STAT[1]

Doctors lambaste federal process for distributing Covid-19 drug remdesivir

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A vial of remdesivir*Gilead Sciences via AP*

Hospitals and physicians around the country are sharply criticizing the federal government for the uneven and opaque way it is distributing its supply of the Covid-19 drug remdesivir.

The experimental drug received an emergency use authorization[6] from the Food and Drug Administration last week, after preliminary data[7]

from a clinical trial showed that it reduced how long it took hospitalized Covid-19 patients to recover. Now, as the drug's producer, Gilead Sciences, tries to ramp up production[8], the U.S. government is starting to distribute the limited number of vials that aren't needed for ongoing research, so that patients can start to see the benefit outside of clinical trials.

About two dozen hospitals are believed to have been chosen to receive the drug so far, but clinicians told STAT it is unclear why some medical centers were chosen to receive coveted doses while others weren't — and who is making those decisions in the first place.

"In my opinion, and I think in the opinion of many of my colleagues, there is a complete lack of transparency about how this decision is being made and who is making it," said Daniel Kaul, an infectious disease physician at the University of Michigan. His hospital's pharmacy department informed him that their center wouldn't be getting any doses of remdesivir after being in contact with the drug's private distributor, AmerisourceBergen, earlier on Wednesday.

"Those of us on the frontlines treating people with Covid-19 need to know what the criteria are and where this drug is going to be available and why those places were selected," he went on."All of us want to make sure limited resources are used in the most efficient fashion. … The government entity making this decision should reveal itself and it should state its criteria."

Even medical centers chosen to receive the drug were in the dark. "I legitimately do not have any insight into how hospitals were selected," said Paul Biddinger, director of Massachusetts General Hospital's

Center for Disaster Medicine and one of the leaders of the hospital's pandemic response.

On Tuesday evening, he said, the hospital's pharmacy got confirmation that it would receive enough remdesivir for about 170 patients. He had heard that three other medical centers in the state also got allocations. Most other Massachusetts hospitals — including some that were among the hardest hit by Covid-19 — would receive none. Biddinger said that on Wednesday, his team was in touch with the Massachusetts Department of Public Health about giving the agency the hospital's allotment, if federal regulations allowed that sort of transfer.

"What we want is to make sure that everyone has fair access to the medication," said Biddinger. "We recognize that there are people from around the state that meet the criteria, and we certainly don't want to be the only hospital [in metro Boston] with access to the medication."

Helen Boucher, chief of infectious diseases at Tufts Medical Center in Boston, said not all the hospitals authorized to receive remdesivir in Massachusetts are the ones with the most Covid-19 patients. "In our state, it's really unclear how the decision was made," she said. "It has us concerned that the maximum number of patients won't benefit."

Mass. General, with 381 patients as of Wednesday, seemed a clear choice for remdesivir. But two others that are receiving doses are much farther down the list: Melrose-Wakefield Hospital had 52 patients, while North Shore Medical Center in Salem had 102, according to a state database[11] of Covid-19 cases. Meanwhile, Beth Israel Deaconess Medical Center in Boston, with 248 cases, and Boston Medical Center, with 238, aren't slated to get the drug.

“Today, the family of a dying patient asked me why we do not have RDV,” Benjamin Linas, a Boston Medical Center infectious disease specialist, tweeted Wednesday night[12], referring to remdesivir. “What am I supposed to say?”

The drug could not only help individual patients, but also the hospitals that have been overwhelmed with them. “There’s lot of talk about ‘Are we going to run out of ventilators and ICU beds?'” said Chuck Morris, the Covid-19 incident commander and associate chief medical officer at Brigham and Women’s Hospital in Boston, referring to worries felt by hospitals around the country. “So any therapy that might translate into avoiding intubation — or fewer days of needing a ventilator or an ICU bed — could be really helpful, not just for that patient, but for a hospital or health system or population.”

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Earlier instances of unapproved drugs being authorized for emergency use have been very different, said Michael Ison, an infectious disease physician at Northwestern Medicine. During the H1N1 flu outbreak in 2009, he explained, the Centers for Disease Control and Prevention created a website as soon as the FDA authorized emergency use for peramivir, so that hospitals could apply for the medicine.

