Pfizer BioNTech Vaccine

Ankita Singh
Himalayan Pharmacy Institute(HMI), Majithar, Sikkim, India

Abstract **- About 240.6 million people in a worldwide who are affected by severe acute respiratory syndrome coronavirus infection (SARS) and resulting they are infected by coronavirus disease (covid 19) . So safe and effective vaccine are needed.**

INTRODUCTION

BNT162b2 is a lipid nano particle formulated ,nucleoside-modified RNA vaccine which are encoding a perfusion stabilized ,membrane-anchored SARS-COV-2 full length spike protein . BNT162b2 is highly efficacious against covid -19 and is currently used for emergency use.

All person who were newly vaccinated during period from December 20,2020 to February 1,2021.In December 2020 ,the vaccine was granted emergency use authorization (EUA)by the food and Drug administration (FDA) as well as an interim recommendation for use among person aged >16 years by the Advisory committee on immunization practice (ACIP) . In May 2021, the EUA and interim ACIP recommendation for Pfizer-BioNTech covid -19 vaccine now administrated were extended to adolescents aged 12-15 years . on August 23,2021 the FDA approved the first COVID -19 vaccine .The vaccine has been known as the Pfizer-BioNTech COVID -19and will now be marketed as Comirnaty ,for the prevention of COVID-19 disease in individuals 16 years of age and older .

The vaccine also continues to be available under emergency use authorization (EUA), including for 12 years of age and older, for the administration of third dose in certain immunocompromised people , for a single booster dose in people:-

- 65 and older
- 18 through 64 years at high risk of severe COVID-19

18 through 64 years of age with frequent institutional or occupational exposures to SARS
-coV-2.

On October 20,2021,the FDA authorized the use of a heterologous (or "mix and match'')booster dose in eligible population with currently available (i.e. ,FDA-authorized or approved) COVID -19 vaccines. Therefore , Pfizer -BioNTech COVID -19 Vaccine recipients falling in to one of the authorized categories for boosters may receive the Moderna COVID- 19 vaccine (half dose)vaccine or Janssen COVID-19 vaccine and should be given at least six months after completing the primary vaccination.

HOW THE PFIZER BIONTECH VACCINE WORK

A piece of the corona virus:- The SARS-COV-2 virus is studded with proteins that it uses to enter human cells. These so-called spike proteins make tempting target for potential vaccines and treatments.

Pfizer BioNTech vaccine is based on the virus's genetic instructions for buildings the spike
protein.

mRNA Inside an Oily Shell

The vaccine uses messenger RNA, genetic material that our cells read to make proteins. The molecule — called mRNA for short — is fragile and would be chopped to pieces by our natural enzymes if it were injected directly into the body. To protect their vaccine, Pfizer and BioNTech wrap the mRNA in oily bubbles made of lipid nanoparticles.

Because of their fragility, the mRNA molecules will quickly fall apart at room temperature. Pfizer is building special containers with dry ice, thermal sensors and GPS trackers to ensure the vaccines can be transported at –94°F (–70°C) to stay viable.

Entering a Cell

After injection, the vaccine particles bump into cells and fuse to them,
releasing mRNA. The cell's molecules read its sequence and build spike proteins. The mRNA from

the vaccine is eventually destroyed by the cell, leaving no permanent trace.

Some of the spike proteins form spikes that migrate to the surface of the cell and stick out their tips. The vaccinated cells also break up some of the proteins into fragments, which they present on their surface. These protruding spikes and spike protein fragments can then be recognized by the immune system.

Spotting the Intruder

When a vaccinated cell dies, the debris will contain many spike proteins and protein fragments, which can then be taken up by a type of immune cell called an antigen-presenting cell.

The cell presents fragments of the spike protein on its surface. When other cells called helper T cells detect these fragments, the helper T cells can raise the alarm and help marshal other immune cells to fight the infection.

