



## Better Healthcare Newsletter from Patrick Malone



Will it be a shot in the arm — or the foot? Americans have invested high hopes in a Covid-19 vaccine. Its development is racing ahead, with researchers deploying novel approaches and governments spending billions of dollars to try to get billions of human bodies to self-generate coronavirus-fighting defenses.

But how safe and effective will a Covid-19 shot be? Can the U.S. government, with an already checkered record in responding to the pandemic, deal with all the p's and q's required to safeguard many millions of children, women, and men? Will the vaccine-hesitant or -resistant undermine the "herd immunity" that will be fundamental to the mass protection provided by a coronavirus shot?

We need to do more than cross our fingers about the rushed research on the regrettably named "Operation Warp Speed" and its race for a coronavirus vaccine. We need to know the risks and rewards of crucial weapons that the world prays will help halt the disease that already has [infected more than 5.7 million Americans](#) and some projections see [killing 300,000 of us by December](#). So let's zoom into the

### IN THIS ISSUE

In quest for safe and effective Covid-19 vaccine, researchers turn to novel approaches and 'warp speed'

Rigorous clinical trials will be crucial

Billions may need this shot. How will they get it? And will they line up to take it?

As pandemic rages, experts also must battle 'infodemic'

Speed hasn't been a major part of the history of vaccines

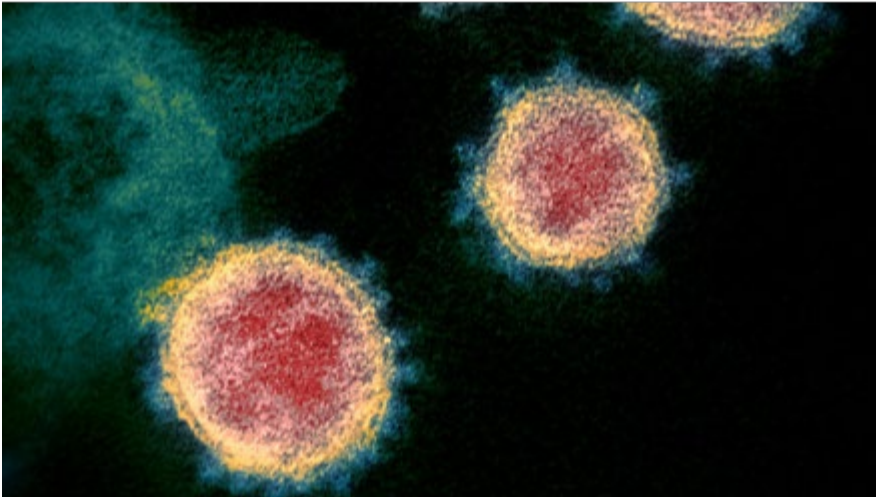
### BY THE NUMBERS

**\$10 billion**

U.S. budget for 'Operation Warp Speed,' which 'aims to deliver 300 million doses of a safe, effective vaccine for Covid-19 by January 2021'

information fast lane about a Covid vaccine ...

## In quest for safe and effective Covid-19 vaccine, researchers turn to novel approaches and 'warp speed'



Just after 2020 began, British and Chinese experts told the world they had taken an innovative scientific step: They [publicly made available the first draft](#) — by experts from the Wellness Trust and the Shanghai Public Health Clinical Center & School of Public Health — of the genome, or genetic blueprint, of a novel respiratory virus detected 10 days earlier. It had begun sickening patients in the Chinese city of Wuhan.

That [online publication attracted global notice](#), including at the National Institute of Allergy and Infectious Diseases headed by Dr. Anthony Fauci, as well as at the agency's Rocky Mountain Laboratories in Montana, and at Northwestern and Purdue universities. As Fauci would note with prescience, "[coronavirus infections \[are\] more than just a common cold.](#)" He told his colleagues they would be confronted with huge challenges in the days ahead if the Chinese outbreak worsened and the world suddenly needed a global response.



Hours after the Chinese shared their fundamental research on the infection now known as Covid-19, medical scientists in the U.S. and around the globe began racing for a coronavirus vaccine.

In the months since, they have built on years of study and painful experience — with killer diseases like the hemorrhagic fever Ebola, and with other fast-spreading, lethal, and debilitating virus-caused respiratory illnesses like severe acute respiratory syndrome ([SARS](#)) and Middle East respiratory syndrome ([MERS](#)). Researchers have aimed to be transparent, cooperative, and collegial, sharing knowledge as never before.

30,000

Target number of diverse participants needed for Phase III clinical trial of just one of several prospective Covid-19 vaccines

-112

Farenheit temperature at which novel coronavirus vaccines may need to be refrigerated to retain viability. That's roughly as frigid as South Pole temperatures.

\$32-\$37

Prospective cost to patients per dose of a coronavirus vaccine. Critics say makers, who are getting big U.S. aid in vaccine development, want to charge twice for their product. It's unclear if patients will foot Covid-19 shots' cost or insurance will cover them, and without co-pays.

### QUICK LINKS

[Our firm's website](#)

[Read an excerpt from Patrick Malone's book:](#)

[The life you save](#)

**Nine Steps**  
to Finding the Best  
Medical Care —  
and Avoiding the Worst

## High-tech targeting of a killer

They also have zeroed in, from the outset, on developing a safeguard by tapping into new technologies that they believed would let them get a vaccine out to the public faster and with great safety and effectiveness. Investigators are working with hundreds of vaccine candidates, including some relying on traditional methods.

But the field of products globally has narrowed fast, especially to those that have zipped into Phase Three, the most important part of clinical trials.

