated," he observes. "There are some rare cases where re-treatment might be necessary."

While some patients report symptoms even six months following antibiotic treatment, it is unclear

what causes these symptoms, notes Auwaerter, although this is a focus of research. However, he says rather than diagnosing a patient with chronic fatigue syndrome or fibromyalgia, some practitioners will say the patient has "chronic Lyme disease," a term with vague diagnostic criteria and no definition.

"You need to have symptoms compatible with Lyme disease, either early or late disease, and supportive evidence, either through an erythema migrans rash, if early, or positive serology tests," Auwaerter says.

A small percentage of patients present with coinfections, Lyme disease and another tick-borne illness. Treatment with doxycycline should effectively treat Lyme disease as well as anaplasmosis, which also spreads by ticks. However, if a patient does not show some improvement within 48 hours of treatment, clinicians should consider other tick-borne illnesses. "Lyme disease with babesiosis is the most common [coinfection]," Auwaerter observes.

Clinicians usually identify babesiosis in contaminated blood viewed through a microscope. Generally, clinicians prescribe two medicines: atovaquone plus azithromycin or clindamycin plus quinine. The latter combination usually goes to severely ill patients.[2]

Experts note babesiosis can be particularly serious in patients without a spleen, who are immunocompromised, or who present with other serious health problems. There should be heightened awareness of potential coinfections in these patients.

While the new guidelines do not present any wholesale changes regarding the diagnosis and treatment of Lyme disease, there are some updates of importance to clinicians. "First, doxycycline, which is part of the tetracycline class, is now recommended for children under the age of 8," he explains. "The FDA used to have dental enamel staining as a warning on the package information, but that seems to be very unlikely with short-course therapy."

Auwaerter notes the American Academy of Pediatrics and the CDC also recommend short-course doxycycline for children younger than age 8 years. "Previously, pediatricians and emergency rooms prescribed amoxicillin for Lyme disease [in this group]," he says.

Another updated recommendation concerns the use of a new two-tier testing algorithm for the serologic diagnosis of Lyme disease. "The FDA has optimized what is called a modified two-tier system that includes two different enzyme immunoassays [EIA]," Auwaerter explains.

Previously, serology testing typically involved using a two-tier testing algorithm that included a first-tier test, either an EIA or an immunofluorescence assay, and then a supplemental immunoblot assay in cases in which the first test results in either a positive or equivocal result. The modified two-tier testing process replaces the immunoblot assay with a second EIA.

"A number of labs have adopted this [newer testing algorithm]," Auwaerter observes. "It works just about as well as the traditional two-tier serology [algorithm], which has been around since 1995, but there is generally a quicker turnaround and it is less expensive to perform. That is something practitioners may see, depending on the lab that the hospital uses."

Frontline clinicians, especially those in areas where there is a higher prevalence of Lyme disease, could see an increase in cases in late spring or early summer. These are the periods when young ticks, called nymphs, are active and biting.

"However, we see [Lyme disease] year-round with adult ticks biting, especially in more temperate areas where there are no hard frosts or freezes," Auwaerter says.

Further, Auwaerter stresses signs of late disease, such as a swollen knee, can happen year-round because it take months or even a year (or longer) for these signs or symptoms to manifest. ■

COMING IN FUTURE MONTHS

- The role of emergency providers in delivering monoclonal antibodies
- Protecting at-risk ED patients
- Using huddles to cut through the flood of health information
- The emergence of social emergency medicine

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Trump HHS Eases Standards Regarding Opioid Addiction Care; Biden Admin Reverses Course

In the final days of the Trump administration, the Department of Health and Human Services (HHS) modified federal regulations to allow more physicians to prescribe buprenorphine and other medication-assisted treatment for opioid use disorder (OUD).[1] But days into his new term, President Biden pressed pause on this plan.[2]

Under revised practice guidelines, physicians using this exemption would have been limited to treating no more than 30 patients with buprenorphine for OUD at any one time, although the cap would not have applied to hospital-based physicians, such as those who work in the ED. The move earned praise from industry groups. Even as a presidential candidate, Biden supported "removing undue restrictions on prescribing medications for substance use disorder."[3] But now, officials in the Biden White House are unsure the move by Trump's HHS was legal.

