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Review Article

IMPACT OF COVID VACCINATION WITH A PHARMACOECONOMIC PERSPECTIVE

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Abstract:

Covid-19 is a contagious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-COC-2). The 1st Known case was identified in Wuhan, China in Dec 2019. The disease has spread across the globe causing an ongoing pandemic. Various vaccines have been developed. As of June 2021, 18 vaccines are authorized by at least one national regulatory authority for public use. 308 vaccine candidates are in various stages of development, with 73 in clinical research, including 24 in Phase I trials, 33 in Phase I–II trials, and 16 in Phase III development. The vaccines may show mild to severe adverse effects.

Key Words: Covid-19, Corona virus, Vaccines, m-RNA vaccine, Pharmacoeconomics.

Introduction:

Covid-19:

Covid-19 is a contagious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-COC-2). The 1st Known case was identified in Wuhan, China in Dec 2019. The disease has since spread worldwide leading to an ongoing pandemic. ⁽¹⁾

According to WHO, COVID-19 is defined as, Corona Virus Disease, 2019 is an infectious disease caused by newly discovered coronavirus. ⁽²⁾

Symptoms:

Covid-19 affects different people in different ways. Most infected people will develop mild to moderate illness and recover without hospitalization ^(3,4,5)

Most common symptoms:

- Fever
- Dry cough
- Tiredness

Less common symptoms:

- Aches and pains
- Sore Throat
- Diarrhea
- Conjunctivitis
- Headache
- Loss of taste or smell
- A rash on skin or discoloration of fingers or toes

Serious Symptoms:

- Difficulty breathing or shortness of breath
- Chest pain or pressure
- Loss of speech or movement

Vaccine: A vaccine is a biological preparation that provides active acquired immunity to a particular infectious disease.⁽⁶⁾

Whereas, the Covid vaccine is defined as a vaccine intended to provide acquired immunity against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus causing coronavirus disease 2019 (COVID-19).^(7, 8)

Types of Vaccine:

As of June 2021, 18 vaccines are authorized by at least one national regulatory authority for public use:^(9, 10)

1. Two RNA vaccines

- A. Pfizer–Biotech
- B. Moderna,

2. Nine conventional inactivated vaccines

- A. BBIBP-CorV,
- B. Chinese Academy of Medical Sciences,

- C. CoronaVac,
- D. Covaxin,
- E. CoviVac,
- F. COVIran Barakat,
- G. Minhai-Kangtai,
- H. QazVac, and
- I. WIBP-CorV),

3. Five viral vector vaccines

- A. Sputnik Light,
- B. Sputnik V
- C. Oxford–AstraZeneca,
- D. Convidecia, and
- E. Johnson & Johnson),

4. Two protein subunit vaccines

- A. EpiVacCorona and

B. RBD-Dimer In total, as of March 2021, 308 vaccine candidates are in various stages of development, with 73 in clinical research, including 24 in Phase I trials, 33 in Phase I–II trials, and 16 in Phase III development.

Classification :^(11,12)

1. Whole Virus Vaccine:

Vaccines include: Sinopharm, Sinovac

Number of doses required: 2 doses, intramuscular

What to know: The whole virus vaccine uses a weakened or deactivated form of the pathogen that causes COVID-19 to trigger protective immunity to it. The two vaccines mentioned above – Sinopharm and Sinovac – both use inactivated pathogens; therefore, they cannot infect cells and replicate, but can trigger an immune response.

Benefits: According to Gavi, the Vaccine Alliance (GAVI), the advantages of an inactivated whole virus vaccine include the fact its technology is well established, it is suitable for people with compromised immune systems, and it's relatively simple to manufacture.

Challenges: Booster shots may be required.

2. Rna or Mrna Vaccine:

Vaccines include: Pfizer-BioNTech, Moderna

Number of doses required: 2 doses, intramuscular

What to know: Since no other existing licensed or approved vaccine uses this type of technology, the Messenger RNA (mRNA) variety could be mistaken for something completely new to healthcare. However, a number of mRNA vaccines have been studied in the past for illnesses and diseases including cytomegalovirus (CMV), influenza, rabies, and the Zika virus. According to the Centers for Disease Control and Prevention (CDC): “Researchers have been studying and working with mRNA vaccines for decades. Interest has grown in these vaccines because they can be developed in a laboratory using readily available materials. This means the process can be standardized and scaled up, making vaccine development faster than traditional methods of making vaccines.”

So how does it reportedly work? The COVID-19 RNA vaccine consists of mRNA molecules made in a lab that code for parts of the SARS-CoV-2 virus – specifically the virus’ spike protein.