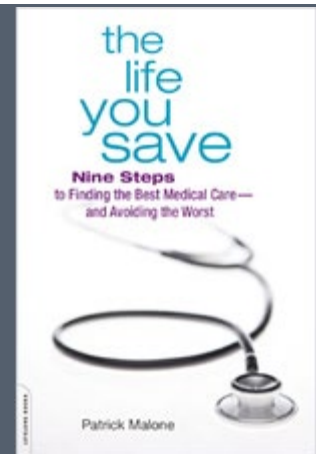
This is the phase in which tens of thousands of volunteers get the vaccine or a placebo without them or their doctors knowing which. This keeps scientists “blind” to biasing factors and the world learns if the vaccines work — that is, that they produce disease resistance safely and widely. And no matter the outcomes (more on this in a second), the public will be reminded of important differences in the Covid-19 vaccine versus others that came before it.

That’s because researchers with the leading vaccine candidates took newer approaches in getting the body to deploy its own remarkable defenses against the coronavirus, and potentially other harmful diseases, too. The Covid-19 vaccine likely will not rely on weakened or dead infectious materials injected into patients, as vaccines against infectious diseases so often have. This approach has been taken as far back as vaccines’ “discovery” by Edward Jenner in the late 18<sup>th</sup> Century. (He inoculated patients with scrapings from those with cowpox to safeguard against smallpox.) Makers today will not have to scale up animal or egg facilities for material in which to grow a Covid-19 vaccine.



Instead, medical scientists around the planet have rooted their inquiry in the Covid-19 genome and high-powered examination of the virus itself, combining this information and more to attack the disease. They are working with novel “platforms” to ferry virus-fighting material into cells. The big war against the coronavirus will be conducted at a microscopic, even molecular, level.

In brief, experts know that Covid-19, like other coronaviruses, attacks so ruthlessly due to spikes on its surface that pierce walls of cells. The spike allows the parasitic



## LEARN MORE



Read our Patient Safety Blog, which has news and practical advice from the frontlines of medicine for how to become a smarter, healthier patient.



## PAST ISSUES

Covid-19 and nursing homes: Should families sue?

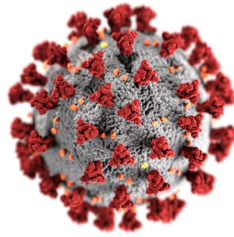
For African Americans, relentless health inequities require urgent redress

Taming the cognitive biases that mess with our decision-making

Will Covid-19 pandemic throw rigorous science into pandemonium?

Protecting hearts, minds and souls in a time of pandemic

You Can Eat This... But



particles to inject genetic coding that corrupts the cell, causing it to become a coronavirus factory, replicating the virus and sending it coursing throughout the body. (Viruses are primal life forms and cannot reproduce themselves, relying on “infection” as their means to replicate and spread).

The new vaccine seeks to disrupt this process in ways that have shown success but have not been tested at a global scale. Researchers now hope to [transport into cells the snippets of genetic code](#) for creating the coronavirus spike. The piece of code lacks information for cells to create the spike or lead to the virus’ replication. But, as preliminary tests and experience have shown, the spike code in the cell triggers the body’s own systems to create potent antibodies to attack infecting Covid-19 and especially targeting its spikes. Two of the Western firms leading the development of a Covid-19 vaccine [rely on different platforms to carry the spike snippet into the cell](#) either with:

- Messenger RNA, aka mRNA. This is a modification of crucial, molecular genetic material RNA (in vaccines in the works by Moderna or Pfizer-BiBioNTech) that can get past body defenses and not create its own negative side effects.
- A non-replicating adenovirus from chimpanzees (as in a possible vaccine from AstraZeneca-Oxford Jenner Institute). The use of such investigator-altered viruses has become familiar and has worked in other therapies to transport vital genetic coding into cells.

### **Will years of research finally pay off?**

Years of study and experimentation could have significant payoffs, if the innovative Covid-19 vaccine succeeds. The approach investigators have taken has, for example, sped up vaccine development significantly. It spared researchers from long, difficult, and often unproductive delving into determining exactly how to attack Covid-19 without harming the body or its systems. The strategy now in play lets the body itself develop and deploy responses that succeed (as scientists have measured and seen).

Investigators, using this latest approach, also will not get bogged down in the risks and problems of cultivating the live coronavirus at scale, then determining how to ensure it is killed or weakened at correct levels to still trigger human protective responses. Doctors administering the new vaccine also will not need to be wary of patients’ potential allergic response — for example, the reactions that

Why Would You?

Looking Ahead:  
Preparing for Long- Term  
Care

Managing Chronic Pain:  
It’s Complicated

Secure Health Records:  
A Matter of Privacy and  
Safety

Standing Tall Against a  
Fall

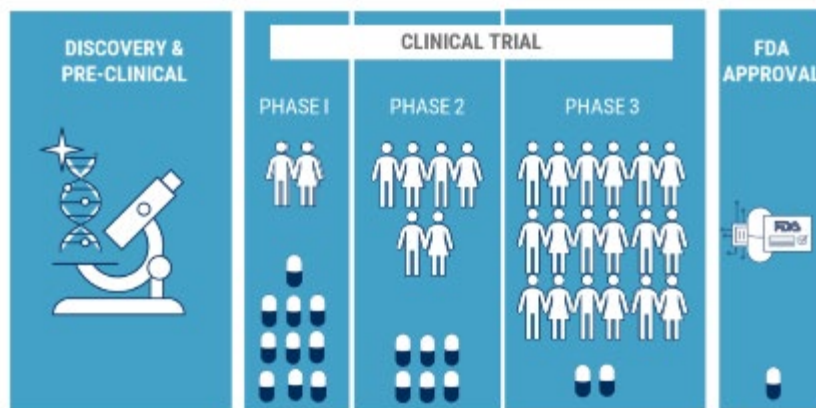
[More...](#)

some people have to flu vaccinations and egg- or chicken-based products.