Making Antibodies

Other immune cells, called B cells, may bump into the coronavirus spikes on the surface of vaccinated cells, or free-floating spike protein fragments. A few of the B cells may be able to lock onto the spike proteins. If these B cells are then activated by helper T cells, they will start to proliferate and pour out antibodies that target the spike protein.

Stopping the Virus

The antibodies can latch onto coronavirus spikes, mark the virus for destruction and prevent infection by blocking the spikes from attaching to other cells.

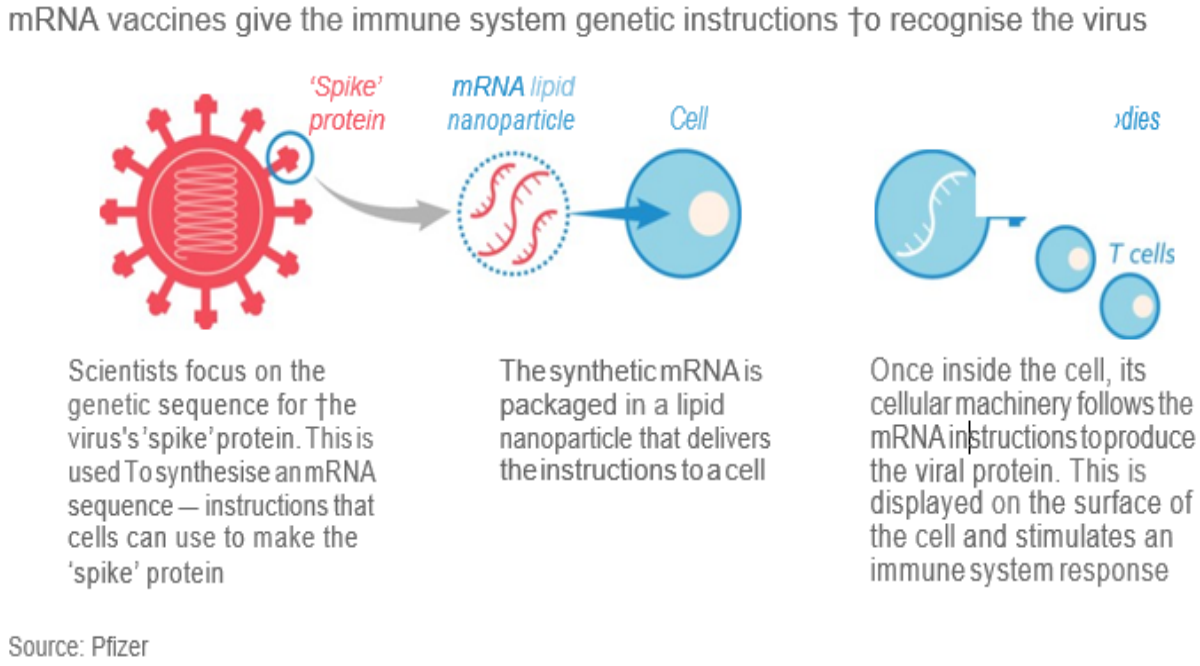
Killing Infected Cells

The antigen-presenting cells can also activate another type of immune cell called a killer T cell to seek out and destroy any coronavirus-infected cells that display the spike protein fragments on their surfaces.

Remembering the Virus

The Pfizer-BioNTech vaccine requires two injections, given 21 days apart, to prime the immune system well enough to fight off the coronavirus. But because the vaccine is so new, researchers don't know how long its protection might last. It's possible that in the months after vaccination, the number of antibodies and killer T cells will drop. But the immune system also contains special cells called memory B cells and memory T cells that might retain information about the coronavirus for years or even decades.

How the Pfizer-BioNTech vaccine works



SAFTEY

Vaccine recipients had local and systematic reaction:-
1.LOCAL REACTION :-pain, erythema, swelling, etc.
2.SYSTEMATIC REACTION:- (e.g., fever, headache, myalgias) at higher rates than placebo recipients, with more reaction following the second dose. Most were mild to moderate and resolved rapidly.

