### Answers to Your Questions About the New Covid Vaccines in the U.S.

Vaccines are rolling out to health workers now and will reach the arms of the rest of us by spring. Here's what you need to know.



The Pfizer-BioNTech Covid vaccines are prepared to be shipped at a Pfizer plant on Dec. 13, 2020 in Portage, Michigan.Pool photo by Morry Gash

### Getting the vaccine

### Why can't everyone get the vaccine now?

There aren't enough doses for everyone, so initially the vaccine will be rationed for those who need it most. It will take time to produce and distribute the vaccine, and then schedule two vaccinations per person, three to four weeks apart. As more vaccines get approved, things will speed up. At least 40 million doses (enough for 20 million people) should be available from Pfizer and Moderna by the end of the year, and much more will come in 2021. How many doses will your state get? Look up your state's vaccine distribution plans <u>here</u>. —*Abby Goodnough* 

#### Who will get the vaccine first?

Here's the expected order for vaccinations:

- Health care workers and people in long-term care facilities: The nation's 21 million health care workers and three million mostly elderly people living in long-term care facilities will go first, starting in December. Initially, there won't be enough doses to vaccinate all health care workers, so states will prioritize based on exposure risk, choosing emergency room staff, for instance, to go first. Or they may offer the vaccine to the oldest health care workers first.
- Essential workers: The 87 million Americans who work in food and agriculture, manufacturing, law enforcement, education, transportation, corrections, emergency response

and other sectors, likely will be second in line, starting early next year. States will set priorities. Arkansas, for example, has proposed including workers in its large poultry industry, while Colorado wants to include ski industry workers who live in congregate housing.

- Adults with underlying medical conditions and people over 65. Health officials are hoping to get any remaining older adults who have not been vaccinated sometime in the first quarter. Some states might decide to vaccinate residents over 75 before some types of essential workers.
- All other adults. Adults in the general population are at the back of the line. They could start receiving the vaccine as early as April, said Dr. Anthony S. Fauci, the nation's top infectious disease expert, although many people likely will have to wait until at least May or June. The vaccine hasn't been approved in children, so it may be several months, or possibly a year, before the vaccine is available for anyone under the age of 16. —*Abby Goodnough, Tara Parker-Pope*

### How will the first doses of the vaccine get to health workers?

Hospitals and medical groups are contacting health workers to schedule vaccine appointments. FedEx and UPS will transport the vaccine throughout most of the country, and each delivery will be followed by shipments of extra dry ice a day later. Pfizer designed special containers, with trackers and enough dry ice to keep the doses sufficiently cold for up to 10 days. Every truck carrying the containers will have a device that tracks its location, temperature, light exposure and motion. Pfizer will ship the special coolers, each containing at least 1,000 doses, directly to locations determined by each state's governor. At first, almost all of those sites will probably be hospitals that have confirmed they can store shipments at minus 94 degrees Fahrenheit, as the Pfizer vaccine requires, or use them quickly. —*Abby Goodnough* 

### How will the vaccine get to nursing homes?

The pharmacy chains CVS and Walgreens have <u>contracts with the</u> <u>federal government</u> to send teams of pharmacists and support staff into thousands of long-term care facilities in the coming weeks to vaccinate all willing residents and staff members. CVS and Walgreens are both planning to administer their first vaccinations on Dec. 21.

More than 40,000 facilities have chosen to work with CVS. Nearly 35,000 picked Walgreens. Each U.S. state has already picked, or will soon pick, either the Pfizer or the Moderna vaccine for all of its long-term care facilities that will be working with the pharmacies. —*Rebecca Robbins, Abby Goodnough* 

### How will the rest of us get vaccinated?

It's likely that when the general public starts getting vaccinated in

April, shots will be scheduled through doctor's offices, CVS, Walgreens and other pharmacies — the same way people get flu shots. However, final plans will depend on what other vaccines besides Pfizer's and Moderna's have been approved. —*Abby Goodnough, Rebecca Robbins* 

