



THE
IMMUNIZATION
PARTNERSHIP

How Vaccines Work Pre-recorded Webinar Script

Slide 1:

Hello and Welcome to The Immunization Partnership presentation on How Vaccines Work.

Slide 2:

Today we will be covering how vaccines work in the human body, the different types of vaccines available, how vaccines are approved in the US, and why vaccines are so important for our communities.

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Vaccines work by using weakened versions of the disease, infection or sometimes something that these diseases make, like a protein or toxin. If you were exposed to these without vaccination, you might get sick or have major issues. But because the vaccine version is weakened, it's much, much safer. And often the worst side effects that people experience is a fever, headache or a sore arm where the vaccine was injected.

It's like training your army before the war begins. If you are scrambling to get your soldiers ready in the heat of battle, you are going to suffer casualties. Vaccines help our body's defenses, known as the immune system, know what to look for. The body then make antibodies to fight specific diseases and infections. So that when you really are exposed to them, you're already prepared. The body can defeat these diseases before they can spread throughout your body or cause much harm.

Throughout this webinar we will do a deeper dive in how the vaccines work in our bodies.

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Before we get into how the vaccines work I want to cover important terminology.

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Pathogen:

In biology, a pathogen in the oldest and broadest sense, is anything that can produce disease. A pathogen may also be referred to as an infectious agent, or simply a germ.

The term pathogen came into use in the 1880s.

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The immune system is the body's defense against infectious organisms and other invaders. Through a series of steps called the immune response, the immune system attacks organisms and substances that invade body systems and cause disease.

The immune system is made up of a network of cells, tissues, and organs that work together to protect the body. One of the important cells involved are white blood cells, also called leukocytes, which come in two basic types that combine to seek out and destroy disease-causing organisms or substances.

Leukocytes are produced or stored in many locations in the body, including the thymus, spleen, and bone marrow. For this reason, they're called the lymphoid organs. There are also clumps of lymphoid tissue throughout the body, primarily as lymph nodes, that house the leukocytes.

The leukocytes circulate through the body between the organs and nodes via lymphatic vessels and blood vessels. In this way, the immune system works in a coordinated manner to monitor the body for germs or substances that might cause problems.

The two basic types of leukocytes are:

- phagocytes, cells that chew up invading organisms

- lymphocytes, cells that allow the body to remember and recognize previous invaders and help the body destroy them

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In immunology, antigens (Ag) are structures specifically bound by antibodies (Ab) or a cell surface version of Ab ~ B cell antigen receptor (BCR). The term antigen originally described a structural molecule that binds specifically to an antibody only in the form of native antigen. It was expanded later to refer to any molecule or a linear molecular fragment after processing the native antigen that can be recognized by T-cell receptor (TCR). BCR and TCR are both highly variable antigen receptors diversified by somatic V(D)J recombination. Both T cells and B cells are cellular components of adaptive immunity.

The antigen may originate from within the body ("self-antigen") or from the external environment ("non-self"). The immune system is supposed to identify and attack "non-self" invaders from the outside world or modified/harmful substances present in the body and usually does not react to self-antigens under normal homeostatic conditions due to negative selection of T cells in the thymus.[5]

Vaccines are examples of antigens in an immunogenic form, which are intentionally administered to a recipient to induce the memory function of adaptive immune system toward the antigens of the pathogen invading that recipient.

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Helper cell is a T cell that influences or controls the differentiation or activity of other cells of the immune system. They play an important role in the immune system, particularly in the adaptive immune system. Helper T cells are arguably the most important cells in adaptive immunity, as they are required for almost all adaptive immune responses.

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An antibody is a large, Y-shaped protein produced mainly by plasma cells that is used by the immune system to neutralize pathogens such as pathogenic bacteria and viruses. The antibody recognizes a unique molecule of the pathogen, called an antigen, via the fragment antigen-binding (Fab) variable region. Each tip of the "Y" of an antibody contains a paratope (analogous to a lock) that is specific for one particular epitope (similarly, analogous to a key) on an antigen, allowing these two structures to bind together with precision. Using this binding mechanism, an antibody can tag a microbe or an infected cell for attack by other parts of the immune system, or can neutralize its target directly (for example, by inhibiting a part of a microbe that is essential for its invasion and survival). Depending on the antigen, the binding may impede the biological process causing the disease or may activate macrophages to destroy the foreign substance.

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Now we are going to review how a disease enters the body.

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Most germs enter the body through the air in sneezes, coughs, or even breaths. Germs can also spread in sweat, saliva, and blood. Some pass from person to person by touching something that is contaminated, like shaking hands with someone who has a cold and then touching your own nose.

