MINISTRY OF HEALTH

AMREF Flying Doctors

EAST AFRICA CENTRE FOR VACCINES AND IMMUNIZATION

COVID VACCINES:

Facts Myths and Misconceptions

AMREF flying doctors Webinar

Dr. Ombeva Malande

Vaccinologist/Senior Consultant (Paed infectious diseases)
Lecturer – Makerere/Egerton University
Research Associate, SMU University, SA
Director – East Africa Centre for Vaccines and Immunization(ECAVI)

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Disclosure

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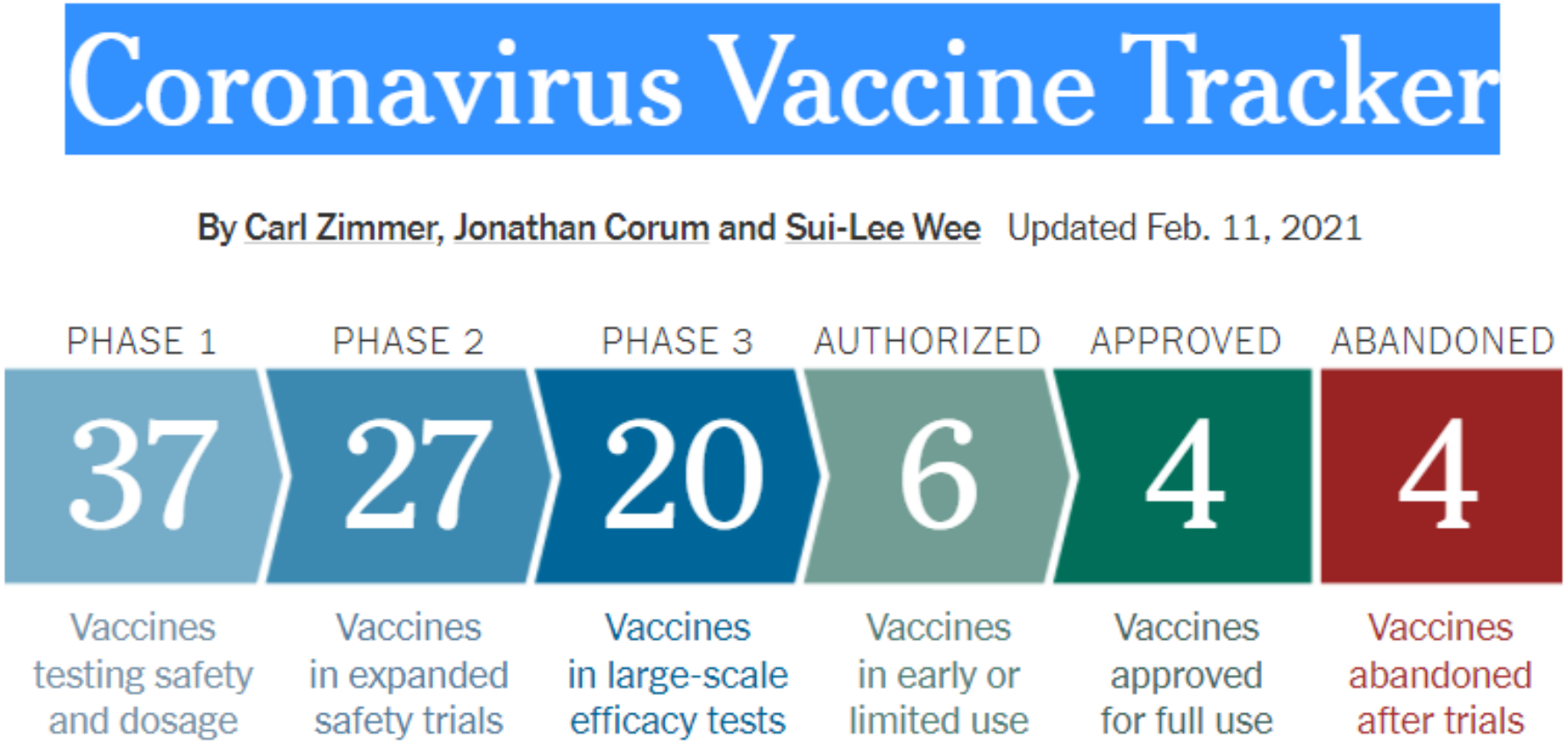
- **NONE**
- **No conflict of interest**

Currently 64 vaccines are in clinical trials P/1&2, on humans, 20 are in final stages. At least 89 preclinical vaccines are under active investigation in animals.



