

## Virus

## 'Mysterious &amp; cunning'

## Docs try hyperbarics in 'coronavirus' fight

By Margie Mason and Robin McDowell

As a New York University medical researcher who works once a week in an emergency room, Dr. David Lee had the luxury of time to think like a scientist while also treating coronavirus patients whose lungs kept giving out. In every case, he saw the same thing: Their blood was starved of oxygen.

One day an idea hit him: Could hyperbaric oxygen therapy, best known for treating divers with the bends, help stave off the need for ventilators and perhaps reduce deaths?

Physiologically it made sense to him, but he soon learned it was also complicated. The therapy, which involves delivering 100% oxygen straight to patients inside a pressurized chamber, is often met with skepticism by the wider medical community because fringe supporters have long touted it as a virtual cure-all without scientific evidence.

So much so that the US Food and Drug Administration wrote a consumer update a few years ago, explaining that the therapy is only approved for 13 types of treatment, ranging from burns to deep wounds and carbon monoxide poisoning. The agency warned patients not to be misled by claims on the Internet that it works for conditions such as cancer or autism.

Still, with medical teams worldwide having little success at saving lives despite throwing everything they had at COVID patients — testing old drugs, trying new ones — Lee believed doctors should be more open to exploring different types of treatments. He brought his theory to Dr. Scott Gorenstein, a colleague at NYU Winthrop Hospital on Long Island with a decade of experience in the field.

Though the treatment is non-invasive, with a long history of safety, both men knew they faced major obstacles. Chief among them: finding funding, and overcoming skepticism about the treatment fueled by hyperbaric spas as well as videos of celebrities like Justin Bieber and LeBron James using portable chambers.

## Promote

"If we were to promote hyperbaric without a rigorous scientific trial, because of the fringe community that's already doing that, the likelihood that it would be accepted by mainstream medical communities is close to zero," said Gorenstein.

Within two weeks, the doctors had approval from an NYU institutional review board for a small, case-control trial that would allow them to compare COVID-19 patients treated with hyperbarics to a control group matched with similar characteristics, such as age, sex, health conditions and oxygen requirements, that did not get it.

Twenty hyperbaric patients, predominantly men age 30 to 79, received up to five 90-minute treatments during the month-long study. Gorenstein said almost all experienced relief of symptoms once sealed inside the clear tube, similar in shape to the old iron lungs once used to treat polio. Some went from having unresponsive "deer-in-the-headlights" dazes to being alert and engaged, while others reported being able to sleep afterward for the first time in days. Eighteen of those patients recovered and were discharged within days or weeks.

Two people died, and the death of one of them halted the study and prompted a hospital safety assessment. It concluded hyperbaric treatment was not the cause, Lee said. The FDA also was asked to review the case, but he said there has not yet been a response.

The control group saw a significantly higher rate of intubations, deaths, and long-term hospitalizations. However, both Gorenstein and Lee stressed that the trial, which will soon be published, was too small to draw any solid conclusions.

"What we've been able to do, I think, is demonstrate that this therapy deserves to be studied in a large way," Gorenstein said, adding the next step would be to secure funding for a larger, randomized control trial at multiple centers.

Scientists remain baffled by the complex nature of COVID-19, its range of victims, its acute and long-haul symptoms, and even the accuracy of tests used to confirm infections. With more than 660,000 people succumbing globally — nearly a quarter of them in the US — there's been little time for robust scientific studies in the race to find effective treatments.

Initial fanfare over the old antimalarial drug hydroxychloroquine and the anti-viral remdesivir quickly died down after it became clear neither was a silver bullet. There's also been excitement over steroids, experimental convalescent plasma, and even antibodies from a Belgian llama named Winter.

## Treatments

What many of those treatments do have is financial backing from pharmaceutical companies, giving them an advantage over hyperbaric and other non-drug therapies. Oxygen, however, is not something that can be patented, and doctors say there are no big profits to be made from using the pressurized pods.

One of the biggest risks in hyperbarics is transporting patients to and from the chamber, given how sick they are and their absolute dependence on supplemental oxygen. There are also questions about how the treatment might affect blood-clotting disorders or if too much oxygen could lead to toxicity and, possibly, seizures.

"My feeling about any kind of intervention, it's really important that that be done through clinical trials. If such data existed, then perfect, it's worth a try," said Mitchell Levy, medical director of the intensive care unit at Rhode Island Hospital and a professor of medicine at Brown University.

"But we want to be really careful that we're not just acting out of desperation, giving things that may be harmful ... or spending a lot of money on ineffective therapies. And that's the challenge of entering this uncharted territory," Levy said.