People still may experience discomfort —headache, sore arms, fatigue, chills, and fever — after getting a dose (or likely two) of the coronavirus vaccine and as their bodies ramp up their defenses. But to be emphatic: The inoculation — carrying just a snippet of viral code — cannot give them the Covid-19 illness, just as a flu shot, contrary to myth, will not give a patient influenza.

The greater risk with the Covid-19 vaccine, in fact, may lie in misinformation about it and in the formidable task of delivering it to billions of people around the world.

## Rigorous clinical trials will be crucial



In America, we call vaccinations "shots." In Britain, they're "jabs." Whatever the name, giant questions hang over the Covid-19 vaccine, especially with its innovative start: Is it safe? Will it provide billions of people the protection they need from this deadly infection that spreads fast and wide?

Randomized clinical trials will provide crucial, fundamental evidence, experts say. Such trials provide the rigorous scrutiny used to safeguard the public with prescription drugs, medical devices, and medical therapies. Evidence from trials can provide a gold standard in protecting patients from medical harms. Their processes can be imperfect — and more needs to be said about this in a moment.

But first it is important to know some trial basics. They can take years, and only a slice of medications, devices, or treatments undergo this form of scientific scrutiny and survive it to become life-saving commercial successes. Researchers and practitioners may spend long periods refining their underlying science before they can put together a product or treatment that merits clinical trial.

The formal testing occurs in roughly three phrases. In the first, a small sample of volunteers (maybe as few as a dozen) help researchers determine if a prospective drug or treatment is safe, at least enough to

proceed to the next experimental stage. In the second phase, a larger group of human subjects — perhaps several hundred — receive the drug or treatment. Researchers assess whether it shows results promising enough to proceed without safety concerns. In the third phase of clinical trials, big numbers of subjects test the drug or treatment. Tens of thousands of participants may be involved. And researchers now must come up with powerful affirmative evidence that their medication, device, or treatment really works, without too many side effects. They have been expected to publish their methods, data, and findings, giving regulators and peers ample opportunity to weigh in on potential flaws, risks, and benefits.

Any experiments involving human subjects also must adhere to stringent protocols. Participants [must provide informed consent](#) — they must be told clearly and in detail what they are getting themselves into, who they will be dealing with and how, and how a drug or treatment may benefit or harm them. They then must assent to their trial role. Senior investigators must oversee and approve study plans, which they also typically submit to leaders and experts at their research institutions and independent review boards. The clinical trial funders — not only private interests like Big Pharma or medical device firms but also U.S. taxpayers, via [major benefactors like the National Institutes of Health](#) — also get briefed in detail about Phase III human tests of drugs or treatments. These also are subject to [regulation and oversight by government agencies, notably the federal Food and Drug Administration](#).

Because of the great urgency with which the world is demanding a coronavirus vaccine, the White House and federal public health officials have tried to eliminate bureaucratic snafus or coordination challenges in the complex clinical trial process to speed up a possible Covid-19 shot. [This has helped 20 prospective vaccine products advance](#) into Phase I, 13 into Phase II, and eight into Phase III. Officials continue to express optimism that a vaccine with good outcomes will emerge in record time to help battle Covid-19.

### **Challenges in the process**

Hiccups in the expedited process already have raised concerns. Moderna, for example, [has taken deserved heat](#) from careful researchers for putting out information about its product via news release, rather than in more precise forms of medical science publishing. The company, now a multi-billion-dollar darling of Wall Street, has defended its disclosures, even as health communications experts have taken popular media outlets to task for their exuberant reporting on the vaccine hunt.

What is known about the leading vaccine candidates, to be fair, is sparse. The first two phases of clinical trials in normal circumstances do not delve deeply into the safety or effectiveness of candidate drugs, medical devices, or medical treatments. And as vaccine researchers hurtle along into the huge third and most decisive phase, reports are growing about the challenges they are encountering.

Federal officials have insisted they will adhere to the highest standards with the vaccine trials, declining to skip steps or take measures that might put patients' health at risk for expediency's sake. As the Washington Post reported:

"The Food and Drug Administration, which has the ultimate say on whether a vaccine has been proved safe and effective, says a vaccine for Covid-19, the disease caused by the coronavirus, will need to prevent disease or decrease symptoms in at least 50% of those who receive it. The effectiveness of the flu vaccine ranges from 40% to 60%, according to the Centers for Disease Control and Prevention."

### **Tens of thousands of test subjects needed**

In the trial stage, however, gathering evidence of a vaccine's safety and effectiveness itself will be a formidable task with logistics nightmares. Investigators typically must spend considerable time ensuring that their trials are conducted correctly — and that they include separate groups that get the test material and others that don't (receiving a placebo, instead). The studies must be blinded, that is, the front-line parties involved in administering a drug or therapy or using a procedure or device can't know which participants are in the placebo group and which not. The selection of who gets what must be randomized.

By the time researchers parse participants according to blinded-standards, they may struggle to get the needed numbers of study subjects — tens of thousands of them. That is the number that will be required for each of several prospective vaccines. Yes, [Uncle Sam is recruiting](#) energetically, and [many Samaritans already have given initial indications](#) online that they will be willing to join in the vaccine hunt. But it gets far more complicated than recruiting, say, eager, youthful, and healthy volunteers.