Myth:

COVID-19 Vaccines manufacture was predetermined and accelerated thus skipping several stages of usual prolonged vaccine manufacture process

Verdict: False

- Researchers rushed the development of the COVID-19 vaccine, so its effectiveness and safety cannot be trusted.
- The mRNA technology has been in development for almost two decades.
- Studies found vaccines to be about 95% effective with no serious or life-threatening side effects.
- Vaccine makers created the technology to help them respond quickly to a new pandemic illness, such as COVID-19.

Further explanation:

- mRNA technology has been in development for years, so the manufacturers could start the vaccine development process early in the pandemic.
- China isolated and shared genetic information about COVID-19 promptly, so scientists could start working on vaccines.
- The vaccine developers didn’t skip any testing steps, but conducted some of the steps on an overlapping schedule to gather data faster.
- Vaccine projects had plenty of resources, as governments invested in research and/or paid for vaccines in advance.
- The mRNA technology allows a faster approach than traditional methods.
- Social media helped companies find and engage study volunteers, and many were willing to help with COVID-19 vaccine research.
- Because COVID-19 is so contagious and widespread, it did not take long to see if the vaccine worked for the study volunteers who were vaccinated.

The vaccine development Process

PRECLINICAL PHASE:

- Test a new vaccine on cells and then give it to animals such as mice or monkeys to see if it produces an immune response. We have confirmed 89 COVID preclinical vaccines in active development.

PHASE 1 SAFETY TRIALS:

- Give the vaccine to a small number of people to test safety and dosage as well as to confirm it stimulates the immune system.

PHASE 2 EXPANDED TRIALS:

- Give the vaccine to hundreds of people split into groups, such as children and the elderly, to see if the vaccine acts differently in them. These trials further test the vaccine's safety and ability to stimulate the immune system.

The vaccine development Process

PHASE 3 EFFICACY TRIALS:

- Scientists give the vaccine to **thousands of people** and wait to see how many become infected, compared with volunteers who received a placebo.
- In June, the F.D.A. asked for evidence that vaccines can ***protect at least 50 percent of those who receive it.***
- In addition, Phase 3 trials are large enough to reveal evidence of relatively rare side effects that might be missed in earlier studies.

EARLY OR LIMITED APPROVAL:

- China and Russia have approved vaccines without waiting for the results of Phase 3 trials. *The rushed process has* ***serious risks.***

FDA strict guidelines to coronavirus vaccine makers seeking early approval

- Proof an experimental vaccine is at least 50% effective
- Vaccine makers to follow volunteers for a median of two months after the final dose- two shots spaced three to four weeks apart.
- Document at least five cases of severe COVID-19 observed in the participants who have received a placebo, - in order to determine the risk of respiratory disease induced by vaccination — a key safety worry for both developers and regulators.

Myth:
Vaccines will cause infertility

Verdict: False

- The vaccines we give cannot cause infertility.
- This rumor has been made about many different vaccines.
- There's no vaccine that causes infertility. The COVID-19 vaccine encourages the body to create copies of the spike protein found on the coronavirus's surface. This "teaches" the body's immune system to fight the virus that has that specific spike protein on it.

Further explanation

- Confusion arose when a false report surfaced on social media, saying that the spike protein on this coronavirus was the same as another spike protein called syncitin-1 that is involved in the growth and attachment of the placenta during pregnancy.

- The false report said that getting the COVID-19 vaccine would cause a woman's body to fight this different spike protein and affect her fertility.

- The two spike proteins are completely different and distinct, and getting the COVID-19 vaccine will not affect the fertility of women who are seeking to become pregnant, including through in vitro fertilization methods.

