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Reviving Immune Protection, A Novel Approach To Vaccine Development

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ABSTRACT

Immunization is cornerstone of public health policy and is demonstration highly cost effective when used to protect child health. Although it could be argued that immunology has not has played an important role in vaccine development so far, since most of the vaccine we use today have been developed and tested experimentally, it is clear that we have a big challenge in front of us in developing new vaccine for pathogens that are difficult to target better know the security of the guardian in addition, the knowledge of huge potential and challenge for vaccine to control disease outbreaks and protect the older population, together with the availability for an array of new technology, make it perfect for immunologists to be involved in designing the next generation of powerful immunogens. This review provides an introductory overview of vaccine immunization and related issue and there by aim to inform a broad scientific audience about the underlining immunological concept.

KEYWORDS

Vaccine – vaccine developed, phase, vaccine manufactures working vaccine, vaccination side effects, history, manufacturing technology, vaccine development, preventable disease.

INTRODUCTION

Vaccine is one of the most Successful Public Health Events in Modern Human History a vaccine can create strong immunity against a specific harmful agent by stimulating the immune system to attack the agent.

Millions of people get vaccinated each year, avoid the annual flu shot, enroll in the childhood vaccination program, or get vaccinated against other infectious diseases. Vaccination is done before the disease occurs, the purpose of which is to prevent of the disease. In addition to preventive vaccination, reactive vaccination can be given during outbreak of an infectious disease or in response to a biological threat.

Although vaccination is a health intervention, vaccine can be successful. Campaigns are impossible without good logistics. The importance of vaccine logistics is demonstrated by the studies on the subject.

In this paper, we structure the literature on vaccine logistics using the priority areas defined WORLD HEALTH ORGANIZATION {WHO}. These key areas enable chains and identify the best ways to develop a strong vaccine supply chain. We will focus on WHO’s first three initiatives. are most related to operations research/operations management [OR/OM].

HISTORY

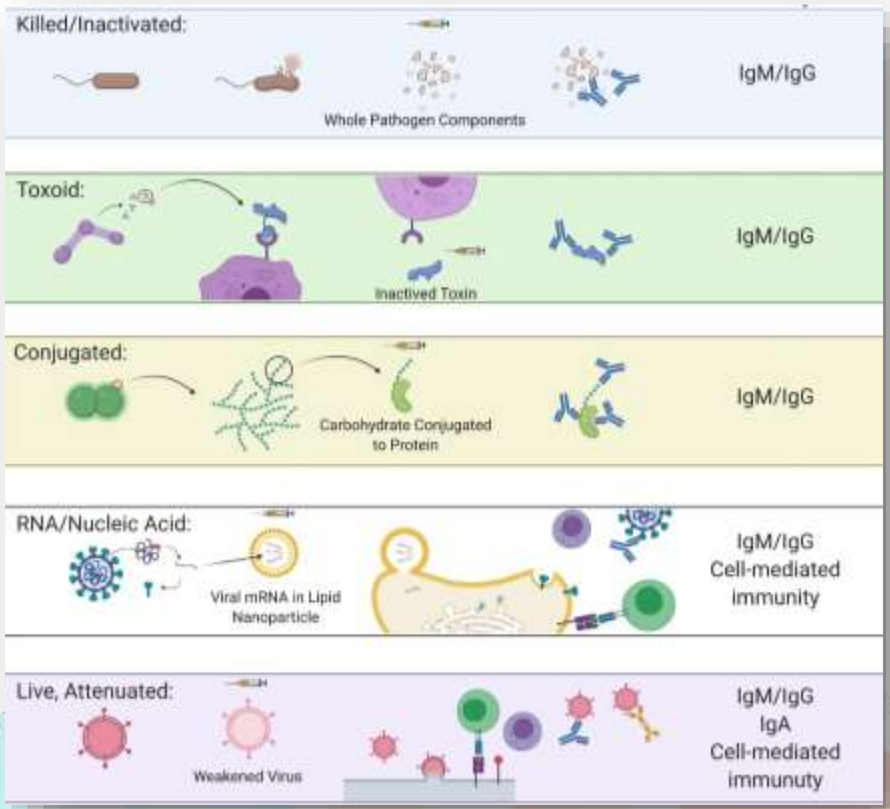
Dr. Edward Jenner created the world;s first successful vaccine. He found that people who had cow disease didi not get smallpox. In 1796, the english docotor edward jenner extened this discovery by injecting 8-year-old james phipps with material collectes from a cowpox wound on the arm of a slav.

WHAT IS VACCINE?

