

# The Washington Post

Moderna's claim of favorable results in its vaccine trial is an example of 'publication by press release'

By William Haseltine      May 19, 2020

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Faith in medicine and science is based on trust. But today, in the rush to share scientific progress in combating covid-19, that trust is being undermined.

Private companies, governments and research institutes are holding news conferences to report potential breakthroughs that cannot be verified. The results are always favorable, but the full data on which the announcements are based are not immediately available for critical review. This is "publication by press release," and its damaging trust in the fundamental methods of science and medicine at a time when we need it most.

The most recent example is Moderna's claim Monday of favorable results in its vaccine trial, which it announced without revealing any of the underlying data. The announcement added billions of dollars to the value of the company, with its shares jumping almost 20%. Many analysts believe it contributed to a 900-point gain in the Dow Jones industrial average.

The Moderna announcement described a safety trial of its vaccine based on eight healthy participants. The claim was that in all eight people, the vaccine raised the levels of neutralizing antibodies equivalent to those found in convalescent serum of those who recovered from covid-19. What to make of that claim? Hard to say, because we have no sense of what those levels were. This is the equivalent of a chief executive of a public company announcing a favorable earnings report without supplying supporting financial data, which the Securities and Exchange Commission would never allow.

There is a legitimate question regarding what Moderna's unsupported assertion means. The scientific and medical literature reports that some people who have recovered have little to no detectable neutralizing antibodies. There is even existing scientific literature that suggests it is possible neutralizing antibodies may not protect animals or humans from infection or reinfection by coronaviruses.

Such "publication by press release" seems to be a standard practice lately. The National Institutes of Health announced last month that the drug remdesivir offered a clear benefit to covid-19 patients with moderate disease, shortening the length of their hospital stay by several days. But did it really? Twenty days after the announcement, the supporting data has still not been published. Without the data, no doctor treating a patient can be sure they are doing the right thing.

Another paper, published the same day, found that remdesivir had no measurable effect on patient survival or the amount of virus detectable in nasopharynx and lung secretions. What then should a practicing physician do? Follow the unsupported advice of a news announcement or a medical report published in a leading scientific journal? This is not an idle question: The NIH announcement triggered a global stampede for limited supplies of the drug.

The case is more nuanced for the vaccine developed by the Jenner Institute at Oxford University, though the mileposts remain the same: It started with a public pronouncement of favorable results from an early study, this time in monkeys, well before any data was publicly released. An NIH scientist working on a trial of the Oxford vaccine gave an interview to the New York Times, claiming the drug was a success.

But the data, released as a prepublication version more than two weeks after the story ran, didn't quite live up to the early claim. All of the vaccinated monkeys became infected when introduced to the virus. Though there was some reduction in the amount of viral RNA detected in the lungs, there was no reduction in the nasal secretions in the vaccinated monkeys. So the positive result reported by the Oxford group turned out not to be protection from infection at all, something most would agree is what a successful vaccine would do. Instead, it lowered only the amount of virus recoverable from the vaccinated monkey's lung.

To the Jenner Institute's credit, it does warn visitors to its website that there have been many false reports about the progress of its vaccine trial. Still, having a scientist working on the trial paint preliminary results in such a positive manner without having yet released the full data is cause for concern.

We all understand the need to share scientific and medical data as rapidly as possible in this time of crisis. But a media announcement alone is not enough. There are ways to

share the data quickly and transparently: posting manuscripts before review or acceptance on publicly available websites or working with journals to allow an early view. Publishing in this manner allows doctors and scientists to reach their own conclusion, based on the evidence available.

The media also bears responsibility. Asking experts to opine on unsubstantiated claims is not useful. Medicine and science are not matters of majority opinion; they are matters of fact supported by transparent data. This is the backbone of scientific progress and our only hope to end this pandemic. We can't give up on our standards now.