At the heart of the issue is the X-waiver. Physicians who want to prescribe buprenorphine or other medication-assisted treatment outside opioid treatment programs have to take a course, apply to the DEA for an X-waiver, and wait weeks before receiving agency approval. "The X-waiver was an outdated and cumbersome barrier to treatment, and it exacerbated stigma for those struggling with opioid use disorder. Now, more than ever, we need compassion and action in treating patients with addiction," **Mark Rosenberg**, DO, MBA, FACEP, president of the American College of Emergency Physicians (ACEP), said in a statement on Jan. 14, shortly after the Trump HHS announcement.[4]

ACEP has long called for an elimination to the X-waiver requirement. In 2020, ACEP rolled out a new accreditation program aimed at nudging EDs across the United States to up their game when it comes to both the treatment of pain and the way they manage patients who present with OUD. *(Read more about the Pain and Addiction Care in the ED, or PACED, program in the November 2020 issue of* ED Management.[5]*)*

The American Medical Association (AMA) classified the X-waiver process as part of a "burdensome regulatory regime" that discourages physicians from prescribing medication-assisted treatment. "Ensuring physician-led teams for treating patients with opioid use disorder is critical to ending the opioid epidemic. Removing the waiver requirement can also help lessen the stigma associated with this treatment and the persistent health disparities in treating substance use disorders," **Patrice Harris**, MD, MA, chair of the AMA opioid task force, said in a statement, also on Jan. 14.[6]

More coverage on this issue will appear in future issues of *ED Management* and in articles on ReliasMedia.com. ■

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CME/CE QUESTIONS

1. **Among roughly 1,400 patients who were treated and discharged from the ED, investigators found patients older than age 60 years were how many more times likely to return to the hospital within 72 hours than patients between the ages of 18 and 39 years?**

   a. Two times
   b. Three times
   c. Four times
   d. Five times

2. **A small percentage of patients present with coinfections — Lyme disease and another tick-borne illness. The most common combination is Lyme disease with:**

   a. babesiosis.
   b. anaplasmosis.
   c. ehrlichiosis.
   d. Rocky Mountain spotted fever.

3. **What should clinical leaders and policymakers consider when looking for ways to address healthcare inequities in their systems?**

   a. Seeking outside help
   b. Staff-to-patient ratios
   c. Surveying patients
   d. Targeted universalism

4. **When it comes to sustaining healthcare staff through the COVID-19 pandemic, what makes the biggest difference to the most number of people?**

   a. More vacation time
   b. Time to talk with peers
   c. Easy access to nutritious food
   d. Confidential links to behavioral health

CME/CE OBJECTIVES

After completing this activity, participants will be able to:

1. Apply new information about various approaches to ED management;
2. Discuss how developments in the regulatory arena apply to the ED setting;
3. Implement managerial procedures suggested by your peers in the publication.

ED ACCREDITATION UPDATE
COVERING COMPLIANCE WITH JOINT COMMISSION STANDARDS

Experts Revisit Processes Surrounding Crisis Standards of Care

With patients overwhelming capacity and resources in short supply, administrators in many regions of the country are implementing crisis standards of care (CSC), an operational change that is necessary when it becomes impossible to meet typical patient-to-staff ratios and other regulatory standards are put in place to optimize care and safety.

However, experts note this transition to CSC has proven to be a bumpy ride for many health systems, with critical decisions made at the bedside in some cases instead of at higher organizational and community levels. They note this ad hoc decision-making has led to a lack of consistency regarding when crisis standards are implemented and placed added pressure on frontline caregivers who already are dealing with unprecedented levels of stress and fatigue.

Leaders are calling for changes to bring more consistency, eliminate overly bureaucratic mechanisms, and place the responsibility for tough decisions up the chain of command where it belongs.

Involve Clinicians

In a CDC Clinician Outreach and Communication Activity (COCA) presentation on the subject on Dec. 17,[1] **Vikramjit Mukherjee**, MD, director of the medical ICU at Bellevue Hospital in New York City, noted that from mid-March to early April 2020, the rapid intake of patients overwhelmed many ICUs and health systems across the city, but these admissions were not evenly distributed across the region.

"The number of patients in Queens and Brooklyn was far [higher] than the number of patients in Manhattan and Staten Island," he explained. "What COVID-19 uncovered, if not magnified, were already-existing social and economic disparities in healthcare access and healthcare delivery."

Bellevue serves as the tertiary referral center for New York City's public hospital system. Most patients admitted to that ICU came from disadvantaged communities with medium to very high poverty levels.

Recognizing that New York City was the epicenter of the COVID-19 epidemic during this period, ICU directors from across the city engaged in a discussion about their CSC experiences. Some observed that crisis standards were implemented in a subjective manner from the frontlines and at the bedside, Mukherjee recalled. Several of those engaged in this discussion, including Mukherjee, contributed to a report on this issue that highlights several of the themes that emerged.[2]

"Most of the participants expressed some degree of frustration that the pre-pandemic crisis standards of care planning did not align well with the realities as they unfolded," Mukherjee said. "Going forward, there was a sense that CSC planning needs to be more operational and that clinicians need to be much more involved from the get-go."