Once injected into the body, the mRNA instructs the cells to produce antigens – such as the spike protein mentioned – which are then detected by immune cells, triggering a response by the body’s lymphocytes.

The killer T-cells destroys the infected cells, while the B-cells and helper T-cells support antibody production. Whoever is exposed to the COVID-19 coronavirus in the future would have an immune system that recognizes it, and in turn fight off the infection.

Benefits: According to the University of Cambridge’s PHG Foundation, advantages include good safety (since there are no live components, there’s no risk of the vaccine triggering disease), reliability, and that it’s relatively simple to manufacture.

Challenges: Disadvantages include unintended effects (such as an unintended immune reaction), ensuring effective delivery into the body (since free RNA in the body is quickly broken down), storage issues, plus the fact that this type of vaccine has never previously been licensed for humans.

3. Non-Replicating Viral Vector:

Vaccines include: Oxford-AstraZeneca, Sputnik V (Gamaleya Research Institute)

Number of doses required: 2 doses, intramuscular

What to know: This type of vaccine introduces a safe, modified version of the virus – known as “the vector” – to deliver genetic code for the antigen. In a COVID-19 vaccine, the “vector” is the spike proteins found on the surface of the coronavirus. Once the body’s cells are “infected”, the cells are instructed to produce a large number of antigens, which in turn trigger an immune response.

Benefits: Viral vector-based vaccination is another well-established technology that can trigger a strong immune response as it also involves both B cells and T cells.

Challenges: Previous exposure to the vector could reduce effectiveness, plus these types of vaccines are relatively complex to manufacture compared to others.

4. Protein Subunit:

Vaccines include: Novavax

Number of doses required: 2 doses, intramuscular

What to know: The protein subunit vaccine contains purified “pieces” of a pathogen rather than the whole pathogen to trigger an immune response. It is thought that by restricting the immune system to the whole pathogen, the risk of side effects is minimized.

Benefits: The protein subunit vaccination is also a well-established technology that’s advantageous for those with compromised immune systems.

Challenges: This type of vaccine is relatively complex to manufacture, and adjuvants and booster shots may be required

Types of Vaccines

- Covid-19 vaccines are safe and effective.
- You may have side effects after vaccination, but there are normal.
- It typically takes two weeks after you are fully vaccinated for the body to build protection (immunity) against the virus that causes covid-19

1. Covaxin:

- Inactivation virus
- 2 shot vaccine
- 2nd dose after 28 days

- Efficacy of 70%-80%
- Developed by India
- Available in India
- Approved by 9 countries

Actions: When administrated immunity cells can still recognize the death virus, prompting the immune system to make antibodies against the pandemic virus.

Efficacy: In comparison to this, Bharat Biotech's Covaxin which has been recently found to be neutralizing against the UK variant has an efficacy rate of over 70 to 80%

It must be four-week interval between two doses

Side effects:

- Red ness swelling, pains at the injection site
- Fever
- Sweating and or chills
- Body pains
- Nausea and vomiting
- Itching and rashes
- Headache

Pharmacoeconomics: Covaxin is the slightly expensive as compare to Covishield for the state government, the vaccines are begin marketed at rs.400, which reduced from rs.600, while for private hospital

And facilities, it will be priced at rs.1200. The vaccine has been sold at rest 150 to the central government.

Composition of Covaxin: Composition of Covaxin includes inactivated coronavirus, Aluminum Hydroxide gel, TLR 7/8 agonist, 2-phenoxyethonal and Phosphate Buffered Saline [NKA]



Fig-1: Covaxin.

Indications: 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; loss of taste or smell of recent onset; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

Contraindication: You should not get **COVAXIN** if you: Had a severe allergic reaction to any ingredients of the vaccine. Had a severe allergic reaction after a previous dose of this vaccine. Currently have an acute infection or fever.

Precautions:

This vaccine is unsafe who might be running with fever at the time of administration or on blood thinning medications, suffering from immune disorder, bleeding problem.

2. Covishield:

- Viral vector (modern chimpanzee adeno)
- 2 shot vaccine
- 2nd dose after 84 days
- Efficacy of 70-90%
- Developed by UK, Sweden India
- Available in India
- Approved by 130+countries

Action: It is made from a weakened version of a common cold virus (known as an adeno virus) from chimpanzees.

Efficacy:

Serum institutions of India s Covishield vaccine. On the other hand, has an efficacy rate of over 70.4%. Its efficacy could reach up to 90 weeks apart. Dosing interval is stretched to 12 weeks or more.