- During the Pfizer vaccine tests, 23 women volunteers involved in the study became pregnant, and the only one who suffered a pregnancy loss had not received the actual vaccine, but a placebo.

Misconception:

The COVID vaccine affects and can change a persons DNA.

Verdict : False

- There are 2 mRNA vaccines - there's no way that mRNA can turn into DNA or change the DNA of our human cells.
- The mRNA of COVID-19 vaccines does enter cells, but not the nucleus of the cells where DNA resides.
- mRNA is the instructions to the body to make a protein. Most vaccines are developed by actually giving a protein or giving a small, tiny component of the virus that we're trying to vaccinate against.
- The mRNA does its job to cause the cell to make protein to stimulate the immune system, and then it quickly breaks down — without affecting your DNA.

Myth: The COVID vaccine contains chemicals that harm the person who gets the vaccine.

Verdict : False

- All the components that go into vaccines are tested for safety, correct dosage and effectiveness - The first 2 FDA authorized vaccines contain mRNA & other normal vaccine ingredients, such as fats (which protect the mRNA), salts, as well as a small amount of sugar. These COVID-19 vaccines were not developed using fetal tissue, and they do not contain any material, such as implants, microchips or tracking devices.
- Every single vaccine goes through a safety evaluation – there is a constant oversight of quality so that every single ingredient that goes into the vaccine is assured to be of the highest quality and safe for use in humans.
- Monitoring goes on even after vaccine has been licensed for use.

Adenovirus vaccine

- Wild Adenoviruses, genetically engineered to express viral antigens found in SARS-CoV-2, usually those of spike protein that coronavirus uses to break into human cells.

- When put into a vaccine, adenoviruses trigger an immune response in the human body, protecting against CoV.
  - The Chinese company CanSino Biologics has an adenovirus vector vaccine called Ad5-nCoV;
  - Johnson & Johnson, via its subsidiary Janssen, uses a genetically modified human adenovirus technology it calls AdVac;
  - Oxford University has partnered with the global pharmaceutical company AstraZeneca for vaccine now being renamed AZD1222.

RNA vaccine

- Involves injecting mRNA into cells - they produce the required viral proteins directly inside the human body.
  - **“A big advantage of mRNA vaccines is that scientists can skip the lab production of proteins by directly injecting the molecular instructions to make the protein into the human body itself.”**
- In this case the RNA sequence is taken from the SARS-CoV-2 virus genome, stimulating an immune response that should later stop the CoV virus.
- Types include Moderna, Pfizer/BioNTech and CureVac from Germany and Belgium.
  - **One advantage to mRNA vaccines is a cheaper, faster production process, making them potentially the most scalable to tackle a global pandemic.**

Inactivated pathogen

- The most traditional approach — the inactivated virus stimulates the immune system to produce antibodies, using killed or weakened virus.
- The Chinese company Sinovac,designed a vaccine by isolating SARS-CoV-2 samples from infected hospital patients and growing the virus in cell lines before inactivating it with a chemical agent. It is called PiCoVacc (for “purified inactivated SARS-CoV-2 vaccine”).
- An international team has a different approach, using a vaccine that is already widely deployed: the BCG vaccine. Trials are currently underway among 10,000 frontline health workers in Australia, run by Murdoch Children’s Research Institute, and in the Netherlands among a further 1,500 health workers.

ANY DRAWBACKS?

- **Growing large volumes of viruses to use in vaccines is a long and arduous process, so the traditional approach will be the slowest to scale up globally.**

DNA vaccine

- Technique does involve injecting a fragment of circular DNA, called a plasmid, into human cells.
- This introduced DNA codes for SARS-CoV-2 viral proteins that are then expressed by the cell and help prime the immune system to fight off an attack by COVID-19.
- Like mRNA, this is a new technology — no DNA vaccines have ever been fully developed and utilized in humans to prevent disease.
- The leading developer is Inovio, which worked with a DNA candidate vaccine against MERS.
- Several other teams are also working on DNA vaccine candidates for the novel coronavirus, including one at the Harvard Medical School.