The successful Covid-19 vaccine will be taken by billions of people, and the [clinical trials must show this treatment is safe and that it works for many different folks](#). Men and women. The young and old. People of different races and ethnicities. African Americans, Latinos, and native peoples have been savaged by the disease, meaning a vaccine will be even more crucial for them. But [researchers have struggled](#) to overcome historic neglect, abuse, and suspicions about doctors, hospitals, and establishment medicine among [black and brown Americans](#). They are not enrolling for vaccine clinical trials in the numbers needed. Pfizer, on the other hand, has said that [more than a third of its research participants \(11,000+ people\)](#) have come from under-represented groups. The company hopes to push their numbers higher.

Older Americans also have suffered disproportionately from the coronavirus, and seniors, similarly to people of color, [may not be suitably represented](#) in the Covid-19 vaccine trials. Vaccine makers haven't, so far, included many [children and pregnant women in their hurried testing](#). Will the public have confidence in the safety and effectiveness of a prospective coronavirus vaccine if the trials are

insufficiently inclusive? Will we give researchers the time needed to run a deep, robust trial?

There is another logistics matter that addresses safety concerns and may test public patience with the vaccine development: global researchers' consensus decision to forgo "challenge" trials. In these tests, participants are deliberately exposed to a disease under study like Covid-19. [Gutsy medical scientists have a history of testing vaccines](#) and other unknown and risky medications and therapies on themselves and their loved ones. But so far, investigators around the world have declined to infect study participants. [This is an ethically fraught way](#) to test the products' effectiveness.

### **Will public patience permit waiting and watching?**

Instead, those in the clinical trial will go about their lives, keeping careful information and getting tested often. Researchers will see if test subjects get Covid-19 or if they do not. With the federal government bungling the pandemic response, there are, alas, many areas of high coronavirus community spread, and clinical trials run in these spots should see ample opportunity for participants to test the vaccine in their routine lives. Still, this all could be a less-than-speedy process. It will take time for subjects to be vaccinated and days or weeks for their bodies to develop vaccine-related protections.

Researchers then must wait for them to be exposed to the coronavirus so they can assess the vaccine. Will they, in the meantime, experience other unwelcome side effects from their shots? Could these become their own obstacle to the vaccine's progress? Will investigators have scoured far and wide enough so the trial participants are not all or mostly young, healthy, and better off so they can, for example, work from home and minimize the contacts they and their loved ones have with broader populations that may have Covid-19?

By the way, people should take major notice of glaring differences in how nations deal with testing of medical therapies. Translation: [Russia and China — autocratic states in which communist parties and dictators rule — have skipped clinical trials](#) of vaccines developed in their countries. They claim without evidence and having subjected the vaccines to the skimpiest of testing, that their coronavirus vaccinations are safe and effective. They have begun giving them to their people, but [Russian experts, for example, are appalled and wary](#). The rest of the world should regard the Russian and Chinese claims and practices with [skepticism and dismay](#), Dr. Anthony Fauci, a leading U.S. infectious disease expert, has said.

**Billions may need this shot. How will they get it? And will they line up to take it?**





Another giant question that must be answered about a Covid-19 vaccine: Does it work?

Besides extracting crucial information on this matter from clinical trials, the question of a Covid-19 vaccine's effectiveness may be colored by multiple concerns. These will include:

### **Matters medical**

As millions of Americans have discovered with prescription drugs, particularly those for difficult diseases like cancer, medical scientists can [develop flawed and even deceptive ways to measure the outcomes of a given treatment](#). This may occur with the Covid-19 vaccine to a degree, blurring what should be the direct issue of whether it works. What happens, for example, if the new vaccines produce antibodies that attack the coronavirus spikes, while still not affecting the progression of viral infection?

The public has gotten a glimpse of the complications of determining crucial coronavirus-related issues with the medical discussions surrounding this vaccine-pertinent issue: Do people with a diagnosed coronavirus infection who go through a bout of the disease (mild or severe) develop protections or even immunity against the disease? As the science and medicine site Stat reported:

“Scientists stress that just because someone has recovered from Covid-19 and produced [antibodies to the coronavirus](#) does not mean they are protected from contracting it a second time. [No one's yet proven that](#). That, then, leaves open the question: What does immunity look like? Experts anticipate an initial coronavirus infection will lend people some level of immunity for some amount of time. But they still don't know what potpourri of antibodies, cells, and other markers in a person's blood will signify that protection. And determining those 'correlates of protection' is crucial both so individuals can know if they are again at risk, and so researchers can understand how well potential vaccines work, how long they last, and how to accelerate their development.”

Investigators have raced on a parallel track to determine the

“correlates of protection” in particular with a traditionally successful disease-fighting approach — the use of [blood plasma taken from individuals who have fought off a disease](#). This component typically is safe and rich in materials, notably proteins or antibodies that battle infections. Clinical trials, however, have not yet shown that blood plasma is an effective coronavirus treatment, and the nation’s top infectious-disease specialists have asked the FDA to hold up on emergency approval for its use. This angered President Trump, who has advocated for this treatment, as he has for other approaches, some with scientific evidence but others lacking it. FDA officials insisted they made their decision independent of White House arm-twisting. But they have given blood plasma therapies an emergency OK, even though they now have backed down from false claims about a high success rate.

Still, even if researchers cannot drill down quickly into the precise ways that therapies combat coronavirus infection, a vaccine may show results and advance into wide use. An [“imperfect” vaccine or even several of them may yet play big roles](#) in slashing Covid-19’s harms, perhaps even by paving the way for even more effective and later preventive measures.

