

Module 3 Video Class 1: Searching for treatments and vaccines

Hello. Welcome back to our massive open online course, Journalism in a Pandemic: Covering Covid-19 now and in the future. Amazingly, we're halfway through. We've looked at what brought us to this point and what the experience of the epidemic is around the globe.

This week, we're going to interrogate story opportunities in the things that might change the course of the epidemic: the possibilities of achieving treatment for Covid-19 illness, and the hope that science might be able to develop a vaccine to prevent coronavirus infection.

To help explore those, in our video segments we'll hear from Dr. Julie Gerberding, former director of the US Centers for Disease Control and Prevention and now executive vice president and chief patient officer of the pharmaceutical company Merck, which is known as MSD outside the United States. Merck is developing a coronavirus vaccine and previously developed a vaccine for Ebola. We'll also hear from WIRED magazine staff writer Meghan Molteni, who's been covering the search for vaccines and treatments since the pandemic began. And as a bonus segment, we'll hear from Gary Schweitzer, founder of the online publication Health News Review, which trains journalists and how to cover medicine accurately and resist hype.

Over the past two weeks, one of the things that has been implicit in the issues and stories we've looked at is the different experiences of the pandemic in the industrialized West, which has mostly well-funded public health systems, and the global South, where many countries do not. The search for vaccines and treatments reframes that inequality. We are all at zero. No one yet has the things we need. So in covering this aspect of the pandemic, we are all starting in the same place.

But also everyone is desperate for something to change the course of this pandemic. That desperation lies behind the first thing we should talk about, which is the confusion over what works for this disease and the false cures that are being promoted. This fits in with what we talked about last week. Misinformation and disinformation and how to push back against them.

The biggest problem here is the drug hydroxychloroquine. It is an old malaria drug, which came onto the scene for Covid-19 after being touted by a French researcher who pushed it in studies, then it was picked up by Silicon Valley tech gurus. And then it became a cause for the U.S. White House and its favorite news network, Fox News.

I've been telling you for a week about hydroxylchloroquine, hydro-oxy-chloroquine, hydro-chloroquine. We're talking about hydroxylchloroquine. It is cheap. It's considered safe. So in a lot of ways, hydroxychloroquine is the ideal medicine. Hydroxy-chloroquine is a very powerful drug.

The American government bought millions of doses of the drug; the Brazilian president fired his health minister for opposing use of it; and it has become the standard of care in sub-Saharan Africa. Nevertheless, hydroxychloroquine has subsequently been shown in studies to not make a difference to the progression of Covid illness, and patients with Covid who are given the drug may be more likely to die than patients who are not taking it.

We've included some stories about hydroxychloroquine in the readings for this week, and we encourage you to think, in your countries, what treatments are being touted for the virus? Can the people pushing them cite scientific evidence? If they cannot, can you tell who is benefiting from the treatments being sold? Is the drug manufactured locally, and who owns those manufacturing plants?

OK. That's the fake treatments. Let's turn now to the real ones.

Unless we can treat or prevent Covid, it is unlikely that our lives will ever be the same. So there's desperate hope directed at the possibilities of treatments and vaccines. That's coming from people who are afraid of getting ill and also from physicians who want not to lose patients to disease.

But there are also unimaginable rewards, reputational and financial, waiting for companies that can achieve a shot or a drug. So this is an area where there is likely to be a lot of hype; the possibility of fraud; and an extreme need for critical, skeptical journalism.

Let's look at the evidence that is required to obtain an approval for a drug. What's called the "gold standard," the study that gives the most reliable evidence is a clinical trial, which goes through several phases:

... from Phase 1, which uses only a few people and tests only for the safety of the compound through Phase 3, in which the drug is given to thousands of people to see whether it works as its creators intended, compared to the effectiveness of another drug that is already on the market.

The major drug licensing agencies - those are for instance, the U.S. Food and Drug Administration, the European Medicines Agency, the Central Drugs Standard Control Organisation in India and the National Medical Products Administration in China - often ask to see further studies after a drug is approved and allowed to be marketed, called Phase 4, which also involves thousands of people. Phase 4 looks for any long term problems with safety and effectiveness, and gives the company ammunition for asking regulators to let them make additional claims about their drug.

You should be aware, if you aren't already, that this process is not quick. From recognizing a promising compound to getting a new drug licensed often takes from 10 to 15 years, and roughly a billion U.S. dollars. It is an expensive, high stakes endeavor and in research terms, it's also high risk? It's estimated that for every drug that makes it all the way to approval. Ten thousand compounds fell out along the way.