Side effects:

- Pain at the injection site
- Redness
- Swelling
- Head ache

- Nausea
- Vomiting's
- Fever
- Muscle pain
- Body pains

Pharmacoeconomics:

The still had initially launched the vaccine at Rs 150 for the central government Rs 400for the state government and Rs 600 for private hospitals. However, the company reduced the price by 25% for state government and is now selling its vaccine doses at 300Rs to state government. Meanwhile the price for the center and private hospitals remains unchanged.

Composition of Covishield Vaccines:

Compositions of Covishield includes inactivated adenovirus with segments of coronavirus, Magnesium Chloride hex hydrate polysorbate 80, Ethanol, Sucrose, Sodium Chloride and Disodium edentate dehydrate (EDTA).



Fig-2: Covisheild.

Indications: The Covishield vaccine are "L-Histamine, L-Histamine hydrochloride monohydrate, Magnesium chloride hex hydrate, Polysorbate 80, Ethanol, Sucrose, Sodium chloride, Disodium edentate dehydrate (EDTA), Water for injection," it pointed out.

Contraindication: Hypersensitivity to the active substance or to any of the excipients listed in section.

Precautions:

Pre-existing allergy, blood thinning medications and one who is planning to conceive should advice to wait postponing their vaccination 3-4 weeks after corona virus.

3. Sputnik

- Viral vector (modified adeno)
- 2 shot vaccination.
- 2ndDose after 28 days
- Efficacy of 85-95%
- Developed by Russia
- Will be available in india shortly

Action:

The vaccine, also known as gam-covid Vac, is a combination of two different adenovirus (A26 and ad5). The adenovirus–viruses that causes covid -19 spike proteins, which prompts the body to make an immune response.

Efficacy:

The Russian vaccine, sputnik v. recently approved by the drug controller general of india (DCGI) has an efficacy rate of 91.5%. It has a high response in curbing the severity of the virus sputnik v must be given in two doses at 21 days interval

Side Effects:

- Head ache
- Fatigue
- Pain at the injection site
- Flu like illness

Pharmacoeconomics:

Dr. Reddy lab in association with Apollo Hospital has priced the sputnik v vaccines at Rs1250 (including the administration charges). However, the vaccine is currently being imported at a price of Rs. 943 and with a 5% GST the cost of the vaccine for every dose comes to Rs. 995.

Indications: The Russian Sputnik V COVID-19 Vaccine (Gam-COVID-Vac) is indicated to build immunity to SARS-CoV-2, which causes COVID-19 disease.

Contraindication:

1. Hypersensitivity to any component of the vaccine, or a vaccine that has similar components; Components:
Active substance: $(1.0 \pm 0.5) \times 10^{11}$ particles containing protein S gene of SARS-CoV-2 virus
Excipients:

polysorbate 80, magnesium chloride hex hydrate, EDTA disodium salt dehydrate, ethanol 95%, water for injection

2. Pregnancy and breastfeeding, ask if the lady is trying to get pregnant. If she is, she has to wait for her period to get the vaccine.

3. Patient below 18 years of age.



Fig-3: Sputnik.

4. Johnson and Johnson Janssen:

Action: The Johnson & Johnson vaccine delivers DNA to your cells to make the spike protein. An adenovirus acts as a delivery vehicle, carrying coronavirus genetic material (DNA).

The adenovirus delivers the little piece of DNA to the cell that will then make the spike protein. After your cells produce the spike protein, your immune system creates antibodies toward the spike protein, protecting you from infection.

"Once the adenovirus gets inside your cell, the spike protein gets manufactured by your own cellular mechanisms."

Composition: The vaccine contains citric acid monohydrate, trisodium citrate dihydrate, ethanol (alcohol), 2-hydroxypropyl - β - cyclodextrin (HBCD) (hydroxypropyl betadex), polysorbate 80, sodium chloride, sodium hydroxide, and hydrochloric acid.

Indications: FDA scientists endorse J&J's covid vaccine, as new data shed light on efficacy committee members to give FDA some indication of how comfortable of an mRNA vaccine but wishes to switch to the Jansen Ad26.COV2.

Contraindication:

(1) Allergic to PEG, should not receive an mRNA COVID-19 vaccine and instead speak to your physician about receiving the Janssen COVID-19 vaccine;

(2) Allergic to polysorbate 80, should not receive the Janssen COVID-19 vaccine and instead speak to your physician about receiving the mRNA COVID-19 vaccines;

(3) A history of polysorbate allergy is a precaution rather than a contraindication to mRNA vaccination and

(4) Vaccination of these individuals (i.e., those with PEG or polysorbate allergy histories) should be undertaken only under the supervision of a health care provider experienced in the management of severe allergic reactions.