That’s because vaccines can help people achieve “herd immunity,” the shared safeguard that occurs when viruses wither when they can’t spread because a significant portion of a given population has infection protection. [Experts continue to tussle over this major component](#) in the battle against Covid-19, arguing over what percentage of the population must achieve coronavirus resistance before wider populations get the protection of herd immunity and [even what this protection might be like](#). Proponents of a “natural” push for this to occur, including by sort of shrugging as big numbers of people get infected (and many suffer “mild” cases), have not disputed that [Covid-19 deaths will spike, with some estimates saying the U.S. toll could hit almost 3 million](#). A vaccine clearly is a needed part of attacking Covid-19.

As mentioned, though, vaccines have varying levels of effectiveness. As [Johns Hopkins University reported](#):

“The most variability in vaccine effectiveness is with flu or influenza vaccines, where effectiveness varies by year and how well the vaccine that year matches the circulating influenza viruses. During seasons when the flu vaccine matches most circulating flu viruses, flu vaccines reduce the risk of flu illness by 50%-60% in the overall population ... The effectiveness of other vaccines routinely used in the U.S. varies, but for most vaccines, 80%-99% of vaccinated people are protected. Two doses of MMR, or Measles-Mumps-Rubella, vaccine, for example, provides about 99% protection against measles.”

With a prospective Covid-19 vaccine, important infection fighting could occur with a less effective shot, as the Brookings Institution think tank reported:

“Since no vaccine will be perfectly effective – Dr. Fauci has said he

could live with a vaccine that was 75% effective, which could be optimistic – that means that at least 80% of the U.S. population (60% divided by 75%) must be vaccinated if the virus is to be tamped down to the point where enough people will feel safe to patronize service establishments and travel so the country and the economy can return to some semblance of normal.”

A Covid-19 vaccine’s best outcomes will be determined not only by what occurs in labs and clinical trials but by factors beyond.

### **Who gets it first?**

Even in best-case scenarios, it will take time to make the billions of doses needed of a new Covid-19 vaccine. This will force experts and governments to determine [priority lists for recipients](#). [This may not be a pleasant process to observe](#), especially given the shambolic federal response to the pandemic.

Little controversy may attach to the idea that doctors, nurses, and other health workers at high risk and in great demand would top the vaccine recipient list. It may make sense to protect public safety by giving some of the first shots to military personnel, law enforcement, and first responders, notably firefighters and paramedics.

But who should be next in line?

Should public health officials reckon with populations most harmed so far by the coronavirus, vaccinating early and heavily among seniors, African Americans, Latinos, native people, and those with underlying conditions? Will public patience be strained if residents of nursing homes and other long-term care facilities, as well as the homeless and incarcerated, are early vaccine recipients?

Should “essential workers” — the lower-paid folks who have kept groceries, warehouses, and delivery services functioning — get inoculated ahead, say, of affluent, white-collar Americans who can work from home? Will elites — including the wealthy, executives, athletes, and celebrities — push to the front of the vaccine line?

Blue-chip panels may try to avert public queasiness about the priorities for administering the vaccine by hashing out a plan. But [political maneuvering and in-fighting already is occurring](#), and this is not a good sign. It may be even more problematic if another fundamental aspect of the mass vaccination campaign also is not handled: its roll-out or execution.

### **How does the vaccine get rolled out?**

A vaccine is not an inoculation. And [producing the vaccine is not the same as ensuring billions of doses of it become available](#). Quickly. Conveniently. Affordably. Safely. The United States, specifically the federal government, has performed poorly already in this pandemic in taking up a central role to [provide Covid-19 tests in the giant numbers and with the speed needed](#). The country still cannot ensure needed

supplies of [personal protective equipment \(PPE\)](#) to health workers, first responders, and others who desperately need it.

Officials insist that a crucial component of Operation Warp Speed focuses on the bedeviling details of not only securing a coronavirus vaccine but also on carrying out a sweeping vaccination campaign. [Trump Administration officials, as the pandemic rolls on, have not been forthcoming](#) about how the vaccination effort will be carried out. Will it rely on traditional systems, with networks established at the state level and involving pharmacies, hospitals, clinics, and doctors' offices? Or will it differ? [The U.S. military may or may not be involved, and Big Pharma will.](#) Enough, though?

One way the U.S. effort has added a lot of speed to the coronavirus vaccine's development has turned on the [federal government taking on billions of dollars in financial risk](#) by, effectively, paying makers in advance to create millions of doses. These may have to be thrown away if the vaccine fails to pass muster. But if the products survive clinical trials, [the country in theory will not have lost any time waiting for vaccine manufacturing to get going.](#)

Vaccine making has been complicated, however, for at least two of the firms with which the Trump Administration has cut billion-dollar deals: Moderna and [Maryland-based Novavax](#). Neither company has brought a vaccine to market before, and they have [joined other aspirants in negotiating lucrative partnerships](#) with companies that have greater experience and capacity to crank out billions of doses.

Just a reminder: Even when vaccines themselves have been found to be safe and effective in clinical trials, [flaws and errors in their manufacture](#) can become [serious problems](#), causing illnesses and deaths.

Vaccine developers and makers, in turn, must work with myriad other enterprises in building a huge supply chain. [Glass makers have become a national interest](#), as experts scour for who can provide the small, specialized vials used to store vaccines. [Needle and syringe makers and suppliers](#), as well as [companies testing other ways of getting vaccines](#) into the body — also are garnering great attention these days, as are truckers — especially companies with refrigerated vehicles.

The prospective [coronavirus vaccine, experts say, likely will need to be kept in the cold](#), whether in transit or storage. So, logistics experts need to secure major sites to serve as hubs where big quantities of vaccine can be first shipped, then distributed. Refrigerated vaccines have proven to be a challenge to traditional, front-line health workers who inoculate many patients. Older Americans, for example, may have [needed to scour for pharmacies or hospitals for shingles shots](#), the vaccine for which required refrigeration and was in short supply and not available in many doctors' offices.