Now, many treatments being looked at for Covid are drugs that already exist. Drug companies are trying to repurpose drugs that were licensed for other diseases, and companies and academic researchers are also scouring their libraries of compounds - which means, their collections of the molecules that didn't look promising enough to develop into drugs.

Starting from an existing drug, or a compound that has undergone some evaluation means that long the process of development can be shortened, but the journalistic responsibilities to examine the process remain the same.

So when a drug is touted or licensed where you live, these are the sorts of questions you can ask. Was there a clinical trial? If it wasn't a clinical trial, what kind of study was done? How many people participated? How were the participants chosen? How many dropped out before the end? Did any of them die? Was there a control group that received a placebo or another drug? What side effects occurred? What were the goals of the study, which are usually called end points? And where they changed along the way? And the participants who took this drug, would they have gotten better even if they didn't?

Reporters asking those questions uncovered, for instance, that the much touted drug hydroxychloroquine, which we were just talking about, had the side effect of causing severe heart problems. And that in a study of another drug, remdesivir, which was heavily touted in the past few weeks and has now become the standard of care in the United States, the endpoints of the study were changed while the study was going on.

It's especially important to ask these questions because right now, much of the science around Covid-19 is being shared not in medical journals, which put new science through a pretty rigorous process of examination, but on sites called preprint servers. What that means is that the usual examination of research for how strong and well-done it is will not have happened - so it's especially important for journalists not to take claims at face value and ask the opinion of experts who were not involved in the research.

Let's make a couple of points about vaccines. That multi-phase process of demonstrating that a drug does what it says it does is usually even more complicated for vaccines and it may take longer. That's because to prove a vaccine works, you must show that it works against natural infection. In other words, you have to go where the disease is and administer it there, and then

wait some uncertain period of time to determine that people were in fact exposed and protected. That's unlike trials for curative drugs, which usually occur in hospitals or outpatient medical settings among people who have been diagnosed with a condition already.

Now, a way to shortcut that process is to guarantee that people have been exposed to a disease by deliberately trying to infect them. These are called human challenge studies, or sometimes controlled human infections. These were done in past medical history, but in the modern era they are considered out of bounds unless they are performed with full informed consent and after review by authorities and medical ethics.

It's a measure of how serious this crisis is that experts and the World Health Organization are talking about allowing human challenge studies. Some prominent medical ethicists have endorsed the idea, and there is currently a nonprofit asking people to sign up to volunteer to be in such a trial.

As of the first week of May, there were eight vaccine candidates in clinical trials and more than 100 in pre-clinical development - that is not yet at the point of being given to people - and that was occurring in at least 12 countries. But there already are a lot of unrealistic expectations.

Here in the US, for instance. President Trump has said that he expects children to be vaccinated before going back to school in the fall. Medical experts say that is impossible. The fastest you can conduct a trial is 12 to 18 months. The quickest vaccine development recorded in history was for the mumps vaccine, and that took 4 years. The Ebola vaccine that was rolled out in West Africa in 2016 was based on a vaccine candidate that was first achieved in 2003.

So for vaccines, the first complexity to look for is the science: How will it be made and tested? The second is the hype: Is effectiveness overestimated, and is the delivery date too soon to be realistic? The third, and this will be very important, is who gets first access to a vaccine that will be needed for the entire world.

If a vaccine is achieved, there will not be one moment when doses for the entire world are available at the same time. As the first doses trickle out, expect there to be ferocious competition for them - and competition as well between a world view that says we are all in this together, and one that says, every country must fight for itself.

In the 2009 H1N1 influenza pandemic, which we talked about in our first module, two countries that housed flu vaccine manufacturing plants, Canada and Australia, stalled on agreements they had made with the World Health Organization to release batches of vaccine for international distribution. They held back the vaccine from their plants until their own citizens were taken care of.

This could turn out to be interesting - because though vaccine development looks like an industrialized-world endeavor, vaccine and pharmaceutical manufacturing is often cited in low and middle income countries. This means that countries of the global south, which might feel at risk of being squeezed out by the industrialized West, which has more money to spend, may turn out to have a surprising amount of leverage in the vaccine race to come.

So to sum up: skepticism, rigor, looking for who benefits. These are our key journalistic tools, and we'll need to apply them to the ongoing stories of treatments and vaccines. The possible arrival of these defenses is essential to what we'll talk about in our final module, releasing next week: what the world looks like from here.