Not so for remdesivir. “Currently there is no way anywhere I’ve seen to figure out how this is being distributed or how they’re making decisions about this,” Ison said.

He found out through his hospital's head of pharmacy that Northwestern would not receive any doses under the emergency use authorization. "This led me to reach out to leaders around the country who are focused on the care of these patients, and found that a huge number of large academic medical centers … didn't have access to this drug," he said. Ison heard that about 25 hospitals have been approved but that the University of Washington, University of California, San Francisco, Emory, Duke, Tufts, and Boston Medical Center had all been told they wouldn't get any of the government's supply of the drug.

The fact that some of the hardest hit hospitals weren't among those selected was concerning, he said. "It raises significant questions about how this was done. It's not clear to anyone. There is no place this information can be found," he said.

In the meantime, he said, UCSF has become something of a clearinghouse for information on which hospitals are getting access to the drug. One infectious disease doctor there posted a map on his Twitter feed[14] of the hospitals that received word of an approval or rejection.

"They [UCSF] are doing what the government should be transparent about," Ison said.

"I'm scared and nervous," said Peter Chin-Hong, a UCSF infectious disease doctor. "There are places that are having a lot more cases than California. But what I'm worried about is, are we ever going to get it [remdesivir]? What is the speed at which we're going to get it? And which hospitals in the area are going to get it if we're going to get it at all."

Chin-Hong said a colleague in UCSF's pharmacy department began collecting information from other hospitals to create a map of which centers were approved to receive the drug and which were denied. Even as the information started to become public Wednesday, it was unclear which part of the federal government was making the decisions about which facilities will get access to the drug, and why.

"We know who the vendor is — AmerisourceBergen — but we don't actually know who is making the decision. Is it Trump? Is it FEMA? Is it science-informed?"

The Federal Emergency Management Agency told STAT that the Department of Health and Human Services is handling remdesivir distribution; a HHS spokesperson said they would look into the matter. Gilead declined to comment.

AmerisourceBergen issued a statement saying it is working with Gilead and the U.S. government to distribute remdesivir to hospitals, "regardless of whether they are AmerisourceBergen customers. Decisions on which hospitals and the quantity of the product they will receive are being made by the government with AmerisourceBergen using our infrastructure and expertise to efficiently move any product we receive from Gilead in keeping with the government's directives."

Related: [8]

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Chin-Hong said patients and doctors in the UCSF system are actively seeking access to the drug. "This morning I got a call from one of the

hospitals in our system in a different county. They didn't have the drug and they just wanted to know what the options were for their patients."

Part of the issue is that the data on the drug's efficacy are still preliminary. "We don't think, for the short term, there will be enough remdesivir to treat everyone," said Mass. General's Biddinger, "and so we would like to prioritize those who are most likely to benefit from the drug."

While many clinicians suspect treating a patient earlier in their illness may provide more benefit, the evidence isn't published yet. That leaves hospital systems in the unenviable position of choosing who will receive medication without all the relevant information.

"The feeling at the end of the day is that it's probably going to have to be a lottery," said Morris of Brigham and Women's, where patients are receiving remdesivir as part of a clinical trial, and which is part of the same system as Mass. General. While there had been discussions of having to invoke crisis standards of care, which can help hospitals ration limited medical resources in an effort to save the greatest number of lives, there were concerns that that could introduce inequities; those who've had less access to the medical system may have more underlying health conditions that could reduce their chances of getting the treatment.

The Infectious Disease Society of America on Wednesday afternoon posted a letter[15] addressed to Vice President Mike Pence urging the administration to create a fair and open process for distributing the drug.

"The plan for distributing remdesivir should be transparent and should be based on state and regional COVID-19 case data and hospitalization rates," the letter stated. "Supplies of remdesivir should be distributed on

a regional basis with equitable distribution within the region to states and within states to hospitals."

The organization, which represents the nation's infectious disease specialists, emphasized that creating such a process is particularly important to eliminate bias and help counteract health disparities that tend to fall along racial lines. "Data on the distribution of remdesivir under the EUA should be publicly available," it wrote. It added that data from the completed clinical trial, the Adaptive COVID-19 Treatment Trial, should be publicly released so that hospitals with a limited supply have the best possible data to inform how to distribute remdesivir among patients.

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