Federal officials, as the summer winds down, [have begun talking with states](#), asking them to develop their own plans for large-scale

immunizations, relying on their experience, contacts, and existing systems and networks. Uncle Sam is telling state officials to act with urgency in their planning, and they say they will cooperate to the max to benefit the public.

At the same time, public health officials across the country have been [pushing back about the federal claims about a speedy and efficient coronavirus vaccination campaign](#). States have asked without getting answers about federal help with PPE for health workers giving out shots and who will pay for the inoculations and the cost of coordinating, staffing, and running sites where they are given. Who will deal with the costs and administration of a complex vaccination program, including records-keeping and juggling supplies of a vaccine that requires multiple doses and refrigeration?

Given all the demands the pandemic already has put on doctors, nurses, and other health workers, as well as hospitals, clinics, and public health services, how will they handle the added strain — including the questions and potential controversies — of a Covid-19 vaccine?

### **People and politics**

What if researchers develop a safe and effective Covid-19 vaccine but people just won't take it, or enough people won't use it, so it has the desired effect?

Public opinion polls have shown that [a consistent third of Americans surveyed will decline to be vaccinated for Covid-19](#) and that number has risen as the pandemic rages. Suspicion of vaccines, public health officials, and medicine in general all play roles in this resistance, which reflects a deep partisan divide (Democrats more likely to get the shot than Republicans), a rural-urban split (city dwellers more likely, while those outside urban areas not), and a racial chasm (African Americans much more strongly objecting).

Hesitancy and outright resistance to vaccines — much of it unfounded and deeply emotional — was a significant health worry even before the pandemic. The World Health Organization, its other issues notwithstanding, declared with great prescience vaccine hesitancy — the delay in acceptance or refusal of vaccines despite their availability — as [one of its top 10 health threats](#) facing the world in 2019.

[Outbreaks of infectious diseases](#), especially those preventable by vaccines, have only intensified recent struggles between evidence-based medicine and fear-mongering “anti-vaxxers,” including those who have taken to extreme protests, such as dumping blood on California lawmakers deliberating on a bill to [crack down on vaccine exemptions for school kids](#).

The anti-vax movement, alas, has found [new energy and allies](#) with the politicians and public figures exploding science denialism and their embrace of counter-factual, conspiracy thinking. Anecdote and personal experience too often have replaced evidence in policy

making. Public health has been politicized as never before, regrettably at the White House itself. The 2020 pandemic will go in textbooks for experts to ask how face masks became objects of scorn and why serious medical treatments were promoted with so little evidence and great risk (hydroxychloroquine, internal disinfectants, Mr. My Pillow's poisonous oleandrin, and expedited blood plasma therapy.)

It is worth noting that investigators can halt clinical trials before their planned schedule — because the evidence developed in stringent scientific fashion shows either such overpowering negative or positive results, influencing the likely study outcome. It creates a real mess when researchers get, say, mixed or uncertain results and fail to spell this out, especially by flouting regulations and accepted practices by failing to make public their study results.



Here's one more vaccine scenario for the informed to mull: Will the president, lagging in his re-election campaign, launch an October surprise? Will Trump, no matter what the clinical trials find and even before their completion, issue an "emergency" approval for one or more of the coronavirus vaccines and order the federal bureaucracy to start using them immediately?

We'll all see. We'll need to maintain hope, caution, and skepticism as we watch to see what medical scientists can develop to prevent the coronavirus or to treat it much better. Vaccines have been game changers and life savers before, eliminating infections that have plagued civilizations for centuries. Just as with any medical intervention, they come with risks. But these have been far outweighed by their benefits.

The world will benefit in a big way if vaccines can help slash the coronavirus' rack and ruin. We can't see them, unrealistically, as the alpha and omega of stopping the Covid-19 pandemic. Even in the most optimistic of scenarios, it will take time for a vaccine or several of them to get into widespread use and for them to show results. They might not be market-ready until this winter, so we may be stuck with Covid-19 in its severity well into 2021, maybe beyond. We've got a lot of work to do in the meantime to fight the disease as we can now — with distancing, hand hygiene, face covering, and common sense. We need to heed experts with demonstrated bona fides and experience in dealing with infectious disease.

As always, of course, here's hoping that you and yours stay safe and healthy through the pandemic, 2020, and beyond!

**Credits:** Top photo, federal Centers for Disease Control and Prevention; large photo of coronavirus' attacking cells, NIAID's Rocky Mountain Laboratories, and smaller photo showing virus and spikes, CDC; photo below left of Sacramento, Calif., vaccination protests, Pauline Bartolone/Capital Public Radio; and photo, below right, Jonas Salk, National Portrait Gallery, Smithsonian Institution; gift of Estrellita Karsh in memory of Yousuf Karsh, © Estate of Yousuf Karsh.

## As pandemic rages, experts also must battle 'infodemic'



The Covid-19 pandemic in just a few months has accelerated yet another line of expert inquiry. It targets not the treatment of the novel coronavirus but the plague of medical and scientific denialism that has accompanied this disease's spread.

For doctors, scientists, public health and medical policy making professionals, the coronavirus "infodemic" comes at the very time when societal progress and technological advancement would seem to augur against the rise of gossip, myth spreading, outright hokum, and humbug.

As [Sylvie Briand](#), a physician and global health communications expert, has observed:

"We know that every [disease] outbreak will be accompanied by a kind of tsunami of information, but also within this information you always have misinformation, rumors, etc. We know that even in the Middle Ages there was this phenomenon.

