

UNIVERSITY OF BASRA COLLEGE OF PHARMACY



COMPARISON OF COVID 19 VACCINES SAFETY

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DEDICATION
This project is dedicated to our parents , our college teachers and to all Iraqi martyrs.
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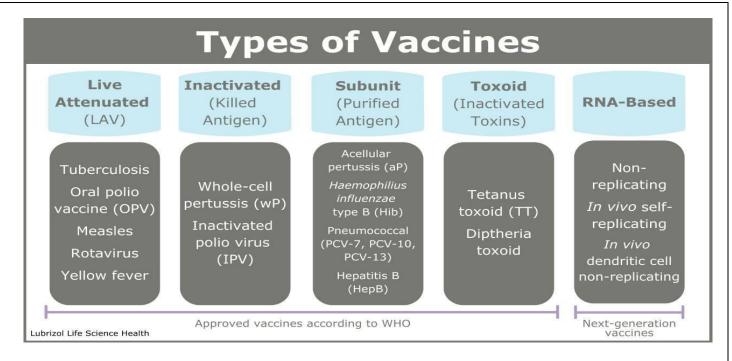
ABSTRACT

During all history era vaccines play an important role in prevention of many dangerous diseases and protect the world from pandemics and now with novel COVID 19 which killed a millions of people throughout the world and as the studies indicate that people perceive COVID-19 as a threatening disease, the demand for a vaccine against the disease could be expected to be high. Vaccine safety concerns might nevertheless outweigh the perceived disease risks when an individual decides whether or not to accept the vaccine .The strongest predictor of COVID-19 vaccination intentions was trusting the safety of the potential vaccine. It is important to take concern about the covid19 vaccines, adverse event of vaccines, safety, pregnancy, and children. There is many vaccines that is available now and pass the phase 3 trials the most popular vaccine is pfizer – biontech ,AstraZeneca oxford, moderna, spuntik, jhonson and jhonson, baharat, sinopharm, also there is many vaccines still in clinical trials The vaccines technique make them differ in mechanism of action, side effect and storage, Until today (23.2%) of the world population has received at least one dose of a COVID-19 vaccine .Three billion doses have been administered globally ,and (41.26) million are now administered each day. Which can give an idea that all vaccines is safe and can be used.

INTRODUCTION

Throughout the world, vaccines prevent more than 2.5 million child deaths each year, with the potential to prevent a further 2 million deaths with greater access to vaccines in the developing world. Edward Jenner was the first to test a method to protect against smallpox in a scientific manner. he is often considered the father of vaccines because of his scientific approach that proved the method worked.by the late(1940), scientific knowledge had developed enough, so that large-scale vaccine production was possible and disease control efforts could begin in earnest. The next routinely recommended vaccines were developed early in the 20th century. These included vaccines that protect against pertussis (1914), diphtheria (1926), and tetanus (1938). These three vaccines were combined in 1948 and given as the DTP vaccine. Further vaccines were developed, including the Bacillus Calmette-Guerin vaccine for tuberculosis and, later in (1960) the vaccines for measles, mumps, and rubella (MMR). The discovery of virus tissue culture methods led to the production of the Salk (inactivated) polio and the Sabin (live- attenuated oral) polio vaccines in (1950).

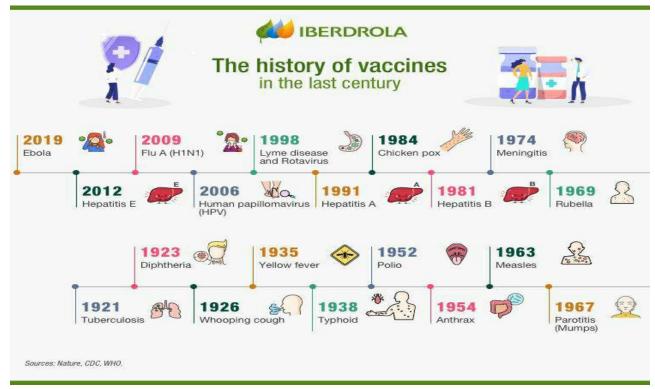
Mass polio vaccination programs have eradicated the disease from many regions around the world. During the 1970s, one vaccine was eliminated. Because of successful eradication efforts, the smallpox vaccine was no longer recommended for use after(1972). While vaccine research continued, new vaccines were not introduced during the (1970)s. The vaccine for Haemophilus influenzae type b was licensed in (1985) and placed on the recommended schedule in (1989).