EFFICACIOUS

The BNT162b2 mRNA vaccine (tozinameran, Pfizer BioNTech) showed 95%or greater efficacy against symptomatic and severe covid-19 disease due to SARS-C0V-2.
BNT162b2 has been shown to highly effectiveness in the real world setting and to have a large public health effect on reducing infections ,hospital admission and death at a time.

Who else can take the vaccine?
The vaccine has been found to be safe and effective in people with various conditions that are associated with increased risk of severe disease .
This include hypertension, Diabetes, Asthma, pulmonary, liver ,or kidney disease as well as chronic infection that are stable and controlled.
WHO recommended the use of the vaccine in pregnant and lactating women as in other adults . WHO does not recommended discontinuing breastfeeding because of vaccination

Who should not take the vaccine?
*People with have a history of severe allergic reaction to any component of the vaccine should not take it and currently no efficacy and safety for children below the age 12 years.

VACCINE STORAGE

The vaccine requires an ultra-low-temperature freezer for storage up to six-month. Temperature- controlled thermal shippers using to dry ice to maintain the recommended temperature of -70degree c to 10degree Celsius for up to 10 days will be needed for transportation. Each thermal shipper should have a residual global positioning system (GPS) temperature-monitoring device.

ONCE A POINTS OF USE (POU) RECIEVES A THERMAL SHIPPER WITH THE VACCINE, THERE ARE THREE OPTIONS FOR STORAGE.

- Ultra -low-temperature freezers, which are commercially available and can extended shelf-life for up to six-month.
- Refrigeration units, which are commonly available in hospital : the vaccine can be stored for five days in such refrigerators at 2-8 degree Celsius.
- The Pfizer thermal shippers in which doses arrive can be refilled with dry ice and used as temporary storage unit for up to 15 days . After 15 days, the vials may be transferred to refrigerated storage at 2-8 degree Celsius for an additional five days, giving a total storage time of 20 days.

Once thawed and stored at 2-8 degree Celsius, the vials may not be frozen or stored in frozen condition .
The various storage options at the POU allow equitable access to the Pfizer vaccine of area with differing infrastructure.

CONCLUSION

COVID-19 mRNA vaccine BNT162b2 has been developed for use in healthy subjects to prevent COVID-19 on exposures to SARS -C0V-2. A two-dose regimen of BNT162b2 conferred 95%efficacy protection against covid -19 in person of 12 years of age or older . Reactogenicity and adverse effect associate with the vaccine were generally milder to less frequent in the older group (<55 years of age)than the younger group (12 to 55 years)and tended to increase after the second dose.

REFERENCES

[1] Lambert PH, Ambrosino DM, Andersen SR et al. Consensus summary report for CEPI/BC March 12-13, 2020 meeting; Assessment of risk of disease enhancement with covid -19 vaccines. Vaccine 2020;38(31):4783 -91.
[2] Food and Drug Administration Comirnaty. Silver spring, MD:US Department of Health and Human Services, Food and Drug Administration;2021.
[3] Advisory Committee on immunization Practices. ACIP meeting information . Atlanta, GA:US

Department of Health and Human service,CDC;2021.

[4] Wallace M, Woodworth KR, Gargano JW Et al. The advisory committee on Immunization practices 'interim recommendation for use of Pfizer- BioNTech COVID-19 vaccine in adolescents aged 12-15 years-United States, May 2021. MMWR MORB MORTAL WKLY Rep 2021; 70:749 -752.

[5] Polack FP, Thomas SJ, KITCHIN N, et al; c4591001 clinical Trial Group.

[6] Safety and efficacy of the BNT162b2 mRNA covid-19 vaccine N Engl J Med 2020.

[7] Allergic reactions including Anaphylaxis After receipt of the first dose of Pfizer – BioNTech COVID-19 vaccine-United States, December 14-23,2020 MMWR, January 6,2021 ,early release accessed 12th January 2021.