"But the difference now with social media is that this phenomenon is amplified, it goes faster and further, like the viruses that travel with people and go faster and further. So, it is a new challenge, and the challenge is the [timing] because you need to be faster if you want to fill the void ... What is at stake during an outbreak is making sure people will do the right thing to control the disease or to mitigate its impact. So, it is not only information to make sure people are informed; it is also making sure people are informed."

Here is what the [New York Times](#) reported leading health care professionals have said must occur as the world prepares for the possibility of a Covid-19 vaccine:



## *Speed hasn't been part of the history of vaccines*

Because they do not typically get major public attention and support, vaccines have not sped to the markets in the way that federal officials now envision with the campaign they have dubbed Operation Warp Speed.

As the [New York Times](#) reported:

"In the history of medicine, rarely has a vaccine been developed in less than five years. Among the fastest to be developed was the current mumps vaccine, which was isolated from the throat washings of a child named Jeryl Lynn in 1963. Over the next months, the virus was systematically 'weakened' in the lab by her father, a biomedical scientist named Maurice Hilleman. Such a weakened or attenuated virus stimulates an immune response but does not cause the disease; the immune response protects against future infections with the actual virus. Human trials were carried out over the next two years, and the vaccine was licensed by Merck in December 1967."

It took far longer to develop a protection against polio, a recent news article reported:

"Research to understand polio was gradual for the first few decades of the 20th century. In 1935, a vaccination was attempted, first on monkeys and then on children in California. Though this vaccine yielded poor results, two more decades of research paved the way for the development of vaccines by Jonas Salk in 1953, and Albert Sabin in 1956. After a trial of more than 1.6 million children, Salk's vaccine was adopted in the US by 1955."

“[A] nationwide task force of 23 epidemiologists and vaccine behavior specialists [recently] released a detailed report — which itself got little attention — saying that [building public confidence in the Covid-19 shot and science and medicine] was urgent. Operation Warp Speed, the \$10 billion public-private partnership that is driving much of the vaccine research, they wrote, ‘rests upon the compelling yet unfounded presupposition that ‘if we build it, they will come.’

“In fact, wrote the group, led by researchers at the Johns Hopkins Center for Health Security and the Texas State University anthropology department: ‘If poorly designed and executed, a Covid-19 vaccination campaign in the U.S. could undermine the increasingly tenuous belief in vaccines and the public health authorities that recommend them — especially among people most at risk of Covid-19 impacts.’ The researchers noted that although billions of federal dollars were pouring into biomedical research for a vaccine, there seemed to be virtually no funding set aside for social scientists to investigate hesitancy around vaccines. Focus groups to help pinpoint the most effective messaging to counter opposition, the authors said, should get under way immediately.”

Researchers at the independent, nonpartisan RAND Corporation think tank have warned for a while now about “truth decay,” what they say is the “diminishing role of facts and data in American public life.” They say this risky situation is characterized by: increasing disagreement about facts and analytical interpretations of facts and data; a blurring of the line between opinion and fact; the increasing relative volume and resulting influence of opinion and personal experience over fact; and the declining trust in formerly respected sources of facts.”

It has been driven by: people’s “cognitive biases; the rise of social media and other changes to the information environment; demands on the educational system that limit its ability to keep up with changes in the information ecosystem; and political and social polarization.”

RAND, WHO, and a consortium of public health organizations called Stronger all have online resources (you can access them by clicking on the group’s hyperlinked names). The expert study

In more recent times, U.S. government scientists in the 1990s started to extend research about two cancer-causing genes to finding a preventive product or vaccine. By 2006, the work had advanced so far that regulators approved the vaccination against human papillomavirus, an infection associated with cervical, anal, and oral cancers. Public health officials, noting the slow uptake of this safeguard, say that widespread adoption of the HPV vaccine in young people (girls and boys) could prevent thousands of cancers and could slash the significant harms of cervical cancer to women.

Even when investigators know a disease is wildly contagious and frighteningly lethal, the efforts to develop a protective vaccine against it can take years and be stymied by bureaucracy, costs, and delays. This is what Scientific American reported about the relatively new vaccine for Ebola, the deadly hemorrhagic fever:

“Work on the vaccine stretches back to the 1990s, when a Yale University researcher, John ‘Jack’ Rose, turned a virus that infects livestock — vesicular stomatitis virus — into a vector that could be used for vaccines. In the 2000s, scientists at Canada’s National Microbiology Laboratory led by Dr. Heinz Feldmann modified the vector to make it a delivery system to show the immune system a critical Ebola protein — creating a safe way to teach the immune system to defend against Ebola virus infection.

“Though the vaccine appeared highly promising in animal testing, it languished for years; the lack of a traditional commercial market for Ebola vaccines meant pharmaceutical companies showed little interest in partnering on its development. That changed with the catastrophic Ebola outbreak in West Africa in 2014, which reignited interest in the vaccine. Clinical trials performed in North America, Africa, and Europe culminated in a Phase 3 trial conducted in Guinea, one of the countries ravaged by the West African outbreak. There the vaccine was proven to be effective.”

With Ebola, wealthier nations did not distinguish themselves with their treatment of the research and expertise in the developing world, nor with their funding for treatments of distant populations. Big Pharma and donors balked at the \$1 billion or so development of a vaccine might have cost. When President Obama poured energy, attention,



from Johns Hopkins and Texas State is online and insightful. This newsletter has discussed how people can be [more savvy consumers of medical-scientific information](#), and I've long recommended the site [healthnewsreview.org](http://healthnewsreview.org). It had gone quiet for a time but is posting anew due to its founder's growing concern about the proliferation of medical and scientific misinformation.

