

An 'Unprecedented' Effort to Stop the Coronavirus in Nursing Homes

Researchers are testing an experimental drug to halt sudden outbreaks. The trial may bring a new type of treatment for the virus.



By Gina Kolata

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The coronavirus crept into Heartland Health Care Center, a nursing home in Moline, Ill., on the last day of July, when a member of the nursing staff tested positive.

It was an ominous sign: The virus can spread through a nursing home in a flash. Older people — who are often sick and frail and need regular hands-on attention — are uniquely susceptible. Staff members who care for residents are at high risk of infection and of unintentionally spreading the virus.

Although nursing home residents make up just 1.2 percent of the United States population, they account for about 40 percent of Covid-19 deaths.

But this time, the nursing home was not defenseless. Heartland was the first facility to participate in a large clinical trial of drug that might protect residents from the infection in nursing homes and assisted living facilities.

Drug companies and the federal government often avoid testing drugs in older people, even if they are the ones who need treatment most. The elderly may have a range of complicating conditions that make difficult to tell if the drug is working, and nursing home and extended care facilities are governed by a raft of complex regulations regarding privacy and access.

Experts say the new research, sponsored by Eli Lilly and the National Institutes of Health, is among the first large clinical trials to involve nursing home residents. And the scientists are delighted.

“These patients are so underserved,” said Dr. Rebecca Boxer, medical director of clinical trials at the Kaiser Permanente’s Institute for Health Research in Colorado. “They do not get access to innovative new drugs and trials.”

The experimental drug is a monoclonal antibody, an artificially synthesized version of coronavirus antibodies produced by the body. In this case, the antibody was “cloned” from those found in the blood of a Seattle man, one of the first patients to survive Covid-19, the illness caused by the coronavirus.

Monoclonal antibodies are one of the great hopes in the war on the coronavirus. They already serve as the basis for effective treatments for arthritis, cancer, lupus — even Ebola. They are difficult to manufacture, however, and expensive.

Despite the obstacles, two companies, Regeneron and Eli Lilly, have forged ahead with clinical trials. The trial in nursing homes is pivotal to Eli Lilly’s effort to determine whether its version can stop the coronavirus.

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“Some people ask, ‘If we have a vaccine, why do this?’” said Dr. Myron Cohen, a University of North Carolina researcher who proposed the trial. “But a vaccine will take a month to produce antibodies, and some populations need a more emergent intervention.”

But it is not easy to do a trial in nursing homes. Because the residents cannot be expected to travel to a clinic for an infusion and subsequent testing and monitoring, the clinical trial must come to them.

Eli Lilly’s researchers are watching facilities in which a single case of Covid-19 appears after having no active cases for at least 14 days. Once the case is reported, a sort of medical SWAT team scrambles to the facility as quickly as possible.

A nursing supervisor at Heartland called Eli Lilly as soon as the home learned of the employee’s positive test. The team wasted no time getting to the facility.

The next day, medical personnel pulled up in two vehicles. One was a moving truck carrying infusion chairs, poles for intravenous infusions, bedside tables, and privacy screens. The other was an R.V. with an interior retrofitted as a mobile lab with infusion materials, a centrifuge, freezers and computers to transmit data.

The team quickly turned Heartland’s large dining room — which was not being used, because the pandemic had put a stop to communal dining — into an infusion center. The day after the medical team arrived, the first residents and staff who agreed to participate received infusions.

Participants are randomly assigned to receive one of two infusions: a placebo, or the monoclonal antibody, designed to latch onto the virus and to block it from entering and infecting cells. At Heartland, 25 of the 80 residents who were approached eventually agreed to join the trial.

The drug should remain in participants’ bodies for at least a month, and possibly as long as three months, the researchers say. Participants and doctors do not know who is getting the antibody and who is not.

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“It’s a little daunting from the patients’ standpoint,” said Dr. Mark Gloth, chief medical officer at ProMedica Senior Care/HCR ManorCare, a nationwide chain of 222 nursing homes and long-term care facilities, including Heartland.

“We have been restricting visitors for months. Some family members say, ‘I can’t even get in there and hold my loved one’s hand. I want to be sure it’s OK with them.’”