All the ingredients in vaccine play an important role in making sure the vaccine is safe and effective, some of this include:

- Antigen: This is weaker or weakened form of a virus or bacteria that we fight against when we get an infection
- Aids, which help to strengthen immune response. This what it.
- Preservative, which ensure a vaccine stays effective.
- Vaccine are products that protect us against serious, often deadly diseases, by helping the body’s natural defense is the immune system to dight them. A vaccine mimics what happens in the body when a germ [usually a virus or bacteria] infects us without killing us.

TYEPE OF VACCINE

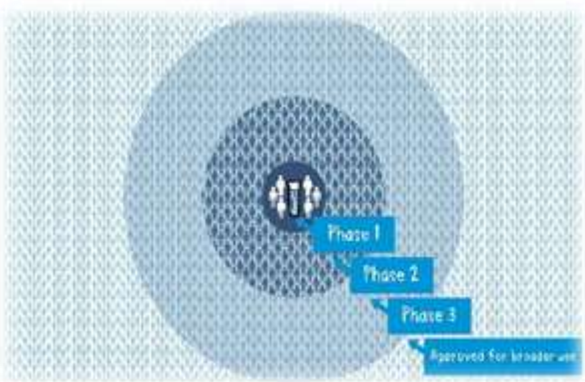


HOW NEW VACCINES ARE DEVELOPED

The research stages of vaccine development are:

- Research and discovery
- Proof of concept
- Testing a vaccine
- Construction
- Approve of the vaccine
- Recommendation the vaccine for use
- Monitoring safety after approval

If the vaccine triggers an immune response, it is the tested in human clinical trials in three phases.



Phase 1

The vaccine is given to a small number of volunteers to assess its safety, confirm it generates an immune response, and determine the right dosage. Generally, in this phase vaccines are tested in young, healthy adult volunteers.

Phase 2

The vaccine will be administered to hundreds of hosts to evaluate its safety and ability to induce an immune response. The participants in this section had the same characteristics (eg, age, gender) as the people for whom the vaccine was administered. There are usually many trials in this category to evaluate different age groups and different vaccines. The group that did not receive the vaccine was included as a comparison group to determine if any changes in the vaccinate d group were caused by the vaccine or occurred by chance.

Phase 3

The vaccine is next given to thousands of volunteers – and compared to a similar group of people who didn't get the vaccine, but received a comparator product – to determine if the vaccine is effective against the disease it was created to project and investigate the safety of a large group of people. Most of the time the test is the third part conducted across multiple countries and multiple sites within a country to assure the findings of the vaccine performance apply to many different populations.

- Large-scale human trials (1,000-10,000 participants)
- Confirm efficacy, monitor side effects, and compare to existing treatments
- Typically lasts 3-5 years

VACCINE MANUFACTURES

The companies with the highest market share in vaccine production are Merck, Sanofi, GlaxoSmithKline, Pfizer and Novartis, with 70% of vaccine sales concentrated in the EU or US (2013). Vaccine manufacturing plants require large capital investments ($50 million up to $300 million) and may take between 4 and 6 years to construct, with the full process of vaccine development taking between 10 and 15 years.

PHASES OF VACCINE DEVELOPMENT

Pre-clinical phase

1. Exploratory phase: Researchers identify and develop vaccine candidates, testing them in lab and animal study.
2. Preclinical development: vaccine candidates are optimized and tested for safety, immunogenicity, and efficacy in animal models.

Clinical phases

1. Phase 1 [first-in-human]; small-scale human trials [20-100 participants], assess safety tolerability and immune response typically lasts 1-2 years.
2. Phase 2 medium large-scale human studies [100-1000 participants] evaluate efficacy, dose efficiency and side effects, usually lasting 2-3 years.
3. Phase 3 studies inhuman involve a large scale and usually take 3-5 years compared to current treatments.

Post-licensure phases

1. **Pivotal phase:** late stage human trials to confirm vaccine efficacy and safety.
2. **Bridging phase:** studies to support vaccine licensing new population or regions.

SEVERAL STAGES OF MANUFACTURING

1. **Research and Development:** Scientists identify and develop a vaccine candidate, testing its safety and efficacy in lab and animal studies.
2. **Cell Culture:** The vaccine virus is grown in cell cultures, such as chicken eggs or mammalian cells.
3. **Harvesting:** The virus is extracted from the cell cultures.
4. **Purification:** The virus is purified and remove the impurities.
5. **Formulation:** The vaccine is formulated with adjuvants, stabilizers, and preservatives.
6. **Filling and Finishing:** The vaccine is filled into vials or syringes and packaged.
7. **Quality Control:** The vaccine undergoes rigorous testing for purity, potency, and safety.
8. **Regulatory Approval:** Regulatory agencies review trial data and grant approval for emergency use or full licensure.
9. **Distribution:** The vaccine is given to health worker give to patient.
10. **Monitoring:** The vaccine's safety and efficacy are continuously monitored through post-marketing surveillance.