Vaccination opponents, to be clear, should not be dismissed lightly. They have organized and have been [funded by a wealthy few and other, undisclosed donors](#). Prominent politicians, including [President Trump and a scion of the Kennedy clan](#), have supported their cause. They may be [helped by, in unwitting or coordinated fashion, malicious actors and foreign adversaries](#). The [gut specialist who gave impetus to this movement has been thoroughly debunked and professionally disgraced](#).

But, like diseases themselves, infodemics require sustained, powerful treatment. Misinformation cannot be allowed to go viral, [upending the rigor of modern science and medicine](#). Experts say that it may not be enough to rebut fact-free assertions by science deniers or those who are opposed to or hesitant about vaccination. They can't be treated as merely misguided or kooks. With the coronavirus, many people may be on the fence.

This means that those with bona fide expertise — please, just because you have the ubiquitous Excel software does not mean that your regression analyses of coronavirus data demand airing — need to get out front, regularly, and say what they know in plain language. Sadly, [public health officials who have done so have faced personal and professional attacks](#). Individuals with influence in specific communities (religious and civic leaders) need to inform themselves about health, medical, and scientific matters and then help to spread accurate, factual information.

We all, individually, need to research widely and carefully. Not everything on the internet is true. We need to analyze information as if our lives depended on it (they do). We can encourage those we know to be scrupulous about spreading what they learn, especially on social media.

When we encounter views that don't square with our own, it may be [helpful to check our cognitive](#)

[and resources into the battle against Ebola](#), notably to try to contain its spread off U.S. soil, his political opponents ripped him for doing so.

While Presidents Bush and Obama pushed for better funding and preparation for pandemics, the record will not be kind to the current administration. To be fair, [public health support — including research and funding for vaccine development — has been starved](#), in this country and globally. Medical scientists, for example, say they [made big strides toward a potential vaccine for a coronavirus](#) implicated in acute respiratory syndrome or SARS — before the disease died back and funding and public interest vaporized.

Operation Warp Speed is working with a budget of at least \$10 billion, federal officials say. The money has gone flying out the door, with [major accountability questions building by the day](#) on the spending and [the officials leading the coronavirus vaccine development](#).

With the pandemic raging, seemingly unchecked, what's the option?

By the way, public support for a possible vaccine already is getting a significant test, with many Americans already responding. [Interested in volunteering to participate in a clinical trial for a prospective vaccine? A federal government site lays out the specifics](#), which potential test subjects should not only review closely but also may wish to discuss with their doctors and loved ones before signing up.

biases, open our minds, and activate our critical thinking. Turn the volume and intensity down. Exercise patience and know that complex discussions may take time. This is crucial to dealing with misinformation now, experts say, citing growing research that indicates that many, long, steady, civil discussions may need to occur with the vaccine-hesitant to try to modify their counter-factual views.

## Recent Health Care Blog Posts

**Here are some recent posts on our patient safety blog that might interest you:**

- The Covid-19 pandemic continues to slam the practice of medicine, with patients' infection fears and treatment delays [putting at serious financial risk the providers of crucial medical services like primary care doctors and pediatricians](#). At the same time, as is too often the case in U.S. medicine, the rich may be getting richer, as resuming care gives patients eye-opening information on the big money in orthopedic and plastic surgery and other cosmetic procedures.
- Voters keep sending Republicans — in statehouses, Congress, and the White House — a clear message: [Americans want affordable, accessible health insurance](#), most notably as offered under the GOP-loathed Affordable Care Act, and especially for the poor and working poor via Obamacare's expansion of Medicaid. This issue, if anything, may be rising in importance to the U.S. electorate as the Covid-19 pandemic rages without check and millions of Americans wrestle with pervasive joblessness that wiped out many people's health insurance coverage. Just weeks after voters in red Oklahoma backed a state constitutional amendment to expand Medicaid and narrowly defied the opposition of powerful GOP politicians who have dominated their state, residents of the "Show Me" state of Missouri showed up in force to approve Missouri's expansion of the program coverage, by a 53% to 47% margin.
- For those trying to [clean up the costly harms that Big Pharma inflicts on Americans](#), the how-to details not only matter, they can be confounding. For evidence, just ask [federal court officials trying to unravel part of the finances of the opioid and overdose crisis](#), or the Trump Administration's soggy efforts to deal with [skyrocketing prescription drug prices and scary medication shortages](#).
- It isn't just the testing for the novel coronavirus that has already anxious Americans upset these days. Controversies also are swirling around existing and developing ways for experts to [screen older patients for cognitive decline, namely dementia and its most familiar form, Alzheimer's disease](#). The condition, which accounts for 60%-80% of dementia cases, is the sixth leading cause of death in the United States overall and the fifth leading cause of death for those age 65

and older, researchers say. Medical scientists have engaged in furious efforts for a while now to determine the condition's causes and to create treatments for it — a response that is sorely lacking now

- **Veterans Affairs officials are taking yet more fire** over medical services provided at the sprawling agency's facilities: An internal watchdog ripped a Washington, D.C., VA emergency room for abusing and sending away a mentally troubled patient who then killed himself. And House members demanded to know why institutionalized and elderly vets were treated for Covid-19 with an antimalarial drug promoted without evidence by President Trump

HERE'S TO A HEALTHY 2020!

Sincerely,

A handwritten signature in black ink that reads "Patrick Malone". The signature is fluid and cursive, with the first name "Patrick" being larger and more prominent than the last name "Malone".

Patrick Malone

**Patrick Malone & Associates**

*Copyright © 2020 Patrick Malone & Associates P.C., All rights reserved.*