THE REALITIES: VACCINES

Vaccine Composition

Vaccines are designed to provide protection against a disease without the risks or complications of the disease itself. The composition of the vaccine may vary from a weakened strain of an otherwise infective agent, such as an attenuated virus, to a non-infectious component of the infective agent, as described in Section 1 below. In addition to containing a modified form of the bacteria, virus or toxin that induces immunity against a specific disease, some vaccines contain other substances that are either added during the manufacturing process or are residual components that remain as a result of the way in which the vaccine is manufactured. These are described below in Sections 2 and 3.

1. Bacteria and viruses

The great majority of current vaccines protect against either viruses or bacteria and are made in the following ways:

Attenuate the virus

The live viruses used in vaccines are weakened (or attenuated) so that they reproduce themselves in only a very limited way inside the body. Examples of live attenuated viral vaccines are the measles, mumps, rubella, varicella and rotavirus vaccines. Fully potent viruses (known as natural or 'wild type' viruses) cause disease by reproducing themselves many thousands or millions of times in the body's cells. However, vaccine viruses usually reproduce fewer than 20 times. Vaccine viruses replicate just well enough to induce the immune system to produce protective antibodies and to make very long-lived 'memory B cells' that remember the infection and produce more antibodies if the natural infectious virus is subsequently encountered.

The advantage of live, attenuated vaccines is that only one or two doses usually provide immunity that is lifelong. The limitation of this approach is that these vaccines cannot be given to people with *severely* impaired immunity, as a greatly weakened immune system may not be able to limit the reproduction of the vaccine virus.

Inactivate the virus

Some viruses in vaccines are completely inactivated (or killed) with a chemical, often formaldehyde. The virus or part of the virus that is killed cannot possibly reproduce itself or cause disease. The inactivated polio and hepatitis A vaccines are made this way. The advantage is that the virus is still recognised by the body's immune system.

The strength of this approach is that the vaccine does not cause even a mild form of the disease that it prevents, and therefore these vaccines can be given to people with impaired immunity. The limitation of this approach is that sometimes several doses must be given to achieve immunity, and persons with impaired immunity may not respond to even multiple doses.

Use part of the virus or bacterium

The part of the virus or bacterium required to 'induce immunity' is identified and separated from the part which causes disease symptoms. The hepatitis B, *Haemophilus influenzae* type b (Hib), and human papillomavirus (HPV) vaccines are examples. In the case of hepatitis B, the vaccine is composed of a protein that resides on the surface of the virus. In the case of the Hib vaccine, only the outer coat or polysaccharide is used, joined on to a protein so that the immune system responds to it.

These vaccines can be given to people with impaired immunity, although this is not always recommended if the person's immune system is too weak to develop a good response.

Use a toxin produced by the bacteria

Some vaccines are manufactured by taking specific bacterial toxins and inactivating them with a chemical. The toxin, chosen because it causes the most serious manifestations of the particular disease, is called a toxoid once it is inactivated in the vaccine. Diphtheria and tetanus vaccines are made from toxoids. In the case of tetanus, very little toxin is sufficient to cause disease and even having tetanus disease does not induce protective antibody. The only way to be protected against tetanus is to be vaccinated using several doses of tetanus toxoid.

2. Additives

Additives are used to stabilise vaccines in adverse conditions (temperature extremes of heat and freeze drying) and to prevent the vaccine components adhering to the side of the vial. Examples of additives include lactose and sucrose (both sugars), glycine and monosodium glutamate (both are amino acids or salts of amino acids), human or bovine serum albumin (both are examples of proteins), and gelatin. They are required to ensure that safe and effective doses of the vaccine are available.

Stabilisers

Some vaccines contain stabilisers to keep them safe and effective under different conditions or different temperatures. Gelatin and lactose-sorbitol are examples of stabilisers.

Adjuvants

Adjuvants are chemicals added to vaccines to enhance immunity. Various forms of aluminium salts are commonly used as adjuvants in vaccines. A recent review of all available studies of aluminium-containing diphtheria, tetanus and pertussis vaccines (either alone or in combination) found that there was no evidence that aluminium salts in vaccines cause any serious or long-term adverse events.

Diluents

A diluent is a liquid used to dilute a vaccine to the proper concentration. In vaccines, this is usually saline or sterile water.

Preservatives

Preservatives are included in some vaccines to prevent fungal or bacterial contamination of the vaccine. Preservatives are mostly used in vaccines that are manufactured as multidose vials. However, in Australia, multidose vials are not routinely used. Examples of preservatives are thiomersal (also spelt thimerosal), phenoxyethanol, and phenol. Thiomersal is a mercury-containing compound and is discussed in more detail in the section "Safety Concerns: General". Phenoxyethanol (a thiomersal alternative) is an aromatic ether alcohol and is also used as a preservative in cosmetics.

3. Remnants from manufacturing

Chemicals are often used during the vaccine manufacturing process and then removed from the final product. For example, formaldehyde might be used to kill a vaccine virus, or antibiotics might be used to prevent bacterial contamination while growing viruses in the laboratory. When these chemicals are removed, sometimes a trace amount may remain. While some of these chemicals might be harmful in large doses, the trace amounts left in vaccines are too small to have a toxic effect.

Further Reading

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