### Can I choose which vaccine I get?

This depends on a number of factors, including the supply in your area at the time you're vaccinated and whether certain vaccines are found to be more effective in certain populations, such as older adults. At first, the only choice will be Pfizer's vaccine, though Moderna's could become available within weeks. —*Abby Goodnough* 

### How long will it take to work?

You won't get the full protection from the Pfizer-BioNTech vaccine until about a week after the *second* dose, based on clinical trial data. The researchers found that the vaccine's protection started to emerge about ten days after the first dose, but it only reached 52 percent efficacy, according to a report in the New England Journal of Medicine. A week after the second dose, the efficacy rose to 95 percent. <u>Read more here.</u> —*Carl Zimmer, Noah Weiland* 

### Safety and side effects

### Will it hurt? What are the side effects?

The injection into your arm won't feel different than any other vaccine, but the rate of short-lived side effects does appear higher than a flu shot. Tens of thousands of people have already received the vaccines, and none of them have <u>reported any serious</u> health problems. The side effects, which can resemble the symptoms of Covid-19, last about a day and appear more likely after the second dose. Early reports from vaccine trials suggest some people might need to take a day off from work because they feel lousy after receiving the second dose. In the Pfizer study, about half developed fatigue. Other side effects occurred in at least 25 to 33 percent of patients, sometimes more, including headaches, chills and muscle pain.

While these experiences aren't pleasant, they are a good sign that your own immune system is mounting a potent response to the vaccine that will provide long-lasting immunity. —*Abby Goodnough, Carl Zimmer* 

#### How do I know it's safe?

Each company's application to the F.D.A. includes two months of follow-up safety data from Phase 3 of clinical trials conducted by universities and other independent bodies. In that phase, tens of thousands of volunteers got a vaccine and waited to see if they became infected, compared with others who received a placebo. By September, Pfizer's trial had 44,000 participants; no serious safety concerns have been reported. — *Abby Goodnough* 

#### If I have allergies, should I be concerned?

People with severe allergies who have experienced anaphylaxis in the past should talk to their doctors about how to safely get the vaccine and what precautions to take. Although severe reactions to vaccines are rare, two health care workers had anaphylaxis after receiving the vaccine on the first day it became available in Britain. Both workers, who had a history of severe reactions, were treated and have recovered. (Anaphylaxis can be life-threatening, with impaired breathing and drops in blood pressure that usually occur within minutes or even seconds after exposure to a food, medicine or substance like latex.) For now, British authorities have said the vaccine should not be given to anyone who has ever had an anaphylactic reaction, but U.S. health experts have said such warnings are premature because severe reactions can be treated or prevented with medications. Because of the British cases, the F.D.A. said it would require Pfizer to increase its monitoring for anaphylaxis and submit data on it once the vaccine comes into use. Fewer than one in a million recipients of other vaccines a year in the U.S. have an anaphylactic reaction, said Dr. Paul Offit, a vaccine expert at Children's Hospital of Philadelphia.

Among those who participated in the Pfizer trials, a very small number of people had allergic reactions. A <u>document published</u> <u>by the F.D.A.</u> said that 0.63 percent of participants who received the vaccine reported potential allergic reactions, compared to 0.51 percent of people who received a placebo. In Pfizer's late-stage clinical trial, one of the 18,801 participants who received the vaccine had an anaphylactic reaction, according to <u>safety data</u> <u>published by the F.D.A. on Tuesday</u>. None in the placebo group did. <u>Read more here.</u> — *Denise Grady* 

## What will happen if serious side effects crop up after the vaccine is rolled out?

Once a vaccine starts to reach large numbers of people, it's possible (and not uncommon) for a small number of severe "adverse events" to occur. Many existing vaccines, including the <u>flu shot</u>, also can cause rare complications, including <u>Guillain</u>-Barré syndrome, seizures and sudden unexplained death. While this sounds frightening, the risk is minuscule when considered over the millions of people who are safely vaccinated each year, and <u>some of these complications</u> can be triggered by the virus itself. Health officials will investigate each event to see if it's simply coincidence — or if it could have been caused by the vaccine. While everyone should be prepared to hear about these reports, they should not be a cause for worry or prompt you to delay getting the vaccine. Your risk of severe complications from Covid-19 is far higher than your risk of complications from the vaccine. <u>Read more here.</u> —Donald G. McNeil Jr.