Also apparent to many ICU directors was the reality that supply/demand mismatches were everywhere, involving all three pillars of surge planning: space, staff, and supplies. Further, clinicians often misunderstood CSC to be limited to the use of ventilator triage or to only involve formal triage processes rather than making the best decisions possible in situations that involve risk to the patient or the provider.

Regarding ventilators, the question most clinicians were confronted with was generally not whether a ventilator was available to a patient, but rather what type of ventilator should be used: a traditional, state-of-the-art machine; a retrofitted, bi-level positive airway pressure

machine; or one of the smaller, portable ventilators supplied by FEMA.

In their report, Mukherjee and colleagues stressed that CSC is not a choice, but rather a last-case scenario that healthcare systems are forced into when all other options have failed.

Develop a Plan

In New York City's public hospital system, there were several innovations that helped minimize the harmful effects of supply/demand mismatches. For example, when looking at space, Mukherjee noted that every day, all the system's ICU directors met to look at surge levels. This helped Bellevue and other facilities anticipate demand and load-balance cases effectively across the system.

ICU staffing was a particular challenge during the early days of the pandemic. Even with all the intensivists working, there was a need for added clinical leadership and administration.

"Many of us took a role as a pit boss as we navigated through the pandemic ... and the role of trainees, which was a little bit up in the air for the first phase, ended up playing an extremely important part in our surge response," Mukherjee said.

To help staff the ICU during this period, Mukherjee maximized the use of existing ICU staff. Critical care staff, recently liberated from closed operating rooms, were called in to help. Other staff who were uptrained to work in the ICU and new workers from other medical centers across the country pitched in.

"Back in April, we were the only [area] that was being [so broadly] affected by the pandemic, and we were lucky to get so much help from our colleagues," Mukherjee said. "Unfortunately ... there are many, many hot spots [now], and this might not be as easy to arrange ... but there were challenges in making sure there was a uniform approach, and making sure that PPE was standardized."

In terms of supplies, many shortages were anticipated, but there were some surprises, too. "We didn't expect the need for deep sedation, and had to be nimble about IV pumps, fentanyl, opiates, and paralytics," Mukherjee noted.

There also were shortages of cooling blankets, tracheostomy kits, and disposable items such as circuits, filters, and even syringes.

Ultimately, the disaster plan Bellevue put in place proved to be less than ideal, but Mukherjee stressed that an imperfect plan is better than no plan.

"We recognized that there is always going to be a supply/demand mismatch," he said. "Even though it wasn't a perfect plan, we had something to fall back on."

Provide Clarity

During their discussions, ICU directors agreed that implementing CSC on the fly is challenging, Mukherjee said.

"There needs to be a clear form of declaration that the CSC context exists at the hospital, hospital system, healthcare coalition, and jurisdictional levels," he stressed. "However, CSC plans must factor in that a formal declaration from the state may not be made in time."

For example, New York state never made a formal declaration for CSC, but such decisions were made at the bedside.

"Institutions need to recognize that whether a formal declaration from the state is made or not, there have to be decisions made in a very sensitive manner at the front lines," Mukherjee noted.

EXECUTIVE SUMMARY

Throughout the COVID-19 pandemic, healthcare practitioners have observed challenges related to the implementation of crisis standards of care (CSC), a declaration that should be made only when all other options have failed. Experts report there has been a lack of consistency in such decision-making. In some cases, CSC decisions are made unnecessarily, putting patients at risk. They advise re-examining plans for CSC devised before the pandemic to incorporate recent lessons learned.

- CSC decisions made at the bedside often are happening in an ad hoc manner rather than moving up the chain of command.
- One area ripe for improvement is the extent to which hospitals collaborate in their response to a crisis.
- CSC planners believed hospital systems confronting a crisis would enter into a CSC footing across the domains of space, staff, and supplies concurrently. During the pandemic, that did not happen.
- Noting fairness is an underlying principle of CSC, experts say the pandemic has adversely affected too many urban medical centers caring for communities of color.

CSC planning also should factor in the emotional impact on frontline practitioners trying to manage a crisis.

"We know that not just the pandemic, but the hard decisions that came with pandemic planning, took a toll on healthcare workers," Mukherjee said. "This is something that needs to be part of our discussions going forward as we address crisis standards of care."

Also ripe for improvement is the extent to which hospitals collaborate in their response to a crisis. For example, in New York City, Mukherjee noted collaboration was excellent *within* health systems, but non-existent *between* health systems. "All of the systems worked well within their silos, and were able to level-load within their silos, but these major institutions were rarely talking to each other, sharing information with each other, or level-loading between institutions," he said. "That is a huge vulnerability that needs a lot of work."

Elevate CSC Decisions

John Hick, MD, a professor of emergency medicine at the University of Minnesota and Hennepin Healthcare in Minneapolis, also spoke during the Dec. 17 COCA presentation.