Side effects: Temporary side effects including headache, fatigue and fever are signs the immune system is revving up -- a normal response to vaccines. And they're common.



Fig-4: Johnson and Johnson.

5. Pfizer and Biotech:²¹

Actions: mRNA, delivered to your body's cells by lipid nanoparticles, instructs the cells to generate the spike protein found on the surface of the novel coronavirus that initiates infection. Instructing cells to generate the spike protein spurs an immune response, including generation of antibodies specific to the SARS-CoV-2 spike protein. mRNA vaccines do not contain any virus particles, meaning that they don't contain weakened or dead parts of a virus or bacterium.

Composition: The ingredients are mRNA, lipids ((4-hydroxybutyl) azanediyl) bis (hexane-6,1-diyl) bis (2-hexyldecanoate), 2 [(polyethylene glycol)-2000]- N, N-ditetradecylacetamide, 1, 2 – Distearoyl – sn - glycerol-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

Indications: The Pfizer-Biotech COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.3 ml each) 3 weeks apart.

Contraindication: Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-Biotech. Immediate allergic reaction[†] of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

Side effects: These side effects happen within a day or two of getting the vaccine.

Throughout the rest of your body:

- Tiredness.
- Headache.
- Muscle pain.
- Chills.
- Fever
- Nausea



Fig-5: Pfizer.

6. Moderna: ^{23,24}

Action: The nucleoside-modified mRNA in the Moderna COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 Spike antigen. The vaccine elicits an immune response to the Spike antigen, which protects against COVID-19.

Composition: Messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, trimethamine hydrochloride, acetic acid, sodium acetate trihydrate, and sucrose

Indications: Moderna COVID-19 Vaccine is authorized and recommended for people 18 years of age and older. All people for whom vaccination is indicated should receive 2 doses 28 days apart.

Contraindications:

Contraindications to either of the mRNA COVID-19 vaccines: Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or to any of its components Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])* Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)* Persons with an immediate allergic reaction to the first dose of an mRNA vaccine should not receive additional doses of either of the mRNA COVID-19 vaccines.

* These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immune.

Side effects: In clinical trials, reactogenicity symptoms (side effects that happen within 7 days of getting vaccinated) were common but were mostly mild to moderate



Fig-6: Moderna.

7. Sniopharm:¹³

Action: The Sinopharm vaccine contains SARS-CoV-2 that has undergone treatment with a chemical called beta-propiolactone. This chemical binds to the virus's genetic material and stops it from replicating and causing COVID-19. the vaccine also contains an adjuvant in the form of aluminum hydroxide, which helps strengthen the body's immune system.

Composition: Active ingredients contain beta propiolactone, inactive ingredients contain disodium hydrogen phosphate, sodium chloride, aluminum hydroxide, sodium dihydrogen phosphate.

Indication: The Sinopharm COVID-19 vaccine, BBIBP-CorV, which the Beijing Bio-Institute of Biological Products (BBIBP) developed, is the first Chinese COVID-19 vaccine that the World Health Organization (WHO) has authorized for emergency use

Contraindication:

1. Known history of anaphylaxis to any component of the vaccine
2. Person who developed anaphylaxis after the first dose should not receive a second dose of the Sinopharm vaccine.

Side effects:

- Redness and swelling at the vaccination site
- Headache
- Fatigue
- Fever
- Facial nerve symptoms



Fig-7: Sniopharm.

8. Coronavac: ^{14,15}

Action: the researchers drew off the inactivated viruses and mixed them with a tiny amount of an aluminum-based compound called an adjuvant. Adjuvants stimulate the immune system to boost its response to a vaccine.

Composition:

Active ingredients: inactivated SARS-CoV Virus

Adjuvant: Aluminum hydroxide

Excipient: Disodium hydrogen phosphate dodecahydrate, sodium dihydrogen phosphate monohydrate, sodium chloride.

Indications: It is indicated for active immunization against diseases caused by sars-cov-2 virus. It is recommended for susceptible people aged 18 and above.

Contraindication:

1. People with history of allergic reaction to CoronaVac or any other inactivated vaccine, or any other component of CoronaVac.
2. People with severe neurological conditions
3. Patients with uncontrolled severe chronic disease
4. Pregnant and lactating women

Side effects:

- Pain, swelling, erythema at injection site
- Headache
- Fatigue
- Myalgia
- Loss of appetite
- Rhinorrhea



Fig-8: Sinovac.

9. Convidecia:^{16, 17}

Action: it is an adenovirus viral vector vaccine. Adenovirus type 5 receptor delivers the gene sequence of S protein into human cells.