# What about my situation? Answers about different types of patients.

#### I had Covid-19 already. Do I need the vaccine?

It's safe, and probably even beneficial, for anyone who has had Covid to get the vaccine at some point, experts said. Although people who have contracted the virus do have immunity, it is too soon to know how long it lasts. So for now, it makes sense for them to get the shot. The question is when. Some members of the C.D.C. advisory committee have suggested people who have had Covid in the past 90 days should be toward the back of the line.<u>Read more here.</u>—Abby Goodnough, Apoorva Mandavilli

### Will it work on older people?

All the evidence we have so far suggests that the answer is yes. The clinical trials for the two leading vaccines have shown that they work about the same in older people as younger people. As the vaccines get distributed, the vaccine makers and the C.D.C. will continue to monitor the effectiveness of the vaccine in people 65 and older who, because of <u>age-related changes in their immune systems</u>, often don't respond as well to vaccination as younger people do. But just as certain flu vaccines have been developed to evoke a stronger immune response in older people, it's possible that one of the new vaccines could emerge as a better option for this age group. It's just far too soon to know. —*Carl Zimmer* 

### I'm young and at low risk. Why not take my chances with Covid-19 rather than get a vaccine?

Covid-19 is by far the more dangerous option. Although people who are older, obese or have other health problems are at highest risk for complications from Covid-19, younger people can become severely ill, too. In a <u>study of more than 3,000</u> people ages 18 to 34 who were hospitalized for Covid, 20 percent required intensive care and 3 percent died.

*Coronavirus Briefing:* An informed guide to the global outbreak, with the latest developments and expert advice.

And as many as one in three people who recover from Covid have chronic complaints, including exhaustion, a racing heart and worse <u>for months afterward</u>. Covid vaccines, in contrast, carry little known risk. <u>Read more here.</u> —*Apoorva Mandavilli* 

### Vaccinating pregnant women and children

### What about women who are pregnant or breastfeeding?

Pregnant and breastfeeding women should consult with their obstetricians and pediatricians about whether to get the vaccine. The Pfizer vaccine has not been tested in pregnant women or in those who were breastfeeding, and federal health officials have not issued any specific guidance, other than allowing these women to be vaccinated if they choose. (The American College of Obstetricians and Gynecologists <u>issued practice guidelines</u> to help women and their doctors talk about vaccination.) In the initial rollout, it will be mostly pregnant health care workers who must weigh the benefits and possible risks. By the time the vaccine is available to pregnant essential workers or to women in the general population, there should be a lot more data available.

Some experts said the virus itself poses greater risks to pregnant women than the new vaccine. Since the 1960s, pregnant women have been urged to receive vaccines against influenza and other diseases. These women are generally cautioned against live vaccines, which contain weakened pathogens — but the Pfizer vaccine does not contain live virus. <u>Read more here.</u> —*Apoorva Mandavilli* 

## Does the vaccine affect fertility or miscarriage risk?

A false claim has been circulating online that the new vaccine will threaten women's fertility by harming the placenta. Here's why it's not true.

The claim stems from the fact that the vaccines from Pfizer and Moderna cause our immune systems to make antibodies to something called a "spike" protein on the coronavirus. The false warnings about fertility are based on the claim that these antibodies could also attack a similar protein that is made in the placenta during pregnancy, called syncytin. In reality, the spike protein and syncytin are similar only in one very small region, and there's no reason to believe antibodies that can grab onto spike proteins would lock onto syncytin.