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When a germ enters the body your immune system immediately recognizes there is a foreign.

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An antigen from the pathogen then attached and as you can see here the health begins to decrease.

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The help cell then comes to the rescue!

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However, the body does not yet have any antibodies to this new pathogen. And the antigen binds to the helper cell.

Slide 16:

The helper cell then takes the antigen to try and create an antibody to the new pathogen.

Slide 17:

But the pathogen is able to replicate because there were no antibodies to fight the pathogen. The person is now sick.

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Now we are going to look at what happens in the body when we have vaccines.

Slide 19:

A vaccine works by training the immune system to recognize and combat pathogens, either viruses or bacteria.

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When we get a vaccine it enters the body with the antigen and the immune system recognizes that it has entered the body.

Slide 21:

The immune system then takes those antigens from the vaccine.

Slide 22:

And brings it to the helper cell

Slide 23:

The helper cell then takes the antigens

Slide 24:

And creates an antibody

Slide 25:

Which then replicate to protect the body.

Slide 26:

Now when a pathogen enters the body that has already received a vaccine, the body knows exactly how to fight it and keep it from making it sick.

Slide 27:

The antibodies bind to the antigens

Slide 28:

And destroy the pathogen and maintaining the health of the body!

Herd Immunity

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Now we will review why having more of our population vaccinated is important in preventing the spread of vaccine preventable diseases.

Herd Immunity or Community is the resistance to the spread of a contagious disease within a population that results if a sufficiently high proportion of individuals are immune to the disease, especially through vaccination.

We will quickly walk through what it looks like when a community is unvaccinated and when a community is vaccinated.

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This is an unvaccinated community.

Slide 31:

A vaccine preventable disease has entered a community. Let see how quickly it spreads...

Slide 32:

As you can see we now have wide-spread disease throughout this unvaccinated community.

Slide 33:

Now lets looks at a vaccinated community

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Here you can see a disease has entered a fully vaccinated community... Let's see how it spreads

Slide 35:

As you can see we have minimal spread of the vaccine preventable disease. Only one other person became ill.

Slide 36:

Now lets look at then a community has more of its population vaccinated.

As you can see here the green dots represent the vaccinated and the blue dots represent the unvaccinated.

Slide 37:

Here a vaccine preventable disease has entered a community... Let's see how it spreads when more of the population is vaccinated.

Slide 38:

We have minimal disease spread!

Slide 39:

The community achieved herd immunity and is protected.

Types of Vaccines

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Now that we have gone over how vaccines work and why herd immunity is so important we are going to review the different types of vaccines available.

There are 3 main types – Live-attenuated, Inactivated and sub-unit/conjugate.

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An attenuated vaccine is a vaccine created by reducing the virulence of a pathogen, but still keeping it viable. Attenuation takes an infectious agent and alters it so that it becomes harmless or less virulent.

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Benefits

- Closest thing to a natural infection
- Often confer lifelong immunity with only one or two doses

Risks

- An attenuated microbe in the vaccine could revert to a virulent form and cause disease
- Not everyone can safely receive live, attenuated vaccines
- Usually need to be refrigerated to stay potent

Currently available live attenuated viral vaccines are measles, mumps, rubella, vaccinia, varicella, zoster (which contains the same virus as varicella vaccine but in much higher amount), yellow fever, rotavirus, and influenza (intranasal).

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An inactivated vaccine is a vaccine consisting of virus particles, bacteria, or other pathogens that have been grown in culture and then lose disease producing capacity.

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Toxoid vaccines are based on the toxin produced by certain bacteria (e.g. tetanus or diphtheria). The toxin invades the bloodstream and is largely responsible for the symptoms of the disease. The protein-based toxin is rendered harmless (toxoid) and used as the antigen in the vaccine to elicit immunity.

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Benefits

- More stable and safer than live vaccines.
- Usually don't require refrigeration
- Risks
- Stimulate a weaker immune system response than do live vaccines
- Likely take several additional doses, or booster shots, to maintain a person's immunity

Types of inactive vaccines in the US

- Hepatitis A
- Flu (shot only)
- Polio (shot only)
- Rabies

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Subunit, recombinant, polysaccharide, and conjugate vaccines use specific pieces of the germ — like its protein, sugar, or capsid (a casing around the germ). Because these vaccines use only specific pieces of the germ, they give a very strong immune response that's targeted to key parts of the germ.