The treatment was first given to a handful of COVID-19 patients in Wuhan, China, with promising results. A study in Sweden plans to recruit 200 participants. Israel, France and Italy are among others trying it. It's also being tested out at several US hospitals, including at the Opelousas General Health System in Louisiana.

Kathy Fuselier, 62, who works in the pharmacy there, said she felt it helped her. "I didn't have to be put on the vent," she said. "Came close, but didn't need the vent."

With a virus as mysterious and cunning as COVID, Lee said it's essential to raise questions. But he added it's just as important to keep an open mind.

"There's a lot of people trying to find solutions," he said, adding hyperbarics could just be one piece of a larger puzzle. "This is not going to be an end-all, be-all." (AP)



Gorenstein



In this March 16, 2020 file photo, a pharmacist gives Jennifer Haller (left), the first shot in the first-stage safety study clinical trial of a potential vaccine for COVID-19, the disease caused by the new coronavirus, at the Kaiser Permanente Washington Health Research Institute in Seattle. The world's biggest COVID-19 vaccine test got underway on July 27 with the first of 30,000 planned volunteers. The experimental vaccine is made by the National Institutes of Health and Moderna Inc, and it's one of several candidates in the final stretch of the global vaccine race. (AP)

## Coronavirus

## No parties and no trips

## Colleges set COVID-19 rules for fall

By Michael Hill

As they struggle to salvage some semblance of a campus experience this fall, US colleges are requiring promises from students to help contain the coronavirus — no keg parties, no long road trips and no outside guests on campus.

No kidding. Administrators warn that failure to wear masks, practice social distancing and avoid mass gatherings could bring serious consequences, including getting booted from school.

Critics question whether it's realistic to demand that college students not act like typical college students. But the push illustrates the high stakes for universities planning to welcome at least some students back. Wide-scale COVID-19 testing, quarantines and plexiglass barriers in classrooms won't work if too many students misbehave.

"I think that the majority of students are going to be really respectful and wear their masks, social distance, keep gatherings small," said incoming Tulane University senior Sanjali De Silva. "But I fear that there will be a distinct group of students that will decide not to do that. And it'll be a big bummer."

Tulane students have already received a stark warning from the school in New Orleans, an early pandemic hot spot. After a summer weekend of large gatherings, Dean of Students Erica Woodley wrote to students, stressing her key point in bold, capital letters.

"Do Not Host Parties Or Gatherings With More Than 15 People, Including The Host. If You Do, You Will Face Suspension Or Expulsion From The University," Woodley wrote, signing off with, "Do you really want to be the reason that Tulane and New Orleans have to shut down again?"

The emphasis on student behavior is part of a broader effort to create safe bubbles on campus even if the virus surges elsewhere. The University of Texas at Austin is not allowing parties either on or off campus. In Massachusetts, Amherst College is prohibiting students from traveling off campus ex-

cept in certain cases, such as medical appointments and family emergencies.

Many universities have spelled out expectations for student behavior in pledges and compacts that cover everything from mask wearing to off-campus travel. The pledges often cover faculty and staff, too.

It's unclear how well these rules will work. Critics say the very nature of the college experience — with cramped housing and intense social activity — works against success. Some colleges are already backing off plans for in-person classes this fall.

"The majority of kids who go to college are civic-minded, responsible people. They're also young," said Scott Galloway, professor of marketing at New York University. "If some of them don't comply, it's a problem. And I think some to many will have a difficult time ignoring every instinct pulsing through their body at that age that they're supposed to socialize and find mates."

## Vaccine

Galloway plans to teach online this fall and return to campus when there's a vaccine.

Outbreaks involving fraternities have already been reported at some schools, including the University of Southern California, the University of Washington and the University of Mississippi. The University of California at Berkeley recently decided to begin the fall semester with fully remote instruction after a local flare-up of cases linked to fraternity parties.

"After weeks of developing a very elaborate plan for a hybrid model in the fall," officials decided "it was just too risky to teach face-to-face," Chancellor Carol Christ said during a virtual event hosted by the Chronicle of Higher Education.

The pledges apply the advice public health officials have been giving since March for college settings. Yale's compact includes a commitment to remain in Connecticut during the fall semester through Nov 21 and a promise not to "invite or host non-

Yale-affiliated individuals" on campus without permission. Ohio State University's "Together As Buckeyes Pledge" includes a promise to conduct daily health checks.

"We want to be clear: Our return to on-campus operations in the autumn is fully dependent on each member of the university community following all requirements and guidance," read a July 24 letter from Ohio State officials.

Cornell University students must agree not to organize, host or attend events that may cause "safety risks" to people, under a school compact released this week. University of Pennsylvania students are warned in the school's compact that alcohol and drugs are not an excuse for risky COVID-19-related behavior. Syracuse University's pledge includes commitments to get a flu shot and to avoid going to social gatherings with more than 25 people.