What's more, the human body generates its own supply of spike antibodies when it fights off the coronavirus, and there's no sign that these antibodies attack the placenta. If they did, you'd expect that women who got Covid-19 would suffer miscarriages. But a number of studies show that Covid-19 does not trigger miscarriages. <u>Read more here</u>. —*Carl Zimmer* 

#### When will vaccines be available for children?

So far, no coronavirus vaccine has been approved for children. New vaccines are typically tested on adults before researchers launch trials on children, and coronavirus vaccine developers are following this protocol. In September, Pfizer and BioNTech began studying their vaccine on children as young as 12. Moderna followed suit in December. If these trials yield good results, the companies will recruit younger children. The FDA will then have to review these results before the vaccines can get emergency authorization. <u>Read more here</u>.—*Carl Zimmer* 

### Why weren't children included in the early studies?

Vaccines are typically tested on adults first in the interest of safety. But once a vaccine is shown to be safe and effective in adults, researchers have to run more trials on children to adjust the dosage for their bodies. Another factor in the wait for a vaccine for children is that they are far less likely to die from Covid-19 than adults are. The Centers for Disease Control and Prevention issued <u>a report</u> in September which concluded that, of more than 190,000 people who died in the United States with Covid-19, only 121 were under the age of 21. —*Carl Zimmer and Katie Thomas* 

### Life after vaccination

### What if I forget to take the second dose on time?

Both the vaccines from Pfizer-BioNTech and from Moderna have two doses, with the booster shot coming a few weeks after the first. Pfizer-BioNTech's second dose comes three weeks after the first, and Moderna's comes four weeks later. The second dose provides a potent boost that gives people strong, long-lasting immunity.

If for some reason you fail to get the second shot precisely three weeks after the first, you don't have to start all over again with another two-dose regimen. "The second dose can be picked up at any time after the first. No need to start the series over," said Dr. Paul Offit, a professor at the University of Pennsylvania and a member of the F.D.A.'s vaccine advisory panel.

And while the two leading vaccines include a second dose, some future vaccine candidates may only require one dose. Johnson & Johnson, for example, is expecting data in January that will show whether its experimental vaccine works after a single dose. In case it doesn't, the company has also started a separate trial using two doses. —*Carl Zimmer, Tara Parker-Pope* 

### If I've been vaccinated, will I still need to wear a mask?

Yes, but not forever. Here's why. The coronavirus vaccines are injected deep into the muscles and stimulate the immune system to produce antibodies. This appears to be enough protection to keep the vaccinated person from getting ill. But what's not clear is whether it's possible for the virus to bloom in the nose — and be sneezed or breathed out to infect others — even as antibodies elsewhere in the body have mobilized to prevent the vaccinated person from getting sick.

The vaccine clinical trials were designed to determine whether vaccinated people are protected from illness — not to find out whether they could still spread the coronavirus. Based on studies of flu vaccine and even patients infected with Covid-19, researchers have reason to be hopeful that vaccinated people won't spread the virus, but more research is needed. In the meantime, everyone — <u>even vaccinated people</u> — will need to think of themselves as possible silent spreaders and keep wearing a mask. <u>Read more here.</u> —*Apoorva Mandavilli* 

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#### Answers to Your Vaccine Questions

With distribution of a coronavirus vaccine beginning in the U.S., <u>here are answers to some questions you may be wondering about</u>:

If I live in the U.S., when can I get the vaccine? While the exact order of vaccine recipients may vary by state, most will likely put medical workers and residents of long-term care facilities first. If you want to understand how this decision is getting made, <u>this article will help</u>.

When can I return to normal life after being vaccinated? Life will return to normal only when society as a whole gains enough protection against the coronavirus. Once countries authorize a vaccine, they'll only be able to vaccinate a few percent of their citizens at most in the first couple months. The unvaccinated majority will still remain vulnerable to getting infected. A growing number of coronavirus vaccines are showing robust protection against becoming sick. But it's also possible for people to spread the virus without even knowing they're infected because they experience only mild symptoms or none at all. Scientists don't yet know if the vaccines also block the transmission of the coronavirus. So for the time being, even vaccinated people will need to wear masks, avoid indoor crowds, and so on. Once enough people get vaccinated, it will become very difficult for the coronavirus to find vulnerable people to infect. Depending on how quickly we as a society achieve that goal, life might start approaching something like normal by the fall 2021.