Figure[1]:Types of vaccines

When the schedule was published again in (1994), the hepatitis B vaccine had been added. As more vaccines became available, an annual update to the schedule was important because of changes that providers needed to know, such as detailed information about who should receive each vaccine, age(s) of receipt, number of doses, time between doses, or use of combination vaccines. New vaccines were also added. Varicella (chickenpox - 1996), rotavirus (1998-1999, 2006, 2008), hepatitis A (2000); pneumococcal vaccine (2001) influenza (2002), hepatitis A (2006)Oral polio vaccine (2000) Pneumococcal and influenza vaccines in (2005) .Rotavirus vaccine is (in 2010) .Meningococcal serogroup B vaccine (2014).HPV (2011 to routinely

Intranasal influenza vaccine (2016).



Figure[2]:History of vaccines

Coronavirus disease (2019) COVID-19 is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late (2019). It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus.

Symptoms may include: fever or chills, cough, shortness of breath, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea. As studies indicate that people perceive COVID-19 as a threatening disease, the demand for a vaccine against the disease could be expected to be high. Vaccine safety concerns might nevertheless outweigh the perceived disease risks when an individual decides whether or not to accept the vaccine. Due to the COVID-19 pandemic, the world faces a novel infectious disease, for which there currently is no treatment or herd immunity. The pandemic poses a serious threat to our health and well-being and researchers are racing to develop and test vaccines against COVID-19. the success of the vaccination program depend on the public's acceptance of the vaccines.

The new available vaccines:-

PFIZETR-BIONTECH

Pfizer-BioNTechmergency Use Authorization (EUA) on Friday, November 20 and authorized on December 11. It is an mRNA vaccine that codes for the virus's spike protein and is encapsulated in a lipid nanoparticle.

MODERNA

OnNovember 16, Moderna issued a preliminary data read out of its COVID-19 vaccine, suggesting an efficacy rate of (94.5%). It was authorized by the FDA on December 19. Like the Pfizer-BioNTech .vaccine, it is an mRNA vaccine.

ASTRAZENECA-UNIVERSITY OF OXFORD

On November 23, AstraZeneca and the University of Oxford announced high-level results from an interim analysis of their COVID-19 vaccine, AZD1222. The analysis was from the trials in the UK and Brazil and demonstrated efficacy of up to (90%). The vaccine was effective at preventing COVID-19, with no hospitalizations or severe cases in people receiving it. The COVID-19 vaccine developed by AstraZeneca and the University of Oxford has been linked to blood clots. More than a dozen European countries have halted distribution of the AstraZeneca-Oxford vaccine as a result. To date, there have been about 222 suspected blood clotting cases in Europe with more than 30 deaths linked to the AstraZeneca-Oxford vaccine, out of 34 million vaccinations. In these cases, the clots are pulmonary embolism, deep vein thrombosis (DVT) or thrombocytopenia.

JOHNSON & JOHNSON

Johnson & Johnson announced on November 15 that it initiated a second global Phase III trial of its Janssen COVID-19 vaccine. They expect to enroll up to 60,000 volunteers world wide. Whereas all of the other three vaccine candidates require two doses about 28 days apart, the J&J vaccine only requires a single dose.

SINOVAC BIOTECH

On January 13,2021, China-based Sinovac Biotech reported that its COVID-19 vaccine had a (50.38%) efficacy in late-stage clinical trials in Brazil. The company's clinical trials are demonstrating dramatically varying efficacy rates.. in Indonesia the trial show efficacy rate of (65%), % in Turkey show (91.25).

RUSSIA'S SPUTNIK V VACCINE

Around November 11, authorized for use in August claimed had an efficacy rate of (92%) after the second dose. On November 24, the organization claimed (95%) efficacy based on new preliminary data. On December 14, 2020, they reported efficacy of (91.4%). It also offered to share one of its two human adenoviral vectors with AstraZeneca to increase the efficacy of the AstraZeneca vaccine. The organization has indicated a dose of the vaccine will cost no more than \$10, about half the cost of the Pfizer vaccine. On February2,2021, The Lancet published Phase III data demonstrating a (91.6%) efficacy against the original strain of the virus.

