

# The Principles of Vaccines

Chapters 1-4 (CDC pink book)

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## What are vaccines?

Antigenic material injected into a host to elicit an immune response.  
Vaccination is the production of active immunity produced by a vaccine.

As Pharmacists it is important to learn about vaccines:

- It is an important health care issue
- You can raise awareness about the importance of vaccination
- Vaccine safety
- Changing recommendations
- Address misinformation
- Be aware of recalls and new vaccines

## Why Immunize?

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Some viral diseases don't have any other cure or treatment

Vaccines work! The widespread use of vaccines has reduced the peak-level of incidence of different viral diseases in the US by  $\geq 95\%$

Immunizing also indirectly protects other people such as infants or those with contraindications

It saves lives

Ex. Measles

Before 1963 there were >500,000 cases/yr and  
400-500 deaths/yr

Now, ~85 cases/yr

## Reported deaths from vaccine preventable diseases and adverse events reported from vaccines in the US

Disease	Pre-vaccine Era*	2005	% change
Diphtheria	31,054	0	-100
Measles	390,852	66	-99
Mumps	21,342	314	-99
Pertussis	117,998	25,616	-78
Polio (wild)	4,953	0	-100
Rubella	9,941	11	-99
Cong. Rubella Synd.	19,177	1	-99
Tetanus	1,314	27	-98
Invasive Hib Disease**	24,856	144	-99
<b>Total</b>	<b>566,706</b>	<b>26,179</b>	<b>-95</b>
<b>Vaccine Adverse Events</b>	<b>0</b>	<b>15,803</b>	<b>+++</b>

\* Maximum cases reported in pre-vaccine era

\*\* Invasive type b and unknown serotype

## The Perfect Vaccine

- 100% effective
- Oral dosage form
- No adverse effects
- Highly immunogenic
  - life-long immunity from a single dose
  - no boosters required
- Cheap
- Stable at room temperature

## Vaccines vs. Drugs

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Vaccines are different:

- Vaccines have a low rate of market entrance
- It is expensive and difficult to get them approved
- Drugs go to a small number of sick people.
  
- Vaccines are administered to millions of healthy people with some exceptions.
- Decreases in disease risks and increased attention on vaccine risks
- Public confidence in vaccine safety is critical
  - higher standard of safety is expected of vaccines
  - vaccinees generally healthy (vs. ill for drugs)

## Vaccine's Journey to the market

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Laboratory, Animals followed by human testing.

### **Pre-Release:**

Phases I, II, III clinical trials

Effectiveness, side effects and common reactions are identified

Vaccines are tested in thousands of persons before being approved and allowed on the market

### **Post-Release**

Identify rare reactions

monitor increases in known reactions

Identify risk factors for reactions

Identify vaccine lots with unusual rates or types of events

- Phase IV Trials
  - ~10,000 participants
  - better but still limited
- Large-Linked Databases
- Clinical Immunization Safety Assessment Network

## Postlicensure Vaccine Safety Activities

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### **Vaccine Adverse Event Reporting System (VAERS)**

- National reporting system, jointly administered by CDC and FDA
- Passive (depends on healthcare providers and others to report)
- Receives ~15,000 reports per year  
([www.vaers.hhs.gov](http://www.vaers.hhs.gov))

### **Vaccine Safety Datalink (VSD)**

Large-linked database

- Links vaccination and health records
- “Active surveillance”
  - 8 HMOs
  - ~2% of the U.S. population
- Powerful tool for monitoring vaccine safety

## The Provider’s Role

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- Immunization providers can help to ensure the safety and efficacy of vaccines through proper:
  - vaccine storage and administration
  - timing and spacing of vaccine doses
  - observation of contraindications and precautions
  - management of vaccine side effects
  - reporting of suspected side effects to VAERS
  - vaccine benefit and risk communication Opportunities for questions should be provided before each vaccination
- Vaccine Information Statements (VISs)
  - must be provided before each dose of vaccine
  - public and private providers
  - available in multiple languages

## Immunology 101

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- The science of differentiating self from non-self
- Defense against invaders
  - Bacterial
  - Viral
  - Fungal
  - Parasitic

## The immune system is...

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- General and specific
- Innate (natural) and acquired (adaptive)
- Active and passive
  - Natural and artificial
- Cell-mediated and humoral
- Primary and secondary immune responses

## Innate immunity

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- Surface barriers
  - Skin
  - Ciliary action of respiratory epithelia
  - Mucus in respiratory and urogenital tracts
  - Acid pH of skin secretions
  - Lysozyme in tears, saliva, perspiration
  - Extreme acidity of stomach
- Normal flora
  - *Staphylococcus aureus* on skin
  - *E. coli* in gut
  - *Candida* in vaginal tract
  - *Corynebacteria diphtheriae* in laryngeal passage

## Acquired Immunity

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- Cell-mediated - these are lymphocytes
  - T cells
    - TH2 (Helper) CD4+ - activate T and B cells
    - TH1 (DTH) - role in allergies
    - TC (Cytotoxic) CD8- kill cells with foreign Ag on the surface
    - Memory
  - B cells
    - Plasma cells (produce antibodies)
    - Memory B cells

## Immunoglobulins

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- IgA - primary antibody in secretions; half-life ~5 days
- IgM - primary antibody response; half-life 5-10 days
- IgG - secondary antibody response; half-life 21-24 days
- IgD - found on B cell surfaces
- IgE - bound to mast cells; amplifies immune response

## Antibody functions

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- *Opsonization* - coating Antigen with Antibody enhances phagocytosis
- *Steric hindrance* - bind to surfaces of microorganisms and prevent attachment to cells
- *Toxin neutralization*
- *Agglutination and precipitation* - bind to surface of microbes and precipitate them; reduces number of infectious units and enhances phagocytosis
- *Complement activation*
  - induces inflammatory response
  - attracts phagocytes to site of infection
  - opsonizes cells with foreign antigens
  - lyses some bacteria and viruses
- *Antibody-dependent cell cytotoxicity* - IgG enables Natural Killer cells to recognize and kill opsonized target cells

# Immunity

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- Active
  - Produced by one's own immune system, e.g., development and recovery from disease
  - More permanent (years)
- Passive
  - Produced by other humans or animals and infused, injected, ingested or absorbed into recipient
  - Transient (weeks to months)

# Active Immunity

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| <ul style="list-style-type: none"><li>• Natural<ul style="list-style-type: none"><li>– Host produces antibodies in response to infection</li><li>– Host develops protective response to live viral vaccine</li></ul></li></ul> | <ul style="list-style-type: none"><li>• Artificial<ul style="list-style-type: none"><li>– Host produces protective immune response to <i>killed</i> cells, <i>detoxified</i> toxins, etc.</li></ul></li></ul> |
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# Passive Immunity

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- Natural
  - Placental transfer of maternal antibodies (IgG)
  - Transfer of maternal antibodies via nursing (IgA)
- Artificial
  - injection of immune serum from person who has recovered from disease
  - transfusion of hyperimmune serum from animal

## When good things go bad...

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- Allergies
  - Hay fever
  - Delayed-type hypersensitivity
  - Anaphylaxis
- Autoimmunity
  - MS (CNS)
  - Amyotrophic Lateral Sclerosis (ALS;  $\alpha$ -motor neurons of spinal cord)
  - Primary biliary cirrhosis (liver)

# Summary

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