If I've been vaccinated, do I still need to wear a mask? Yes, but not forever. The two vaccines that will potentially get authorized this month clearly protect people from getting sick with Covid-19. But the clinical trials that delivered these results were not designed to determine whether vaccinated people could still spread the coronavirus without developing symptoms. That remains a possibility. We know that people who are naturally infected by the coronavirus can spread it while they're not experiencing any cough or other symptoms. Researchers will be intensely studying this question as the vaccines roll out. In the meantime, <u>even vaccinated people</u> will need to think of themselves as possible spreaders.

Will it hurt? What are the side effects? The Pfizer and BioNTech vaccine is delivered as a shot in the arm, like other typical vaccines. The injection won't be any different from ones you've gotten before. Tens of thousands of people have already received the vaccines, and none of them have reported any serious health problems. But some of them have felt short-lived discomfort, including aches and flu-like symptoms that typically last a day. It's possible that people may need to plan to take a day off work or school after the second shot. While these experiences aren't pleasant, they are a good sign: they are the result of your own immune system encountering the vaccine and mounting a potent response that will provide long-lasting immunity.

Will mRNA vaccines change my genes? No. The vaccines from Moderna and Pfizer <u>use a genetic molecule to prime the immune</u> <u>system.</u> That molecule, known as mRNA, is eventually destroyed by the body. The mRNA is packaged in an oily bubble that can fuse to a cell, allowing the molecule to slip in. The cell uses the mRNA to make proteins from the coronavirus, which can stimulate the immune system. At any moment, each of our cells may contain hundreds of thousands of mRNA molecules, which they produce in order to make proteins of their own. Once those proteins are made, our cells then shred the mRNA with special enzymes. The mRNA molecules our cells make can only survive a matter of minutes. The mRNA in vaccines is engineered to withstand the cell's enzymes a bit longer, so that the cells can make extra virus proteins and prompt a stronger immune response. But the mRNA can only last for a few days at most before they are destroyed.

#### Will my employer require vaccinations?

Employers do <u>have the right</u> to compel their workers to be vaccinated once a vaccine is formally approved. Many hospital systems, for example, require annual flu shots. But employees can seek exemptions based on medical reasons or religious beliefs. In such cases, employers are supposed to provide a "reasonable accommodation" — with a coronavirus vaccine, for example, a worker might be allowed to work if they wear a mask, or to work from home. —*Abby Goodnough* 

### How will we know when things are getting better?

The test positivity rate in your community will be an indicator of how things are going. This number is the percentage of overall tests given in a community that come back positive. The lower the number, the fewer new cases and the less likely you are to cross paths with someone who has the virus. "The best number is zero," Dr. Fauci said. "It's never going to be zero, but anywhere close to that is great." —*Tara Parker-Pope* 

### When can we start safely doing normal things, like going to the movies or the theater?

Public health officials estimate that 70 to 75 percent of the population needs to be vaccinated before people can start moving freely in society again. If things go well, life could get a lot better by late spring and early summer. "It depends on the uptake of the vaccine and the level of infection in the community," Dr. Fauci said.

Given the surveys so far showing significant public reluctance to get vaccinated, however, it may take awhile to see widespread community protection, he said: "If it turns out that only 50 percent get vaccinated, then it's going to take much, much longer to get back to the kind of normality that we'd like to see." —*Tara Parker-Pope* 

### Will these vaccines put a dent in the epidemic?

The coronavirus vaccines will be much less effective at preventing

death and illness in 2021 if they are introduced into a population where the virus is raging — as is now the case in the U.S. A vaccine that's 95 percent effective, as Moderna's and Pfizer's versions <u>appear to be</u>, is a powerful fire hose. But the size of a fire is still a bigger determinant of how much destruction occurs.