Viral proteins

- Genes that code for proteins from the pathogen — in COVID's case, mostly the notorious spike protein — are spliced into different viruses, which are then mass-produced.
  - Sanofi Pasteur tried repurposing its earlier SARS vaccine efforts into COVID. Its recombinant DNA approach in cell lines has already been licensed to produce an influenza vaccine,
  - A team at the University of Pittsburgh, whose members had already worked on SARS and MERS and quickly repurposed their spike protein vaccine to target SARS-CoV-2
  - Novavax has developed a way to package SARS-CoV-2's spike proteins into nanoparticles that should enhance immune response by better mimicking the virus.
  - In Canada, Medicago has been producing virus-like particles of the coronavirus — expressed in leaves of Nicotiana benthamiana, a wild relative of tobacco

Misconception

MYTH: If I've already had COVID-19, I don't need a vaccine.

Verdict : False

- The Center for Disease Control (CDC) recommends that those who have had COVID-19 get the vaccine.
- There is not enough information currently available to say if or for how long people are protected from getting COVID-19 after they have had it (natural immunity).
  - Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this.
  - Several subjects in the Pfizer trial who were previously infected got vaccinated without ill effects. Some scientists believe the vaccine offers better protection for coronavirus than natural infection.
  - Due to the severe health risks associated with COVID-19 and the fact that re-infection with COVID-19 is possible, people may be advised to get a COVID-19 vaccine even if they have been sick with COVID-19 before.

Myth:

- Getting the COVID-19 vaccine means I can stop wearing my mask and taking coronavirus precautions.

Verdict: False

- Individuals who get the COVID-19 vaccination still need to practice infection prevention precautions.
  - Keep your mask on, and continue staying at least 6 feet from people outside your household, until further notice.
  - Vaccines do not stop the coronavirus from entering your body; **they only prevent you from developing moderate to severe COVID-19.**
  - It's not yet clear if people vaccinated for COVID-19 can still carry and transmit the virus, even when they themselves don't get sick.

Myth:

- Getting the COVID-19 vaccine gives you COVID-19.

Verdict: False

- The vaccine for COVID-19 cannot and will not give you COVID-19.
- The mRNA vaccines instruct your cells to reproduce a protein that is part of the SARS-CoV-2 coronavirus, which helps your body recognize and fight the virus, if it comes along.
- The COVID-19 vaccine does not contain the SARS-Co-2 virus, so you cannot get COVID-19 from the vaccine.
- The protein that helps your immune system recognize and fight the virus does not cause infection of any sort.