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Benefits

- chances of adverse reactions to the vaccine are lower

Risks

- Likely take several additional doses, or booster shots, to maintain a person's immunity

Types of inactive vaccines in the US

- Hib (*Haemophilus influenzae* type b) disease
- Hepatitis B
- HPV (Human papillomavirus)
- Whooping cough (part of the DTaP combined vaccine)
- Pneumococcal disease
- Meningococcal disease
- Shingles

How Vaccines are approved

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Now we are going to go into the process of vaccine approval in the US.

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Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers.

The vaccine is only licensed if:

- It's safe and effective.
- The benefits outweigh risks.

The phases of clinical research are the steps in which scientists do experiments with a health intervention in an attempt to find enough evidence for a process which would be useful as a medical treatment. Or in this case the vaccines we give.

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Before beginning a phase I trial, the sponsor must submit an [Investigational New Drug](#) application to the FDA detailing the preliminary data on the drug gathered from cellular models and animal studies.

Phase I trials are the first stage of testing in human subjects.^[6] They are designed to test the safety, side effects, best dose, and formulation method for the drug.

Normally, a small group of 20–100 healthy volunteers will be recruited.^{[2][6]} These trials are often conducted in a clinical trial clinic, where the subject can be observed by full-time staff. These clinical trial clinics are often run by [contract research organization](#) (CROs) who conduct these studies on behalf of [pharmaceutical companies](#) or other research investigators. These studies are usually conducted in tightly controlled clinics called CPUs (Central Pharmacological Units), where participants receive 24-hour medical attention and oversight.

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Phase II trials are performed on larger groups (100–300) and are designed to assess how well the drug works, as well as to continue Phase I safety assessments in a larger group of volunteers and patients. When the development process for a new drug fails, this usually occurs during Phase II trials when the drug is discovered not to work as planned, or to have adverse effects.

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This phase is designed to assess the effectiveness of the new intervention and, thereby, its value in clinical practice.^[1] Phase III studies are randomized controlled **multicenter trials** on large patient groups anywhere from 300–3,000 and are aimed at being the definitive assessment of how effective the drug is, in comparison with current 'gold standard' treatment. Because of their size and comparatively long duration, Phase III trials are the most expensive, time-consuming and difficult trials to design and run, especially in therapies for **chronic** medical conditions.

Once a drug has proved satisfactory after Phase III trials, the trial results are usually combined into a large document containing a comprehensive description of the methods and results of human and animal studies, manufacturing procedures, formulation details, and shelf life. This collection of information makes up the "regulatory submission" that is provided for review to FDA. They will review the submission, and, it is hoped, give the sponsor approval to market the drug. The FDA will then pass along the data to The Advisory Committee on Immunization Practices and the National Vaccine Advisory Committee for review and recommendations.

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The Advisory Committee on Immunization Practices, is a committee within the United States Centers for Disease Control and Prevention that provides advice and guidance on effective control of vaccine-preventable diseases in the U.S. civilian population.

The ACIP was established in 1964 by the US Surgeon General to assist in the prevention and control of communicable diseases, it recommends licensed new vaccines to be incorporated into the routine immunization schedule, recommends vaccine formulations, and reviews older vaccines to consider revising its recommendations.^[1]

Both private insurers in the United States and the federal government use ACIP recommendations to determine which vaccines they will pay for

Regularly scheduled ACIP meetings are held three times a year. Notices of each meeting, along with agenda items, are published in the **Federal Register** in accordance with the requirements of the **Federal Advisory Committee Act** (FACA). A vote on vaccine recommendations may be taken when a quorum of at least eight eligible ACIP members are present. Eligible voters are those members who do not have a **conflict of interest**. If there are not eight eligible voting members present, the ACIP executive secretary can temporarily designate ex officio members as voting members, as provided in the committee charter.^[3] Meetings are advertised and open to the public, and are now available online via webcast. The minutes of each meeting are available on the CDC website within 90 days of the conference.

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Established in 1987, the National Vaccine Advisory Committee (NVAC) recommends ways to achieve optimal prevention of human infectious diseases through vaccine development, and provides direction to prevent adverse reactions to vaccines. This advice is presented to the Assistant Secretary for Health who serves as the Director of National Vaccine Program on matters related to program responsibilities.

Functions of NVAC

Studies and recommends ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States.

Recommends research priorities and other measures the Director of the National Vaccine Program should take to enhance the safety and efficacy of vaccines.

Advises the Director of the Program in implementation of sections 2102 and 2103 of the Public Health Service Act.

Identifies the most important areas of government and non-government cooperation that should be considered in implementing sections 2102 and 2103 of the Public Health Service Act.

These two committees are essential to reviewing and advising the states on the recommended vaccines.

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Thank you so much for listening! If you have additional questions please feel free to email info@immunizeUSA.org.