According to the authors of a <u>paper in the journal Health Affairs</u>, at the current level of infection in the U.S. (about 200,000 confirmed new infections per day), a vaccine that is 95 percent effective — distributed at the expected pace — would still not be enough to end the terrible toll of the virus in the six months after it was introduced. Almost 10 million or so Americans would contract the virus, and more than 160,000 would die.

Measures that reduce the virus's spread — like <u>mask-wearing</u>, <u>social distancing</u> and <u>rapid-result testing</u> — can still have profound effects. Public health officials hope that people will continue to take these precautions at least until the country reaches a vaccination rate of 70 to 75 percent. —*David Leonhardt* 

### Will I be required to provide proof of vaccination to travel?

In the coming weeks, major airlines including United, JetBlue and Lufthansa plan to introduce a health passport app, called CommonPass, that aims to verify passengers' coronavirus test results — and perhaps soon, vaccinations. CommonPass notifies users of local travel rules — like having to provide proof of a negative virus test — and then aims to check that they have met them.

Although no plans are in place yet to require proof of vaccination for travel or other activities, electronic vaccination credentials could have a profound effect on efforts to control the virus and restore the economy. They could prompt more employers and college campuses to reopen. And developers say they may also give some consumers peace of mind by creating an easy way for movie theaters, cruise ships and sports arenas to admit only those with documented virus vaccinations. <u>Read the full story.</u>— *Natasha Singer* 

## How long will the vaccine last? Will I need another one next year?

That is to be determined. It's possible that coronavirus vaccinations will become an annual event, just like the flu shot. Or it may be that the benefits of the vaccine last longer than a year. We have to wait to see how durable the protection from the vaccines is. Immunity from coronavirus infections <u>appears to last</u> for months, at least, so that may be a hint about vaccines. —*Carl Zimmer* 

### How the different vaccines work

How do these new genetic vaccines work?

The Pfizer-BioNTech and Moderna vaccines <u>use a genetic</u> <u>molecule to prime the immune system.</u> That molecule, known as mRNA, is packaged in an oily bubble that can fuse to a cell, allowing the molecule to slip in. The cell uses the mRNA to make proteins from the coronavirus, which can stimulate the immune system. While the immune protection from these vaccines may last for months or perhaps even years, their mRNA does not — it is destroyed by our cells within days. Although these are described as "genetic" vaccines, the vaccines don't alter your genes in any way. —*Carl Zimmer* 

## What do the vaccine developers mean when they say their vaccines are 95 percent effective?

Vaccine developers test their vaccines in clinical trials. The fundamental logic behind these trials was worked out by statisticians <u>over a century ago</u>. Researchers vaccinate some people and give a placebo to others. They then wait for participants to get sick and look at how many of the illnesses came from each group.

In the case of Pfizer, for example, the company recruited 43,661 volunteers and waited for 170 people to come down with symptoms of Covid-19 and then get a positive test. Among those who got sick, 162 had received a placebo shot, and just eight had received the real vaccine. This result shows that receiving a vaccine dramatically lowered the chances of getting Covid-19 compared to receiving a placebo.

The difference is expressed as efficacy: the Pfizer-BioNTech vaccine has an efficacy rate of 95 percent. (If there were no difference between the vaccine and placebo groups, the efficacy would be zero. If none of the sick people had been vaccinated, the efficacy rate would have been 100 percent.) A vaccine's efficacy rate and effectiveness rate are different: Efficacy is a measurement made within the strict confines of a clinical trial, whereas effectiveness refers to how a vaccine works in the real world. No one knows yet the true effectiveness of these new vaccines. —*Carl Zimmer* 

## Was the Pfizer vaccine part of the government's Operation Warp Speed?

Pfizer did not accept federal funding to help develop or manufacture the vaccine, unlike front-runners Moderna and AstraZeneca. Pfizer did get a \$1.95 billion deal with the government to deliver 100 million doses of the vaccine. The arrangement is an advance-purchase agreement, meaning that the company won't get paid until they deliver the vaccines. <u>Read</u> <u>more here</u>. —*Carl Zimmer and Katie Thomas* 

## What does the rollout of the Pfizer vaccine mean for the other vaccines in the race?

Researchers were heartened by the strong results of the vaccine

developed by Pfizer and BioNTech. "It gives us more hope that other vaccines are going to be effective too," said Akiko Iwasaki of Yale University.