How some of the Covid-19 vaccines compare

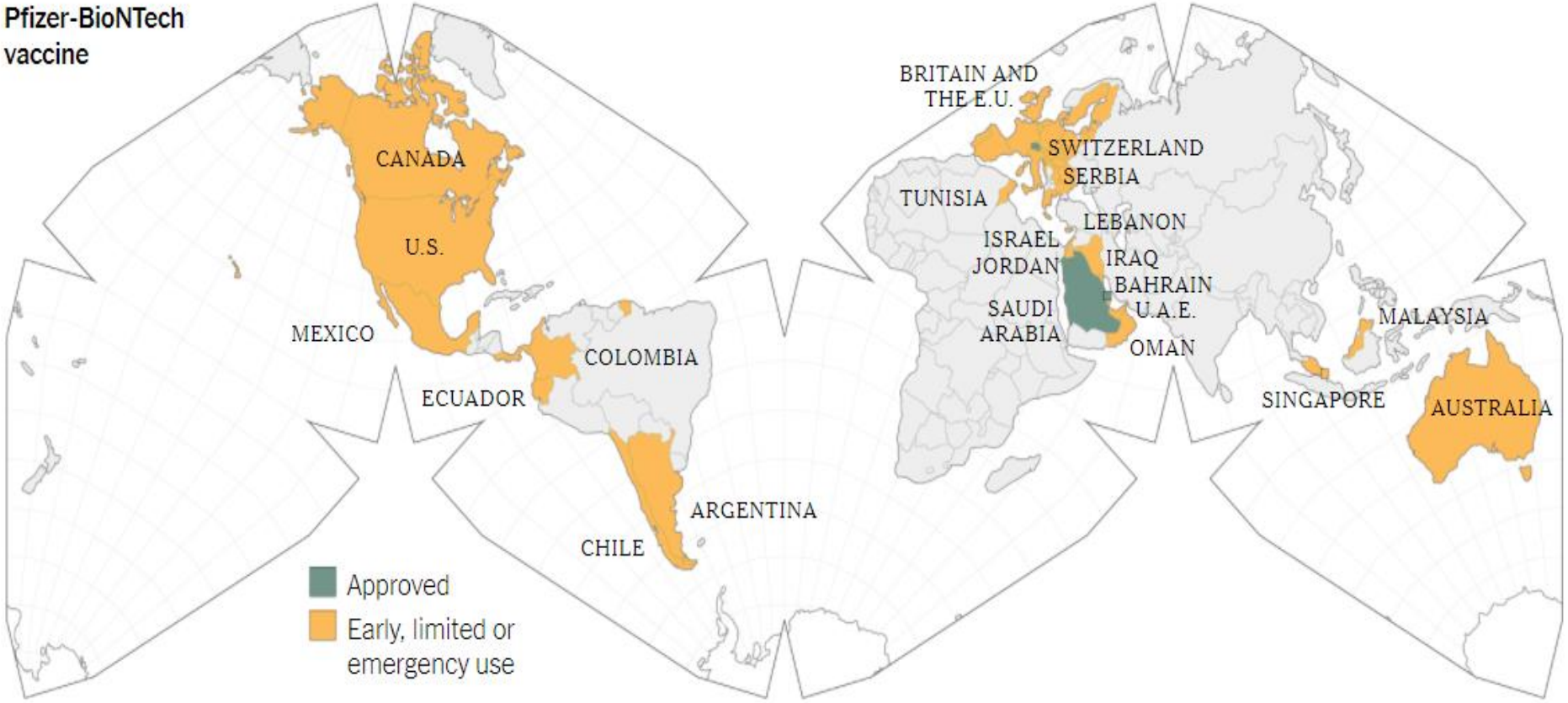
Company	Type	Doses	How effective*	Storage
Oxford Uni-AstraZeneca	Viral vector (genetically modified virus)	x2	62-90%	Regular fridge temperature
Moderna	RNA (part of virus genetic code)	x2	95%	-20C up to 6 months
Pfizer-BioNTech	RNA	x2	95%	-70C
Gamaleya (Sputnik V)	Viral vector	x2	92%	Regular fridge temperature

