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# Pharmacoepidemiology and Drug Safety with Special Reference to Vaccines and Biologicals used as Diagnostics

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# Abstract

Different kinds of vaccines from conventional to molecular types are nowadays manufactured to combat infections. But it is the owner of livestock who should determine the potential form of the same which may prove helpful as prophylactic measure against various diseases. Judgment about the effectiveness of a vaccine type depends upon its compatibility, administration route and dose, cost effectiveness and maintenance of proper cold chain.

Keywords: Diseases; Effectiveness; Livestock; Vaccines

# Introduction

Vaccines are the biological preparations which can be therapeutic or preventive to various kinds of infections. It helps to boost the resistance of the host by invading against the pathogenic microorganisms which affect the host to lower its immune response.

Different kinds of vaccines from conventional to molecular types are nowadays manufactured to combat mainly viral infections in fishes. But it is the owner of fish farm who should determine the potential form of the same which may prove helpful as prophylactic measure against various diseases. Judgment about the effectiveness of a vaccine type depends upon its compatibility, administration route and dose, cost effectiveness and maintenance of proper cold chain [1].

# Types

Vaccines can be of various types, viz., live virus vaccines, live attenuated or inactivated virus vaccines and protein vaccines. Killed virus vaccines are of another category which contain virulent microorganisms made inactivated or killed by the use of chemical or heat. Examples are the Influenza (flu), cholera, bubonic plague, polio and hepatitis A vaccines.

Large numbers of such vaccines are available. Some of the examples are GTV and tisue culture vaccines of rinderpest,  $R_2B$  vaccine of Newcastle disease, fowl pox and sheep pox vaccines. In siome diseases, temperature sensitive mutant strains are used as vaccines. A large number of viral inactivated vaccines are used in animals and birds. The examples are IBR, FMD, sheep pox, equine influenza and hog cholera vaccines.

# Naturally occurring virulent virus vaccines

There are some examples of this type of vaccines. Virulent herpes turkey virus is used in chickens to control Marek's disease. Herpes turkey virus is antigenically similar to Marek's disease virus and is not pathogenic to chickens. Pigeon po virus may be used as first dose in chickens against fowl pox. This is preferred especially for layers to avoid any reaction. Goat tissue vaccine (GTV) was available previously to control rinderpest in cattle, vaccination was done with virulent rinderpest virus along with rinderpest hyperimmune serum to minimize reaction (serum-virus simultaneus vaccine). To control rotavirus infection in pigs, bovine rotavirus can be used as vaccine. In some diseases, virulent virus can be ginven by unnatural routes. In case of infectious laryngotracheitis (ILT) of chickens virulent virus is given by cloacal route. Orf live virus is injected in sheep in inguinal region. To control contageous bovine pleuropneumonia (CBPP), the injection of live organisms is given in caudal fold region of tail.

Attenuated live virus vaccines can also be obtained by employing the technique of genetic engineering. In the viral genome, the gene which is responsible for virulence is excised and removed. The virus without the gene respnsible for virulence can be usd as attenuated live virus vaccine. Pseudorabies virus vaccine for swine has been obtained by removing thymidine kinase (TK) gene which is responsible for its virulence.

# Virus vectored vaccine

This is a new approach of immunization in human beings and animlas. In this approach, the genes of viruses respinsible for protective antigens are introduced in the genome of large viruses which can be used as vectors. Viruses used as vectors may be fowl pox, vaccinia, herpes and adenoviruses. It should be ensured that the vectored vaccine replicates and does not cause any untoward reaction in the vaccinated animal. As an example, the genes of rabies virus responsible for protective antigens have successfully been incorporated into the genome of vaccinia virus which has been used as a vaccine to immunize animals against rabies.

Under normal circumstances, virulent viruses cannot be used as vaccines. To make them safe for animal vaccination, the viruses are inactivated by physical and chemical agents. Physically, heat or ultraviolet rays are used to kill the viruses. These agents should inactivate the virus without denaturing the proteins acting as antigens. The pH and ionic environment of the medium also affects the rate of heat inactivation of the viruses.

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Commonly used chemical agents for viruse inactivation are formldehyde, beta-propiolactone, and ethylamine. Formaldehyde in a proper dilution, say 1:4000 is used for inactivation of the virus at 37°C until there is no residual infectivity and it maintains antigenicity and immunogenicity. Beta-propiolactone is considered to be a good inactivating agentas it is hydrolysed completely within hours to nontoxic products. The drawbacks of inactivated vaccines are the use of alrgerand repeated doses to maintain immunogenicity.

#### **Experimental vaccines**

Virus subunit vaccine: Whole virion does not act as antigen but only the epitope portion on the protein surface of the virus acts as antigen for antibody production. It is desirable to include only the antigenic or the epitopic portion of the virus surface in the vaccine and discard the remaining portion of the virus. Protein subunit of microorganism (which would constitute a 'whole-agent' vaccine), the epitope portion of it can induce an immune response. The type of vaccines is highly specific in nature. One of the disadvantages of sub-unit vaccines is that it is lowly immunogenic and needs an adjuvant. Recombinant subunit vaccines are in use for infectious pancreatic necrosis (IPN).

**DNA vaccine:** Viral genes or antigenic proteins are excised and cloned in prokaryotic cells by recombinant DNA technology. When these genes are expressed in prokaryotic cells, the resultant proteins are harvested from host cells and used as vaccine in the concerned species of animals. DNA vaccines against Infectious hepatic necrosis (IHN) and Vibrio infection, VHN are under developmental and experimental stages.

**Synthetic peptide vaccine:** The amino acid sequences of viral peptides are determined first and then antigenic sites (epitopes) are located on the proteins. It is then possible to synthesize short peptides

corresponding to antigenic determinants to which neutralizing antibodies bind [1].

## **Other Types of Vaccines**

## **Conjugate vaccines**

Certain bacteria have polysaccharide outer coats that are poorly immunogenic. By linking these outer coats to proteins (e.g. toxins), the immune system can be led to recognize the polysaccharide as if it were a protein antigen. This approach is used in the *Haemophilus influenzae* type B vaccine.

#### Adjuvants

Various substances have been added to vaccines and certain formulations have been devised in an attempt to render vaccines more effective. Aluminum salts have gained acceptance as human vaccine adjuvants and even veterinary vaccines are largely dependent upon the use of aluminum salts. Currently, many new vaccines are under development and there is a desire to simplify vaccination schedules both by increasing the number of components per vaccine and decreasing the number of doses required for a vaccine course [2].

#### Conclusion

Proper schedule of administration, route of administration, effectiveness, maintenance of cold chain and cost efficiency are some of the primary governing factors for use of any vaccine.

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