The Moderna vaccine, which is next in line for approval, has an efficacy rate of 94.5 percent, essentially the same as the Pfizer-BioNTech vaccine. A <u>vaccine from AstraZeneca and the</u> <u>University of Oxford</u> has shown confusing trial results, with efficacy rates between 60 and 90 percent, depending on the strength of the doses that volunteers received. And the French company Sanofi had a major disappointment in its early clinical trials, finding that its vaccine couldn't provoke an immune response in people over 55. The company is now reformulating its vaccine to start new trials. —*Carl Zimmer and Katie Thomas* 

#### Reporting contributed by:

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#### Words to Know About Vaccines

Confused by the all technical terms used to describe how vaccines work and are investigated? Let us help:

- Adverse event: A health problem that crops up in volunteers in a clinical trial of a vaccine or a drug. An adverse event isn't always caused by the treatment tested in the trial.
- Antibody: A protein produced by the immune system that can attach to a pathogen such as the coronavirus and stop it from infecting cells.
- Approval, licensure and emergency use authorization: Drugs, vaccines and medical devices cannot be sold in the United States without gaining approval from the Food and Drug Administration, also known as licensure. After a company submits the results of clinical trials to the F.D.A. for consideration, the agency decides whether the product is safe and effective, a process that generally takes many months. If the country is facing an emergency — like a pandemic — a company may apply instead for an emergency use authorization, which can be granted considerably faster.
- **Background rate:** How often a health problem, known as an adverse event, arises in the general population. To determine if a vaccine or a drug is safe, researchers compare the rate of adverse events in a trial to the background rate.
- Efficacy: The benefit that a vaccine provides compared to a placebo, as measured in a clinical trial. To test a coronavirus vaccine, for instance, researchers compare how many people in the vaccinated and placebo groups get Covid-19. Effectiveness, by contrast, is the benefit that a vaccine or a drug provides out in the real world. A vaccine's effectiveness

may turn out to be lower or higher than its efficacy.

- Phase 1, 2, and 3 trials: Clinical trials typically take place in three stages. Phase 1 trials usually involve a few dozen people and are designed to observe whether a vaccine or drug is safe. Phase 2 trials, involving hundreds of people, allow researchers to try out different doses and gather more measurements about the vaccine's effects on the immune system. Phase 3 trials, involving thousands or tens of thousands of volunteers, determine the safety and efficacy of the vaccine or drug by waiting to see how many people are protected from the disease it's designed to fight.
- Placebo: A substance that has no therapeutic effect, often used in a clinical trial. To see if a vaccine can prevent Covid-19, for example, researchers may inject the vaccine into half of their volunteers, while the other half get a placebo of salt water. They can then compare how many people in each group get infected.
- Post-market surveillance: The monitoring that takes place after a vaccine or drug has been approved and is regularly prescribed by doctors. This surveillance typically confirms that the treatment is safe. On rare occasions, it detects side effects in certain groups of people that were missed during clinical trials.
- **Preclinical research:** Studies that take place before the start of a clinical trial, typically involving experiments where a treatment is tested on cells or in animals.
- Viral vector vaccines: A type of vaccine that uses a harmless

virus to chauffeur immune-system-stimulating ingredients into the human body. Viral vectors are used in several experimental Covid-19 vaccines, including those developed by <u>AstraZeneca</u> and <u>Johnson & Johnson</u>. Both of these companies are using a common cold virus called an adenovirus as their vector. The adenovirus carries coronavirus genes.

• **Trial protocol:** A series of procedures to be carried out during a clinical trial.

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