Properties and Components of a Vaccine

1. Vaccine properties

In addition to an ability to stimulate effective immunity, the World Health Organization (WHO) has stated that the ideal vaccine would have the following properties:

1) **Availability**: Readily cultured in bulk or accessible source of subunit.
2) **Effectiveness**: Must induce protective levels of immune response. Gives life-long immunity
3) **Dosing program**: One dose induces protective immunity.
4) **Safety**: Eliminate any pathogenicity. No side effects.
5) **Stability**: Retains biological activity for a long time at different temperatures, preferably not requiring refrigeration.
6) **Administration**: Can be co administered with other vaccines at one visit and suitable for administration early in life.
7) **Manufacture**: Can be easily scaled-up and at low cost (Cheapness).

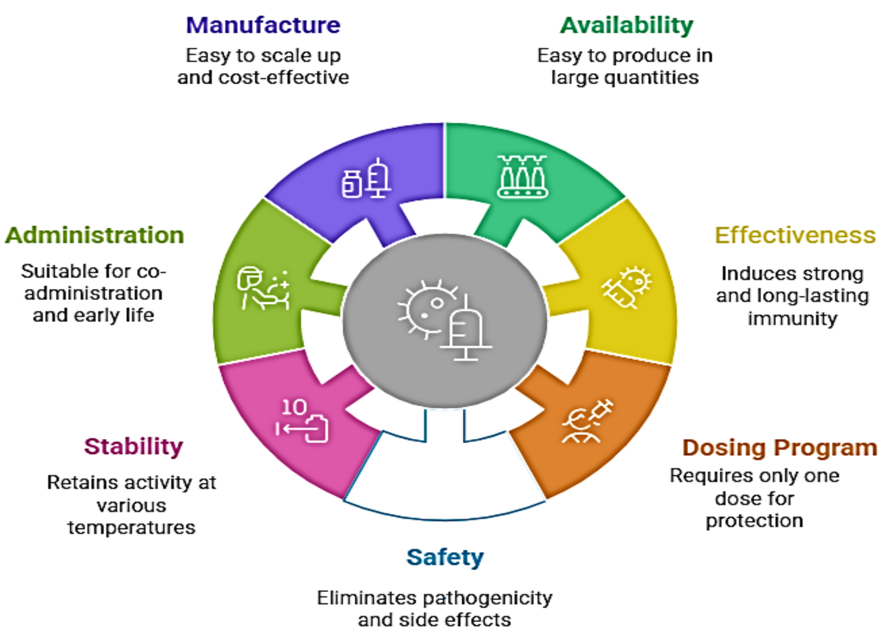

Figure-1: Properties of vaccines.

2. Components of a Vaccine

The effectiveness, safety, and stability of a vaccine depend largely on its **components**. Each component plays a specific role in ensuring that the vaccine elicits a protective immune response, remains stable during storage, and is safe for administration. Understanding the components of vaccines is essential for students of biotechnology.

Vaccines typically consist of several components including **antigens, adjuvants, , stabilizers, antibiotics ,preservatives ,surfactants, residual substances, and diluents**, with explanations of their functions, types, mechanisms of action, and examples.

A typical vaccine contains several key components:

1- Antigens

- Antigens are the active ingredients in vaccines that trigger the immune system to recognize and respond to specific pathogens, such as viruses or bacteria.
- They can be whole organisms that have been weakened or killed (inactivated vaccines) or fragments of the pathogen, such as proteins or sugars (subunit vaccines) derived from a pathogen (bacterium or virus) or produced using recombinant DNA technology.

2. Adjuvants

An ***adjuvant*** (from the Latin, *adjuvare*, “to help”) is a substance that, when mixed with an immunogen, enhances the immune response against the immunogen.

Interest in the identification of adjuvants for use with vaccines is growing because many new vaccine candidates lack sufficient immunogenicity

They have been utilized for many years, primarily in inactivated (killed) vaccines, to encourage the immune system's reaction to vaccine components. By adding adjuvants to vaccines, manufacturers find to not only amplify but also accelerate and prolong the specific immune response elicited by vaccine antigens.

❖ Adjuvant mechanisms include :

(1) Increasing the biological or immunological half-life of vaccine antigens

(2) Increasing the production of local inflammatory cytokines.

(3) Improving antigen delivery and antigen processing and presentation by APCs, especially the dendritic cells.

❖ Types of Adjuvant :

- **Aluminum Salts (Alum):** Most widely used adjuvant, Examples: aluminum hydroxide, aluminum phosphate
- **Oil-in-Water Emulsions:** Examples: MF59, AS03.
- **Toll-Like Receptor (TLR) Agonists:** Examples: Double-stranded RNA analogs ,lipopeptides.

3.Stabilizers:

Stabilizers play a crucial role in maintaining the potency and effectiveness of vaccines, especially during storage and transportation.

This is particularly important in regions where the cold chain, the system for storing and transporting vaccines at optimal temperatures, may be variable or unreliable. Without proper stabilization, vaccines can experience degradation, leading to a loss of antigenicity and a decrease in the ability to induce immunity, particularly in the case of live attenuated vaccines (LAVs).

Several factors can influence the stability of vaccines, **including temperature fluctuations and the pH level of the vaccine**. To counteract these destabilizing factors, stabilizing agents are added to vaccine formulations. For example, in oral poliovirus vaccine (OPV), magnesium chloride ($MgCl_2$) serves as a stabilizing agent, while magnesium sulfate ($MgSO_4$) is used in measles vaccines. Other common stabilizers include lactose-sorbitol and sorbitol-gelatin.