Lee Rouland was at Heartland Health to recover from a pressure sore and agreed to join the study. "Somebody has to go first," he said. Jordan Gale for The New York Times

Lee Rouland, 45, was in the nursing home recovering from a serious pressure sore when he was asked if he wanted to join the study. He readily agreed.

A paraplegic since falling from a fire escape when he was 22, Mr. Rouland was unable to leave his room because he cannot sit in his wheelchair. So the investigators came to him. The infusion took an hour.

For the next two hours, the team monitored Mr. Rouland's vital signs: heart rate, blood pressure, blood oxygen levels. Because he cannot easily travel to a lab for subsequent tests, investigators plan to visit to his home once he leaves Heartland.

He's worried, of course. If he got the drug, it might cause adverse reactions. But "somebody has to go first," Mr. Rouland said.

The study is being undertaken at nursing homes and extended care facilities across the United States and will enroll 2,400 residents and staff. Eli Lilly hopes to enlist 500 facilities — so far, about 125 have agreed to join the study — and the company anticipates enrolling 40 to 80 participants at each site.

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Frequently Asked Questions

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Why does standing six feet away from others help?

The coronavirus spreads primarily through droplets from your mouth and nose, especially when you cough or sneeze. The C.D.C., one of the organizations using that measure, bases its recommendation of six feet on the idea that most large droplets that people expel when they cough or sneeze will fall to the ground within six feet. But six feet has never been a magic number that guarantees complete protection. Sneezes, for instance, can launch droplets a lot farther than six feet, according to a recent study. It's a rule of thumb: You should be safest standing six feet apart outside, especially when it's windy. But keep a mask on at all times. even when you think you're far enough apart.

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There are obvious advantages to testing the drug in nursing homes. Residents are all in one place, making it easy to do contact tracing. And the rocket pace of a nursing home outbreak makes it easier to see if the coronavirus can be halted with this drug.

Monoclonal antibodies are difficult to make. The drug, if it works, is expected to be expensive — an infusion of a monoclonal antibody can cost thousands of dollars. Eli Lilly has not announced what it will charge for the drug if it is approved for marketing.

There is no guarantee of success, and previous attempts to do studies in nursing homes have fallen short. Nursing home residents can be difficult participants: Many have dementia, or have difficulty seeing and hearing. Yet they or, in some cases, someone designated to make decisions for them, must provide informed consent.

“Informed consent is very scripted and can be incredibly challenging, especially with an infused experimental drug,” Dr. Boxer said. Potential participants have to read and understand a form that explains the risks and the adverse side effects that can occur.

Then, she said, participants usually have to repeat back in their own words what they are being asked to do. The people soliciting informed consent most often are not nursing home staff, since they have to be credentialed by an ethics board that approved the study.

Yet “they need to understand the limitations of working with the very old and disabled,” Dr. Boxer said.

Often, residents will want someone else to sign the consent form for them, but states have varying regulations governing who may be authorized. Some residents with dementia might agree one day but forget the next that they agreed to take part, and then reverse their decision.

Nursing homes are very protective of patient privacy. But research regulations allow investigators, in some circumstances, to review patients' medical records to identify patients who might be eligible for a study.

“There just isn't a culture in nursing homes that is attuned to doing research and clinical trials,” said Dr. Mathew Wynia, director of the Center for Bioethics and Humanities at the University of Colorado.

When Dr. Cohen, who is working with the National Institute of Allergy and Infectious Diseases to run clinical trials of antibodies, thought of the nursing home trial, he began calling chief executives of nursing home chains.

“At the end of the calls, I was really shaken up,” he said. “They explained the unbelievable suffering of clients and families.”

Residents who were infected were dying alone, no visitors allowed, he learned. Staff members were falling ill. Nursing home executives were eager to participate in the study.

In Citrus Heights, Calif., a staff member at a nursing home tested positive earlier this month. The moving van and R.V. appeared the next day, and Katy Tenner, 37, a staff dietitian, was among those who volunteered for the study.

The infusion and monitoring took so long she had to get the treatment on her day off. Every day for the next 56 days, she has to have her vital signs checked. Every week she has to have a coronavirus test.

But she is excited about the study. So often, she said, she drives home from work, listening to news on the radio and “bawling my eyes out, hearing about my fellow health care workers dying from this virus.”

“This could be a weapon to fight it and maybe outsmart it,” she said.