"I think that people will really keep each other in check. I know I will," said Suhail Kumar, an incoming Syracuse sophomore. "If I see my roommates unmasked or not following protocol, I'm definitely going to let them know because I don't want to jeopardize anything for myself."

Failure to comply with the pledges will be treated as a disciplinary violation.

Syracuse students can face "serious consequences" for violating COVID-19 guidance, and students who host large parties could face sanctions up to suspension and expulsion, according to the school's web site.

At Penn, incoming senior Ben Zhao is optimistic the new rules will be followed.

Zhao, who is from the Chicago suburb of Northbrook, Illinois, is looking forward to being back on campus after an interrupted spring semester, even with the prospect of online classes. He misses his friends, the school newspaper, where he is executive editor, and studying with classmates.

"They're all big things that I don't want to necessarily miss out on for my senior year," he said. (AP)



In this photo provided by Marilyn Hessler and Syracuse University, a student wearing a mask wheels her belongings up a ramp to move into her dorm, on Aug 2, at Syracuse University in Syracuse, NY. (AP)



Andrews



Morrison

## Health

**Melbourne virus deaths up:** Australia has reported the fewest number of new daily cases in its virus hotspot, Melbourne, since last month. But it also reported the nation's highest daily death total since the virus outbreak began.

The state of Victoria reported 322 new infections and 19 new deaths on Monday, with 14 of the deaths connected to outbreaks at aged-care facilities.

Australian Prime Minister Scott Morrison said he was more hopeful now that cases are stabilizing in Victoria than he has been at any time over the past week.

But state Premier Daniel Andrews cautioned that not too much could be read into a single day's worth of data, and that some of the state's most stringent lockdown measures had only come into effect at midnight Sunday.

The number of new cases was the lowest recorded in Victoria since July 29.

The figures did not include new infections and deaths from other Australian states, although Victoria has been accounting for the vast majority of both in recent weeks.

Since the outbreak began, Australia has reported more than 21,000 infections and more than 300 deaths. (AP)

**NH woman gets new face:** For the second time in a decade, a New Hampshire woman has a new face.

Carmen Blandin Tarleton, whose face was disfigured in an attack by her ex-husband, became the first American and only the second person globally to undergo the procedure after her first transplant began to fail six years after the operation. The transplant from an anonymous donor took place at Boston's Brigham and Women's Hospital in July.

The 52-year-old former nurse is expected to resume her normal routine, which all but ended when the first transplant failed a year ago.

"I'm elated," Tarleton told The Associated Press, in an exclusive telephone interview from her home in Manchester. She is still healing from the operation so photos are not being made available of her new face.

"The pain I had is gone," she said. "It's a new chapter in my life. I've been waiting for almost a year. I'm really happy. It's what I needed. I got a great match."

More than 40 patients worldwide have received face transplants, including 16 in the United States. None of the American

patients had lost their donor faces until Tarleton.

But in 2018, a French man whose immune system rejected his donor face eight years after his first transplant underwent a second. The doctor who did the transplant, Dr Laurent Lantieri of the Georges Pompidou European Hospital in Paris, said that patient is "doing very well."

Dr Bohdan Pomahac, who did Tarleton's first face transplant, was hesitant to do another and favored doing reconstruction surgery instead. But his team became convinced of the merits of a second transplant after Tarleton described how much the first one improved her life.

"She really wanted to try one more time," said Pomahac, who led the 20-hour,

second surgery. A team of around 45 clinicians removed the failing transplant and then prepared sensory nerves and blood vessels in the neck for the surgical connection. The face was then transplanted and Tarleton will gain sensory and motor function in the coming months.

Unlike her first transplant, the donor this time around was considered a much better tissue match. Because of her previous injuries before the first transplant, 98% of donors were incompatible matches. Even then, the first face led to several cases of acute rejection, in which the body attacks the new face and strong drugs are needed to suppress the immune system.

"Now, I am very optimistic and hopeful that it will last a lot longer than the first transplant," said Pomahac, who has described the match as miraculous. "But, of course, that is wishful thinking, speculation. I don't know. She really got lucky."

Brian Gastman, a plastic surgeon at the Cleveland Clinic who led its last two face transplants, said Tarleton's case illustrates the limitations of these procedures.

"When you look at most organ transplants, there is a shelf life," Gastman said. "We are getting to the point where these face transplantations are hitting against the maximum number of years someone can have one in."



A health worker inside a mobile lab takes nasal swab sample for COVID-19 testing through rapid antigen methodology in New Delhi, India on Aug 10. India is the third hardest-hit country by the pandemic in the world after the United States and Brazil. (AP)