4.Antibiotics

Used during the manufacturing phase to prevent bacterial contamination of tissue culture cells in which viruses are grown. Usually only trace amounts appear in vaccines, for example, MMR and IPV vaccines each contain less that 25 Micrograms of neomycin per dose.

5.Preservatives

Preservatives prevent microbial contamination during storage and multi-dose vial use. Their primary role is to prolong the shelf life of the vaccine and preserve its sterility, particularly once the vial has been accessed for multiple administrations. In addition to preventing microbial growth, preservatives contribute to maintaining the integrity and efficacy of vaccines throughout their storage and usage.

Thiomersal and phenol represent common preservatives employed in certain vaccines.

6. Surfactants (Emulsifiers)

Surfactants prevent aggregation of vaccine components and maintain uniform distribution. **Examples**: Polysorbate 80 ,Triton X-100.

7. Residual Substances from Manufacturing

During vaccine production, small traces of materials used in the manufacturing process may remain. These residuals include antibiotics (neomycin, streptomycin) administered during production to prevent bacterial contamination, along with residual proteins (Egg proteins) or DNA fragments from cell cultures.

8. Diluents

Diluents are sterile liquids used to reconstitute freeze-dried vaccines to injectable form before administration and maintain sterility. **Examples**: Sterile water for injection and Normal saline.

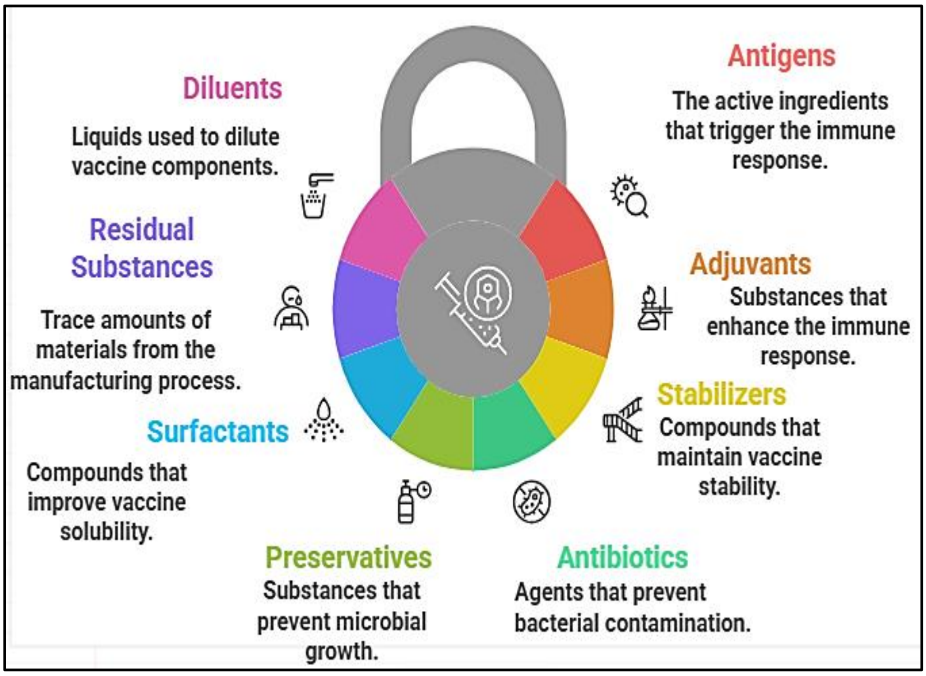

Figure-2: Components of vaccines.

TABLE -1: Adjuvants: Currently Licensed for Use in the United States

Adjuvant Name (Year Licensed)	Adjuvant Class	Components	Vaccines (Disease)
		Adjuvants licensed for use in human vaccines	
Alum*(1924)	Mineral salts	Aluminum phosphate/Aluminum hydroxide	Various
MF (Novartis; 1997)	Oil in water emulsion	Squalene, polysorbate 80 (Tween 80; ICI Americas), sorbitan trioleate (Span 85; Croda International)	Fluad (seasonal influenza), Aflunov (prepandemic influenza)
AS03 (GlaxoSmithKline; 2009	Oil in water emulsion	Squalene, Tween 80, α-tocopheral	Pandremix (pandemic influenza), Prepandrix (pre-pandemic influenza)
Virosomes (Berna Biotech; 2000	Liposomes	Lipids, hemagglutinin	Inflexal (seasonal influenza), Epaxal (hepatitis A)
AS04* (GlaxoSmithKline; 2005)	Alum-absorbed TLR4 agonist	Aluminum hydroxide, MPL	Fendrix (hepatitis B), Cervarix (human papilloma virus)
		Adjuvants being tested in clinical trials but not licensed for use	
Cp 7909, CpG 1018	TLR agonist	CpG oligonucleotides alone or combined with alum/emulsions	—
Imidazoquinolines	TLR7 and TLR8 agonists	Small molecules	—
PolyI:C	TLR3 agonist	Double-stranded RNA analogs	—
Pam3Cys	TLR2 agonist	Lipopeptide	—
Flagellin	TLR5 agonist	Bacterial protein linked to antigen	—
Iscomatrix	Combination	Saponin, cholesterol, dipalmitoylphosphatidylcholine	—
AS01	Combination	Liposome, MPL, saponin (QS21)	—
AS02	Combination	Oil in water emulsion, MPL, saponin (QS21)	
AF03	Oil in water emulsion	Squalene, Montane 80, Eumulgin B1 PH	—
CAF01	Combination	Liposome, DDA, TDB	—