NOVAVAX

On January 28, 2021, Novavax announced that its COVID-19 vaccine, NVX- CoV2373, hit the primary endpoint with a vaccine efficacy of (89.3%) in its Phase III trial in the UK. The vaccine is a protein-based COVID-19 vaccine candidate. It also has data from the South Africa Phase IIb trial and several Phase I, II and III trials. It has demonstrated high clinical efficacy against the UK and South Africa variants as well. The vaccine contains a full-length, prefusion spike protein made using the company's recombinant nanoparticle technology and its proprietary saponin-based Matrix-M adjuvant. It is stable at 2 to 8 degrees C and shipped in a ready-to-use liquid formulation.

CAN SINON BIOLOGICS

Can Sino Biologics vaccine was co-developed with the Chinese military. It has an efficacy rate of (65.7%) at preventing symptomatic cases. on February 8, 2021. The Phase III trial includes 30,000 participants and demonstrated (90.98%) efficacy in preventing severe disease. It only requires a single shot. In a trial in February, the vaccine demonstrated an efficacy of (65.7%) in preventing symptomatic cases. But in April, the company noted that its efficacy rate seemed to drop over time but should have a rate of (50%) or more five to six months after inoculation.

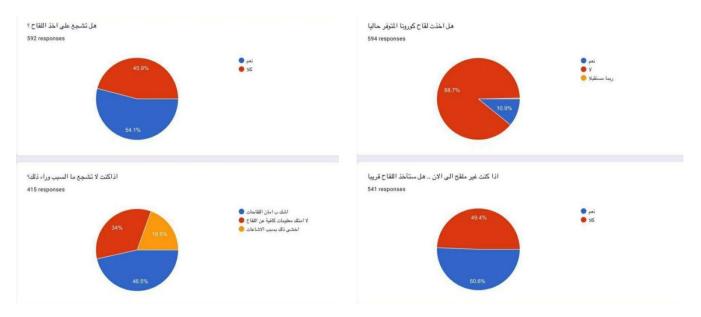
BHARAT BIOTECH

On April 22, 2021, India's Bharat Biotech reported interim data from the Phase III trial of its COVID-19 vaccine COVAXIN, which demonstrated a (100%) efficacy against severe infection. The vaccine was developed with seed strains from the Indian Council of Medical Research's (ICMR) National Institute of Virology. It is a highly purified and inactivated vaccine. A second interim analysis suggested a (78%) efficacy against mild, moderate and severe disease, and (70%) efficacy against asymptomatic disease. Does not require sub-zero storage, no reconstitution requirement, and ready to use liquid in multi-dose vials, stable at 2-8 degrees C...

RESULTS AND DISCUSSION

STUDY QUESTIONNAIRE:-

A questionnaire done by about 600 person with different ages to see what they think about covid19 vaccines as shown in figure[3].



Figure[3]:Questionnaire 1

(89%) of people in the report didn't take the vaccines and about (46%) never promote vaccination and (49%) will never take the vaccines the reason of that was:-

- (47%) of people don't trust the vaccines.
- (34%) of people don't have more information about vaccines.
- (20%) of people fear because of tales.



Figure[4]:Questionnaire 2

The people were asked why they don't trust the vaccines (55%), they said "we didn't had more information" and (46%) of them hear about dangerous side effects.

AS CONCLUSION FOR THIS QUESTIONNAIRE:-

We should give the community people the real information about covid19 vaccines, their safety and side effects.

How some of the Covid-19 vaccines compare

Company	Type	Doses	Storage
Oxford Uni- AstraZeneca	Viral vector (genetically modified virus)	×2	2 to 8°C (6 months)
Moderna	RNA (part of virus genetic code)	x2	-25 to -15°C (7 months)
Pfizer-BioNTech	RNA	x2	-80 to -60°C (6 months)
Gamaleya (Sputnik V)	Viral vector	x2	-18.5°C (liquid form) 2 to 8°C (dry form)
Sinovac (CoronaVac)	Inactivated virus (weakened virus)	×2	2 to 8°C
Novavax	Protein-based	x2	2 to 8°C
Janssen	Viral vector	×1	2 to 8°C (3 months)

Source: UK government, Reuters

BBC

Figure[5]:COVID 19 vaccines comparison.