*preliminary phase three results, not yet peer-reviewed

Source: Respective companies, WHO

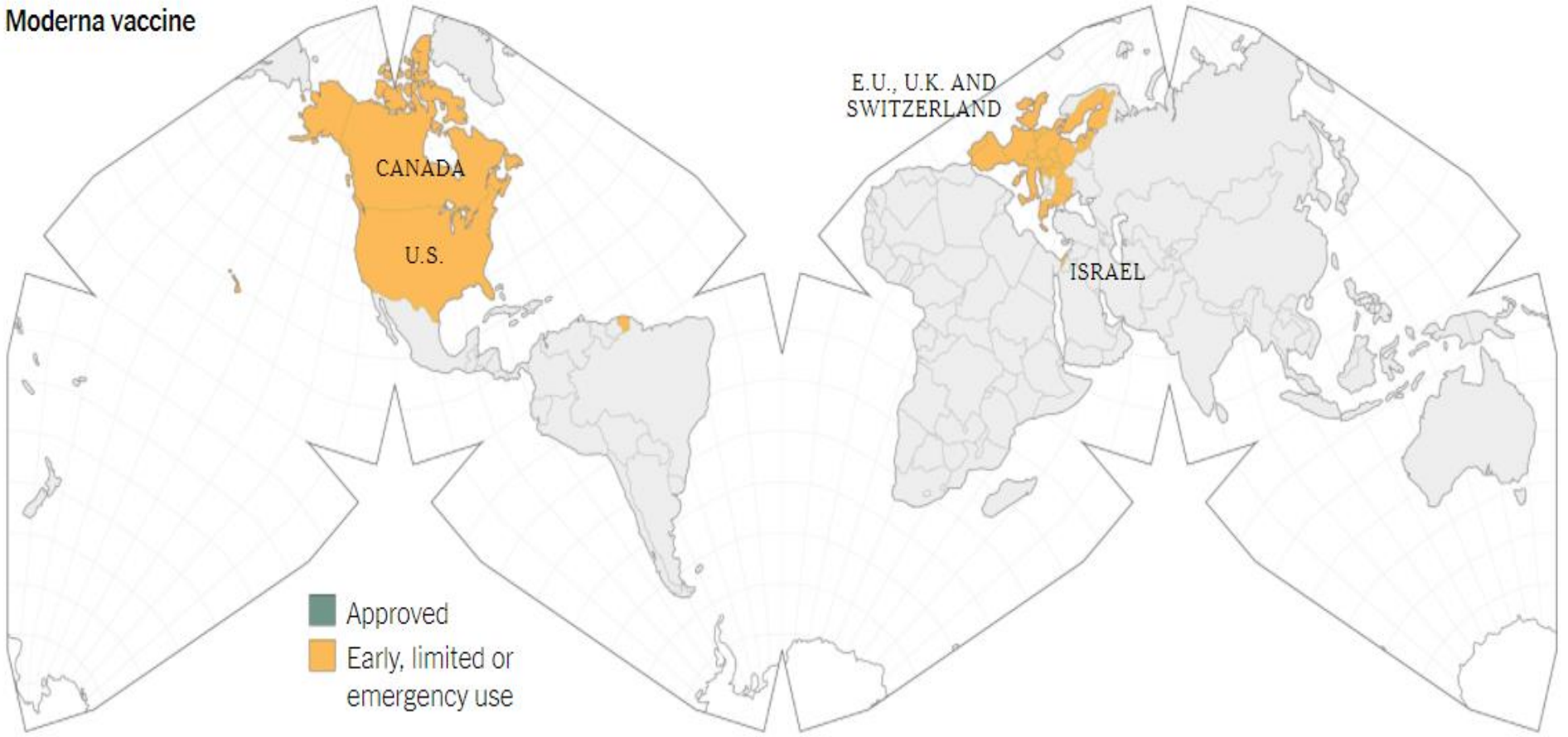
Pfizer & Biontech Vaccine

VACCINE NAME: Comirnaty (also known as tozinameran or BNT162b2)
EFFICACY: 95%
DOSE: 2 doses, 3 weeks apart
TYPE: Muscle injection
STORAGE: Freezer storage only at –94°F (–70°C)



Moderna RNA vaccine

VACCINE NAME: mRNA-1273
EFFICACY: 94.5%
DOSE: 2 doses, 4 weeks apart
TYPE: Muscle injection
STORAGE: 30 days with refrigeration, 6 months at –4°F (–20°C)



AstraZeneca and Johnson & Johnson

VACCINE NAME: AZD1222 (also known as Covishield in India)
EFFICACY: 62% to 90%, depending on dosage
DOSE: 2 doses, 4 weeks apart
TYPE: Muscle injection
STORAGE: Stable in refrigerator (2-8 degrees) for at least 6 months

Leading vaccines

Developer	How It Works	Phase	Status
Pfizer-BioNTech	mRNA	2 3	Approved in Bahrain, Saudi Arabia, Switzerland. Emergency use in U.S., E.U., other countries.
Moderna	mRNA	3	Emergency use in U.S., U.K., E.U., others.
Gamaleya	Ad26, Ad5	3	Early use in Russia. Emergency use in other countries.
Oxford-AstraZeneca	ChAdOx1	2 3	Emergency use in U.K., E.U., other countries.
CanSino	Ad5	3	Limited use in China.
Johnson & Johnson	Ad26	3	
Vector Institute	Protein	3	Early use in Russia.
Novavax	Protein	3	
Sinopharm	Inactivated	3	Approved in China, U.A.E., Bahrain. Emergency use in Egypt, other coutries.
Sinovac	Inactivated	3	Emergency use in China, Brazil, others.
Sinopharm-Wuhan	Inactivated	3	Limited use in China, U.A.E.
Bharat Biotech	Inactivated	3	Emergency use in India.