Having entered the cells, the gene is transcribed to express the S protein, which serves as an antigen that triggers the host's immune response.

Composition: Convidecia is a viral vector vaccine similar to AstraZeneca's AZD1222 and Gamaleya's Gam-COVID-Vac. It can be stored in less extreme cold conditions compared to Mrna vaccines.

Indications: the vaccine is indicated to prevent COVID-19 disease caused by SARS-Cov-2 corona virus.

Contraindication: Individuals with a known history of severe allergic reactions to any component of the vaccine are contraindicated

- Individuals who have fever, an acute disease or a breakout of an underlying chronic disease should postpone the vaccination

Side effects:

- Fever
- Redness
- Swelling
- Pain



Fig-9: Covindécia.

10. Epivac Corona: ^{25, 26}

Action: According to researcher, the peptides and the viral part of the chimeric protein should immunize people who received this vaccine against the SARS-CoV-2 coronavirus and trigger the production of protective antibodies.

Composition: The patented vaccine composition contains three peptides. In all of these patents the carrier protein with an amino acid sequence derived from two parts, a bacterial maltose binding protein and viral nucleocapsid protein.

Target: SARS-CoV-2

Indications: EpiVacCorona vaccine is indicated to prevent COVID19 disease caused by SARS-Cov

Contraindications:

- Pregnant ladies
- Children

- Individuals who have fever, an acute disease or a breakout of an underlying chronic disease should postpone the vaccination

Side Effects:

- Mild headache
- Pain and swelling at the site of injection
- Mild fever
- Irritability



Fig-10: Epivac.

11. Minhai:

Minhai covid vaccine is an inactivated virus vaccine developed by Minhai Biotechnology Co. and Kangtai Biological Products Co. Ltd. in China.

The vaccines have applied for national drug production registration approvals, but have obtained clinical approvals.

Side effects:

- Common side effects in some individuals could be mild fever,
- Pain and swelling at the site of injection



Fig-11: Minhai.

12. QazCovid-In:

- The QazCovid-in vaccine, an inactivated vaccine, was developed and tested in the Kazakh Research Institute for Biological Safety Problems. It demonstrated high efficacy, safety, and immunogenicity at 96% in initial Phase I and II trials (NCT04530357), and will now be undergoing upcoming Phase III trials
- QazCovid-in is currently in a stage 3 trial to be completed by July.
- All 222 people who participated in the first two stages have developed immunity to COVID19, with no major side effects reported, according to its Kazakh developer, the research institute for biological safety problems.



Fig-12: QazCovid.

13. Covivac:¹⁹

Action: CoviVac Russia COVID-19 Vaccine is a whole-virion vaccine that uses viruses that have already been killed (inactivated). **CoviVac**-Russia vaccine includes all the elements of the virus. The **CoviVac**-Russia is a two-shot vaccination and is recommended for use from 18 to 60 years old

Composition: One dose of 0.5 ml is composed only of 3 µg or more of SARS-CoV-2 strain AYDAR-1 antigen inactivated by beta-propiolactone and the following excipients

- 0.3–0.5 mg of aluminum hydroxide (adjuvant)
- 0.5 ml or less of phosphate buffer solution composed of disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, sodium chloride, and water for injection

Indications: The CoviVac vaccine is recommended for persons aged 18-60 years

Contraindication:

- Pregnant and lactating women

- People exhibiting acute respiratory viral infections, and those suffering from exacerbation of chronic disease, according to the vaccine administrating manual
- CoviVac is also contraindicated for patients below 18 years of age
- Vaccination be conducted from 2 to 4 weeks after recovery from acute febrile conditions and acute infections and noninfectious diseases

Side effects:

- Fever
- Fatigue
- Headache
- Body aches
- Chills
- Nausea



Fig-13: Covivac.

14. RBD-Dimer: ²⁷

Action: As described in Cell, the CoV spike receptor-binding domain (RBD) is an attractive vaccine target for coronaviruses but is constrained by limited immunogenicity; however, a dimeric form of MERS-CoV RBD offers greater protection. The RBD-dimer significantly increases neutralizing antibodies compared to a conventional monomeric form and protected mice against MERS-CoV infection. CoV RBD-dimer have been produced at high yields in pilot scale production.

Composition: Vaccine against MERS-CoV and SARS-CoV is prepared by using coronavirus RBD using a monomeric RBD protein or a protein fusing a monomeric RBD and an Fc region.

Side effects: There is currently no publicly available peer-reviewed data about the safety or efficacy of the dimeric receptor-binding domain, or RBD-dimer, vaccine. One preprint paper states that no serious adverse events were reported during a trial.

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