MANUFACTURING TECHNOLOGY

- mRNA Technology (e.g., Pfizer-BioNTech, Moderna)
- Adenovirus Vector Technologies (eg, AstraZeneca, Johnson & Johnson)
- Protein synthesis technology (e.g. novavax).
- Inactivated Whole Virus Technology (e.g., Sinopharm, Sinovac)

OTHER TECHNOLOGY

1. **Cell culture technology:** using cell lines for vaccine production increasing efficiency and scalability.
2. **Recombinant DNA technology:** The possibility of vaccine development using genetic engineering.
3. **Assistive technology:** enhancing the immune response and the effectiveness of the vaccine.
4. **Manufacturing and delivery system:** improve vaccine efficacy, shelf life, and handling process.
5. **Process analytical technology [PAT]:** stream enabling real time monitoring and control of manufacturing processes.
6. **Single use system:** reducing contamination risk and increasing flexibility.
7. **Continuous manufacturing:** streamlining production reducing costs and enhancing quality
8. **Microbioreactors:** the ability to produce small, high-throughput vaccines.
9. **mRNA technology:** facilitating rapid vaccine development and production.
10. **Digitalization and automation:** enhancing efficiency quality and compliance in vaccine manufacturing.

Example of vaccine manufacturing technology include:

- Merck's proprietary HPV vaccine manufacturing technology.
- Pfizer mRNA based on COVID-19 vaccine development.
- Sanofi's influenza vaccine manufacturing using cell culture technology.

These Advancements Have Improved Vaccine Production Capacity, Reduced Costs, And Enabled the Development of More Effective and Safer Vaccines.

SEVERAL FACTORS AFFECTING ON VACCINE PROTECTION

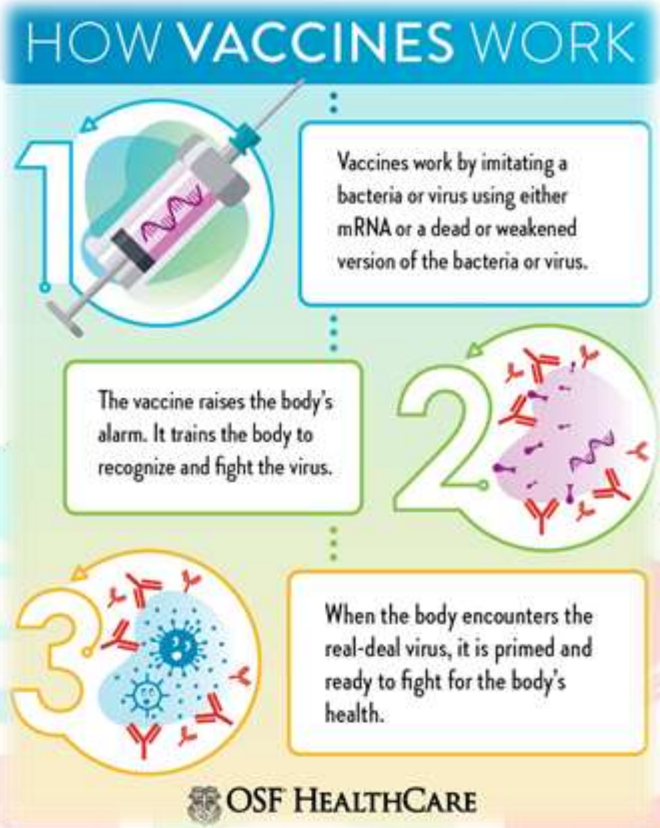
1. **Age:** Vaccine effectiveness may vary by age with older adults or young children potentially having weaker immune response.
2. **Health status:** Underlying health conditions such as a weakened immune system or chronic illness can affect the effectiveness of the vaccine.
3. **Types of vaccine:** Different types of vaccine can provide different levels of protection.
4. **Dropping and supplementing:** Deviations from specific production schedule may reduce storage or disrupt performance.
5. **Storage and handling:** Improper vaccine storage or handling can compromise potency.
6. **Immune Status:** weakened immune system [e.g. HIV/AIDS, cancer, immunosuppressive therapy] can reduce vaccine effectiveness.
7. **Health Conditions:** certain health conditions [e.g, diabetes, kidney disease] can affect vaccine effectiveness.
8. **Diet status:** A poor diet nutrition can weaken the immune system and reduce the effectiveness of vaccine.
9. **Vaccine quality:** vaccine effectiveness can be reduced.