Myth

The side effects of the COVID-19 vaccine are dangerous.

Verdict: False

- The COVID-19 vaccine can have side effects, but the vast majority are very short term —not serious or dangerous.
- Some include pain at injection site; body aches; headaches or fever, lasting for a day or two.
- These are signs that the vaccine is working to stimulate the immune system.
- If you have allergies — especially severe ones that require you to carry an EpiPen — discuss the COVID-19 vaccine with your doctor, who can assess your risk and provide more information about if and how you can get vaccinated safely.

Myth:

- Now that we have a vaccine for COVID-19, we can make vaccines for the common cold, HIV and other diseases.

Verdict: False

- The thousands of viruses that cause various diseases are very different. Many change (mutate) year by year, making it difficult to develop one vaccine that works for a long period of time.

- Developing vaccines for some disease-causing viruses is tough. For example, the virus that causes HIV can hide and make itself undetectable by the human immune system, which makes creating a vaccine for it extremely difficult.

- The common cold can be caused by any one of hundreds of different viruses, so a vaccine for just one of them would not be very effective.

Myth:

People with underlying conditions shouldn't get vaccinated.

This is FALSE

People who have underlying conditions—like diabetes and heart disease, for example—are at a high risk for getting complications from COVID-19, so it's even more reason why they should get vaccinated

Myth:

People with suppressed immune systems shouldn't get vaccinated.

This is FALSE.

- People with suppressed immune systems (like from cancer treatments or autoimmune diseases) should definitely get vaccinated.
- The vaccine will not cause harm since it doesn't contain a live virus
- Those with suppressed immune systems will still get protection from COVID-19, just not as much protection as those with healthy immune systems.

Myth:

If I'm pregnant or breastfeeding, I definitely shouldn't get vaccinated.

This is False.

- The CDC believes it is fine for pregnant women to get the vaccine
  - If you're pregnant and in a group that should be urgently vaccinated, like a healthcare worker, you should get vaccinated.
  - If you're concerned about the risks versus the benefits, talk to your doctor.
  - But we know pregnant women who contract viruses can have complications or pass diseases to their babies, and the same goes for breastfeeding. Since the vaccine is not a live virus, you can't pass anything to the baby.

Other general myths about vaccines

Myth : Vaccines cause autism.

- The widespread fear that vaccines increase risk of autism originated with a 1997 study published by Andrew Wakefield, a British surgeon. The article was published in The Lancet, a prestigious medical journal, suggesting that the measles, mumps, rubella (MMR) vaccine was increasing autism in British children.

- The paper has since been completely discredited due to serious procedural errors, undisclosed financial conflicts of interest, and ethical violations. Andrew Wakefield lost his medical license and the paper was retracted from The Lancet.

- Nonetheless, the hypothesis was taken seriously, and several other major studies were conducted. None of them found a link between any vaccine and the likelihood of developing autism.

- Today, the true causes of autism remain a mystery, but to the discredit of the autism-vaccination link theory, several studies have now identified symptoms of autism in children well before they receive the MMR vaccine. And even more recent research provides evidence that autism develops in utero, well before a baby is born or receives vaccinations.

Myth: Infant immune systems can't handle so many vaccines.

- Infant immune systems are stronger than you might think. Based on the number of antibodies present in the blood, a baby would theoretically have the ability to respond to around 10,000 vaccines at one time.
  - Even if all scheduled vaccines were given at once, it would only use up slightly more than 0.1% of a baby's immune capacity - and scientists believe this capacity is purely theoretical.
  - The immune system could never truly be overwhelmed coz the cells in the system are constantly being replenished.
  - In reality, babies are exposed to countless bacteria and viruses every day, and immunizations are negligible in comparison.
- Though there are more vaccinations than ever before, today's vaccines are far more efficient. Small children are actually exposed to fewer immunologic components overall than children in past decades.

Myth: Natural immunity is better than vaccine-acquired immunity.