"In retrospect, when we look back at the work that the Institute of Medicine's committees on crisis standards of care have done over 2009, 2012, and 2013, certainly we had not had contact with an enemy like this," Hick said. "We recognize certain shortcomings in the [CSC] framework ... and some of the operational recommendations that were made."

For instance, before COVID-19, CSC planners thought hospital systems confronting a crisis would enter into a CSC footing across the domains of space, staff, and supplies at the same time. In reality, that did not happen. Instead, Hick pointed out the healthcare system entered into CSC almost immediately from a PPE standpoint, particularly regarding N95 respirators.

"I give the CDC tremendous credit for constructing an extremely rational, well-thought-out sequence of graceful degradation of materials, from conventional to contingency to crisis-relative to N95 respirators," Hick said.

He explained that when moving from a conventional to a contingency footing, one makes adaptations that enable staff to provide care that is functionally equivalent to conventional care without any added risk to the patient or provider. "It is just done in a somewhat different way," Hick added.

However, when contingency moves to crisis, that is a threshold where the clinician, hospital, and health system determine they need to allocate resources in a way that increases the risk of a bad outcome to the patient. While it is not uncommon for individual providers to essentially move to a crisis mode by making certain implicit triage decisions, such decisions should be made at the systems level.

"If you are making a decision that is not in the bounds of 'usual,' or it puts a patient at significant risk, that is really a marker that it needs to be kicked up to a systems level," Hick explained.

Many health systems have set up special triage teams to engage in this type of decision-making, but Hick noted such decisions have revolved around life-support interventions, such as the use of ventilators. However, what the pandemic has made clear is clinicians need access to much more immediate counsel on a range of potential CSC concerns.

"Whether this is a medical director on call or a critical care physician on call, [they need] someone they can touch base with when they are bordering into a crisis phase," Hick said.

The key is moving the decision up the chain to the hospital level, the systems level, and then to the regional and state levels.

"It is very possible that, just like ripples across a pond, you can diffuse the impact across other institutions," Hick said. "It is important that we try to avoid CSC as much as possible, not only for the patient's benefit but also from an equity lens."

Hick noted many urban level I trauma centers that serve communities of color have been much more adversely affected by the pandemic than other hospitals.

"Making sure that impact is diffused so that we can provide the best care possible to a patient regardless of what their community situation may be is so important to making sure that this system is fair," he said. "Fairness is ultimately the underlying the principle of CSC, along with consistency."

Avoid Ad Hoc Decisions

Investigators have found that when individual providers have the power to make CSC declarations, they may not be aware there are resources at the hospital, system, or regional levels that may negate their need to make such a declaration. "However, CSC exists any time that a provider is having to make decisions that put patients at risk," Hick noted.

Particularly when providers are under stress, they want bright lines

and firm answers, and there often are not many of those. However, Hick noted that when providers are in question, they should consult with a senior provider who is up the chain. The issue likely is not that provider's alone.

"It is probably a systems issue, and you are probably not the only provider or hospital experiencing it," Hick offered. "It needs to be raised up, and it demands and deserves standard work, a standard approach."

The goal is to avoid ad hoc decisions whenever possible.

"If it is not a decision that you normally make, and you feel like you are in a resource-constrained situation, you should validate that up the chain," Hick observed. "You don't want to make assumptions at the provider level, and to be doing triage that doesn't necessarily need to be done. Knowing what resources are available to you is incredibly important, and staying within the scope of practice to the degree possible."

Hick acknowledged decisions often need to be made quickly. Consequently, he urged administrators to ensure they are providing policy support, procedural support, and clinical decision support to bedside providers so they have an action plan from which to work.

"When they have clinical decisions they feel are out of bounds or novel, they can reach up and make sure to integrate a senior clinician, office medical director, or incident command consultation into that decision," Hick explained.

Ultimately, CSC conditions in any domain should last for as short a period as possible.

"We should be striving to get back to contingency as quickly as possible, using regional mechanisms, standard work, and standardized approaches," Hick said.

Health systems should rethink how they train and use their workforce, providing them with added flexibility to respond to crises and other adverse events. Still, Hick also voiced concern healthcare leaders have short-term memories.

"I just think it is incumbent on all of us to channel the frustration and some of the pain to make sure that ... when we face this challenge again that we don't make the same mistakes," Hick stressed. "We forgot about the 2009 H1N1 [pandemic] too quickly because it didn't have the impact we anticipated. We cannot afford as healthcare providers or healthcare systems to not learn the lessons from COVID-19."

More information on the planning and implementation of CSC is available from the Health and Human Services Assistant Secretary for Preparedness and Response online at this link: http://bit.ly/3bXdauj. ■

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