WORKING OF VACCINE

- **Introduction of antigen:** a vaccine contains a small harmless piece of virus or bacteria [antigen] which is introduced to the body through injection, oral route, or nasal spray.
- **Immune cell recognitions:** immune cells such as dendritic cells recognize the antigen and ingest in.
- **Processing and presentation:** cells process the antigen and present it to the t-cell [a type of immune cell] as a signal to activate the immune response.
- **Activation of t-cell:** t-cell recognize the antigen and become activated to fight the virus or bacteria.
- **Production of antibodies:** activated t-cell stimulate b-cell [another type of immune cell] to produce antibodies, which are proteins that specially bind to the virus or Bactria
- **Neutralization of virus/bacteria:** antibodies neutralize the virus or bacteria by blocking its enter the host cells or die.
- **Formation of memory cells:** activated t-cell and b-cell form memory cells which remember the specific virus or bacteria enabling a rapid and effective immune response if exposed again in the future.
- **Long-term immunity:** through this process the vaccine provide-long immunity to certain disease protecting people from the disease and reducing the risk of admission.

Different type of antigens such as

- whole Inactivated virus
- Live attenuated virus
- Protein-based antigens
- mRNA based antigens



COVID-19 VACCINE

Table of vaccine-preventable disease

Smallpox	Year
Rabies	1798
Typhoid	1885
Cholera	1896
Plague	1896
Diphtheria	1897
Pertussis	1923
Tetanus	1926
Tuberculosis	1927
Influenza	1927
Yellow fever	1945
Poliomyelitis	1953
Measles	1963
Mumps	1967
Rubella	1969
Anthrax	1970

Meningitis	1975
Pneumonia	1977
Adenovirus	1980
Hepatitis B	1981
Rotavirus	1998
Lyme disease	1998
Dengue fever	2019
Human papillomavirus	2006

What is coronavirus disease…?

Corona virus disease 2019 is a infections disease caused by the SARS-CoV-2 coronavirus. The first know discover in Wuhan, china, in December 2019.

Covid-19 vaccine help your bodies develop immunity to the virus that causes COVID-19 without us having to get the illness. Different COVID-19 vaccine work differently our bodies, but they all protect against the virus that causes COVID-19.

How vaccine developed

COVAXIN, India's indigenous COVID-19 vaccine by Bharat biotech is developed in collaboration with the Indian Council of Medical Research [ICMR]-National Institute of Virology [NIV].

WHO and its partners are committed to accelerating the development of COVID-19 vaccines while maintaining the highest standards on safety. Vaccine go through various phase of development and testing there are usually three phases to clinical trials, with the last one designed to assess the ability of the product to protect against disease, which is called efficacy all phases assess safety.

The last phase, III are usually conducted in a large number of people often 10" s of thousand. After that, the vaccine the national regularity authority must review and decide whether the vaccine is safe and effective on the market, and a policy committee, who will decide how the vaccine should be used.

Now, give the urgent need for COVID-19 vaccine, unprecedented financial investments and scientific collaborations are changing how vaccine are developed.

Vaccination

Both co-vaccination and covid-19 vaccines are used to kill the corona virus.

What is COVAXIN: BHARAT BIOTECH COVID-19 VACCINE is an inactivate [killed] vaccine, and hence, there is no chance of infected with Bharat biotechnology's COVID-19 vaccine to prevent the 2019 coronavirus disease caused by SARS CoV-2.

Covidshield was developed by the SII, university oxford and AstraZeneca while covaxin was developed by Bharat biotech and ICMR. [Indian Council Of Medical Research].

Vaccine Side Effects

Most people do not have any serious side effects from the vaccines. Most side effects, such as pain at the injected site, are mild and disappear quickly.

Common Side Effects Of Vaccine

Adverse effect is mild after vaccination. They include.

- Pain, swelling or redness where the shot was given.
- Mild fever
- Chills feeling tired headache
- Muscle and joint aches

Serios Side Effects

- Difficulty breathing.
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Conclusions

In this review we discuss publication on the vaccine supply chain. This topic originates in the epidemiological community, but has recently also found its way into the OR/OM community. By analyzing the various aspects of the vaccine supply chain, we connect the logistical questions that play a role in vaccination. In short, we identify three main challenges of vaccine logistics are increasing the efficiency effectiveness of the vaccine supply chain preparing for unexpected outbreak and preparing for invasions. Biology based our extensive literature review, we conclude that the vaccine supply chain is useful from an OR/OM perspective, and identify research opportunities for the OR/OM community. It can help to improve countries in different ways. A vaccine trains the immune system to produce antibodies when it encounters an infection. However, because the vaccine only contains dead or weakened types of bacteria, such as viruses or bacteria it will not cause disease or cause you any problems. Vaccine against infectious disease are knock-on risk of infection.

Although all vaccine shares certain public good properties in term of basic research and development, the spillover effects in consumption of vaccines providers the key rationale for broad public support of vaccine financing.

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