- In some cases, natural immunity — meaning actually catching a disease and getting sick– results in a stronger immunity to the disease than a vaccination.
- However, the dangers of this approach far outweigh the relative benefits.
- If you wanted to gain immunity to measles, for example, by contracting the disease, you would face a 1 in 500 chance of death from your symptoms.
- In contrast, the number of people who have had severe allergic reactions from an MMR vaccine, is less than one-in-one million.

Myth: Vaccines contain unsafe toxins

- People have concerns over the use of formaldehyde, mercury or aluminum in vaccines.
- It's true that these chemicals are toxic to the human body in certain levels, but only trace amounts of these chemicals are used in FDA approved vaccines.
- In fact, according to the FDA and the CDC, formaldehyde is produced at higher rates by our own metabolic systems and there is no scientific evidence that the low levels of this chemical, mercury or aluminum in vaccines can be harmful.

Myth: Better hygiene and sanitation are actually responsible for decreased infections, not vaccines.

- Vaccines don't deserve all the credit for reducing or eliminating rates of infectious disease - Better sanitation, nutrition, and the development of antibiotics helped a lot too.
- But when these factors are isolated and rates of infectious disease are scrutinized, the role of vaccines cannot be denied.
- **One example is measles in the United States.**
  - When the first measles vaccine was introduced in 1963, rates of infection had been holding steady at around 400,000 cases a year.
  - And while hygienic habits and sanitation didn't change much over the following decade, the rate of measles infections dropped precipitously following the introduction of the vaccine, with only around 25,000 cases by 1970.
  - **Another example is Hib disease.**
    - According to CDC data, the incidence rate for this malady plummeted from 20,000 in 1990 to around 1,500 in 1993, following the introduction of the vaccine.

Myth: Vaccines aren't worth the risk.

- Despite parent concerns, children have been successfully vaccinated for decades.
- In fact, there has never been a single credible study linking vaccines to long term health conditions.
- As for immediate danger from vaccines, in the form of allergic reactions or severe side effects, the incidence of death are so rare they can't even truly be calculated.
  - For example, only one death was reported to the CDC between 1990 and 1992 that was attributable to a vaccine.
  - The overall incidence rate of severe allergic reaction to vaccines is usually placed around one case for every one or two million injections.

Myth: Vaccines can infect my child with the disease it's trying to prevent.

- Vaccines can cause mild symptoms resembling those of the disease they are protecting against.

- A common misconception is that these symptoms signal infection.
  - In fact, in the small percentage (less than 1 in one million cases) where symptoms do occur, the vaccine recipients are experiencing a body's immune response to the vaccine, not the disease itself.
  - There is only one recorded instance in which a vaccine was shown to cause disease.
    - This was the Oral Polio Vaccine (OPV) which is no longer used in the U.S. Since then, vaccines have been in safe use for decades and follow strict Food and Drug Administration (FDA) regulations.

Myth: We don't need to vaccinate because infection rates are already so low in the United States.

- Thanks to "herd immunity," so long as a large majority of people are immunized in any population, even the unimmunized minority will be protected.
  - With so many people resistant, an infectious disease will never get a chance to establish itself and spread.
  - This is important because there will always be a portion of the population – infants, pregnant women, elderly, and those with weakened immune systems – that can't receive vaccines.
  - But if too many people don't vaccinate themselves or their children, they contribute to a collective danger, opening up opportunities for viruses and bacteria to establish themselves and spread.
  - International travel is growing quickly, so even if a disease is not a threat in your country, it may be common elsewhere. If someone were to carry in a disease from abroad, an unvaccinated individual will be at far greater risk of getting sick if he or she is exposed.

CONTINUED…

Myth: We don't need to vaccinate because infection rates are already so low in the United States.

- Vaccines are one of the great pillars of modern medicine.
  - Life used to be especially brutal for children before vaccines, with huge portions being felled by diseases like measles, smallpox, whooping cough, or rubella, to name just a few. Today these ailments can be completely prevented with a simple injection.
- So as science continues to advance and tackle new challenges, people should not forget how many deaths and illnesses vaccines have prevented, and how they continue to protect us from potentially devastating forms of infectious disease.


Thank you