Safety of covid19 vaccines and their side effect differ from one to another one also they differ between the dose and storage as shown below.

***** What is the type of each of the available vaccines?

Pfizetr-BioNTech: RNA.

AstraZeneca-Oxford: Viral vector (non replicated).

Sinovac CoronaVac: Inactivated virus.

Gamaleya Sputnick V: Viral vector (non replicating 2 serotypes).

Moderna: RNA.

Nvavax: Protein – based.

Janssen: Viral vector.

***** What are the dose and frequency of each of the available vaccines?

Pfizetr-BioNTech: 2 doses, 21 days apart.

AstraZeneca-Oxford: 2 doses, 4-12 weeks apart.

Sinovac CoronaVac: 2 doses, 28 days apart.

Gamalyea Suptink V: 2 doses, 21 days apart.

Bharat BioNTech: 2 doses, 14 days apart.

Moderna: 2 doses, 28 days apart.

Novavax: 2 doses, 21 days apart.

Janssen: 1 dose.

* What are the storage requirements of each of the available vaccines?

Pfizer BioNTech: -80 to -60°C.

AstraZeneca Oxford: 2 to 8°C.

Sinovac CoronaVac: 2 to 8 °C.

Gamaleya Sputnik V: - 18 and below (liquid form).

Bharat BioNTech: 2 to 8°C.

Moderna: -25 to -15 °C.

Novavax: 2 to 8 °C.

Janssen: -20°C (2 years), 2-8 c (3 months).

***** Waht is the efficacy of each vaccines based on phase III clinical trials?

Pfizer BioNTech: (95%) against symptomatic covid-19.

Oxford AstraZeneca: (70.4%) against symptomatic covid-19.

Sinovac Coronavac: (65.91%).

Gamaleyasputnik V: (91.6%) against covid-19.

Bharat BioTech: (80.6%) against covid-19.

Moderna: (94.1%) against symptomatic covid-19.

Novavax: Awaiting official phase III interim journal publication.

Janssen: (66.1-66.9%) against confirmed moderate to severe COVID-19.

***** Waht are side effects reported observed in phase III clinical trials?

Pfizer: Short term mild to moderate pain at injection site, fatigue, headache.

Oxford AstraZeneca: Injection site pain and tenderness, Fatigue, headache, fever, myalgia.

Sinovac Coronavac: local lymphadenopathy at injection site, possible allergic reaction, convulsion.

Gamaleya Sputnik V: pain on injection site, hyperthermia, swelling.

Bharat BioTech: headache, fatigue, fever, baby ache, abdominal pain, Nausea, vomiting.

Moderna: pain erythema or swelling on injection site, fever, headache, fatigue, myalgia, arthralgia, Nausea, vomiting, chills.

Novavax: Awaiting official phase III interim journal. publication.

Jansen: pain , redness , swelling , tiredness , headache , muscle pain , chills , fever , Nausea.

CONCLUSION

According to the previously mentioned information and more time required to get post marketing event ,we cannot confirm which vaccine is the best one so far, but According to the efficacy and side effects, we have three vaccines that are considered as the best compared to other vaccines, namely Pfizer, AstraZeneca and Moderna . Because the effectiveness of Pfizer is (95%) and the side effects are in only headache, fatigue and pain at the site of the injection, and the effectiveness of AstraZeneca is (90%). The side effects are fever, headache, anxiety, vomiting, nausea, pain at the site of the injection. While Moderna is (94%) effective, side effects are pain at the injection site, fever , vomiting , nausea, headache , anxiety. But depending on the storage conditions, the Pfizer vaccine needs certain storage conditions. It needs a special container with dry ice and store it at a temperature of -94 degrees Fahrenheit. Whereas AstraZenka and Moderna vaccines are stored at 2-8 °C.

RECOMMENDATIONS

- The companies have to striving hard to produce the highest number of vaccines with the highest quality and safety to ensure that it will reach all over the world.
- We recommend the United nations to Patent filing because this issue is related with the lifesaving of all the people.
- Ministry of Health in all countries have to provide the appropriate storage conditions for these vaccines especially those which need special storage conditions to ensure their safety.
- Each company should have a method to convey all the information about the vaccines and their safety in simple way to all people with different education levels to ensure that the people can trust the vaccines safety and take it.

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