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What the public didn't hear about the NIH remdesivir trial

POSTED BY



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[COVID-19](#), [Dr. Anthony Fauci](#), [politics and health](#)

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This will not be an article that questions the medical evidence being discussed.

It will focus solely on how the message was communicated to a global audience.

I believe that when the results of the NIH-sponsored remdesivir trial – [Adaptive COVID-19 Treatment Trial \(ACTT\)](#), sponsored by the National



Institute of Allergy and Infectious Diseases – are published, the potential benefits will be described as Dr. Anthony Fauci briefly described them yesterday. We should also learn then, for the first time, something about adverse events from the use of the drug in that trial.

But the setting and the manner of Fauci’s announcement that remdesivir would become the “standard of care” is troubling. Sitting on a couch in the White House, mostly speaking extemporaneously, with the Scientist-in-Chief sitting a few feet away waiting to hear what he wanted to hear from Dr. Fauci – this is far less than the ideal environment for the delivery of what was described as “quite good news.”



Fauci emphasized that the study’s primary endpoint was time to recovery. He called it “highly significant....A 31 percent improvement doesn’t seem like a knockout 100 percent, but it is very important proof of concept.” We’ll come back to the primary endpoint issue at the end of this piece.

He said the mortality rate “trended” towards being better but “has not yet reached statistical significance.”

So, why was the announcement made so soon? Fauci said, “We have an ethical obligation to let people in the placebo group know so they can have access.”

That statement is true, but Fauci’s White House announcement reached far more than the people in the placebo group and both President Trump and Dr. Fauci knew that.

[Reuters reports:](#)

Several scientists interviewed by Reuters felt the White House setting seemed inappropriate for the release of highly anticipated government-funded trial data on the Gilead therapy.

They had expected it to be presented simultaneously in a detailed news release, a briefing at a medical meeting or in a scientific journal, allowing researchers to review the data.

Reuters quoted a reaction from Steven Nissen, MD, the chief academic officer at the Cleveland Clinic:

“Am I encouraged from what I’ve heard? Yes, I’m encouraged. But I want to get a full understanding of what happened here, and not get it via a photo opportunity from the Oval Office.”

Reuters continued:

Results from a third study in China suggesting remdesivir failed to help COVID-19 patients were released in the British medical journal *The Lancet* after review by a peer group of scientists.

“That’s the only thing I’ll hang my hat on, and that was negative,” said Dr. Eric Topol, director and founder of the Scripps Research Translational Institute in La Jolla, California.

He was unimpressed by remdesivir’s modest benefit.

“It was expected to be a whopping effect,” Topol added. “It clearly does not have that.”

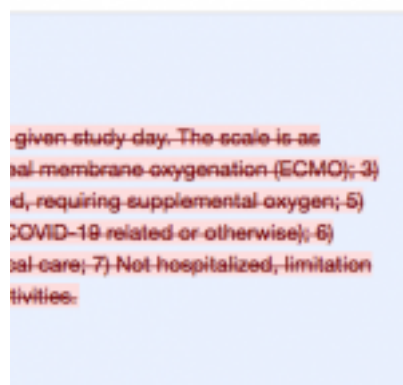
When Fauci, still on the White House couch, was asked about the Chinese trial published in *The Lancet*, he criticized it, calling it “underpowered” and “not an adequate study.”

So the way in which Fauci’s announcement was made has been criticized.

Some have suggested that his comments represent a conflicted double standard; he used his White House platform to praise his agency's sponsored study (not published nor peer-reviewed), while slamming a peer-reviewed and published Chinese study.

Finally, though, many on social media – but noticeably few in mainstream news media – have pointed to the fact that primary endpoints or outcomes were shifted by the researchers in the NIH trial just within the past two weeks. Fauci didn't acknowledge that in his upbeat pronouncement at the White House. He said that the study's primary endpoint was time to recovery. Yes, that has been the primary endpoint for the last two weeks. But not before that. The trial started February 21.

Researchers on Twitter have posted this excerpt from the [online history of changes for this study](#):



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For the general public, this is somewhat akin to the football field being shrunk so that the goal line is not 100 yards away but only 50 yards away – after the game has already begun.

But, of course, this is no game.

To be sure, there can be legitimate reasons for outcome shifting or changing primary endpoints. And in the spirit of this piece, I will not challenge the science. Actually, I can't on this point because I haven't seen the reasons for this shift published anywhere.

Instead, I will stick to my analysis of what yesterday's announcement revealed, what it did not reveal, and how it was communicated.

And for those reasons, I submit that yesterday would be an important case study for lessons in ethical science journalism, science communication, and academic/government research announcements.

You can refer to [the Addenda at the end of my article yesterday](#) to see more reactions from journalists, clinicians and researchers.

Addenda:

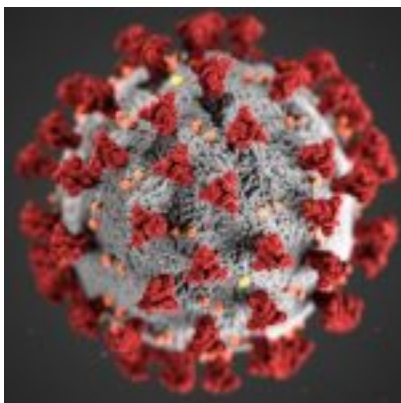
On April 30, Meg Tirrell of CNBC reported on an email response from the National Institute of Allergy & Infectious Diseases on the shifted endpoint.

On May 5, STAT reported, [Were researchers wrong to move the goalposts on remdesivir? In the end, it may not have mattered](#). But that article didn't address the communications questions I have raised above. Regardless of whether it was wrong to move the goalposts, it was clearly wrong to fail to disclose that move while touting the unpublished results in a public statement made from the White House couch. It was only when scientists, some on Twitter, and some journalists pointed to the evidence that the goalposts had been moved that any public discussion or explanation was made by the researchers. It shouldn't have happened that way. And that was my original point above.

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