Principles of Communicable Diseases Epidemiology

LECTURE - 4

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It is the system of storage and transportation of the vaccine at low temperature (cold condition) from the manufacture till it is consumed.

System that ensures vaccine :

1. **Potency**
2. **Quality**
3. **Safety**

Importance of cold chain

1. Obtaining the vaccines from the manufacturers
2. Storing and transporting the vaccines
3. Maintaining the supply of vaccines
4. Having information about essential equipments, supply of electricity etc
5. Keeping the vaccine at low temperature
6. Protecting the vaccine from sunlight exposure
7. Maintaining the potency of vaccines.

Importance of cold chain

- **The cold chain is standard practice for vaccines throughout the pharmaceutical industry**

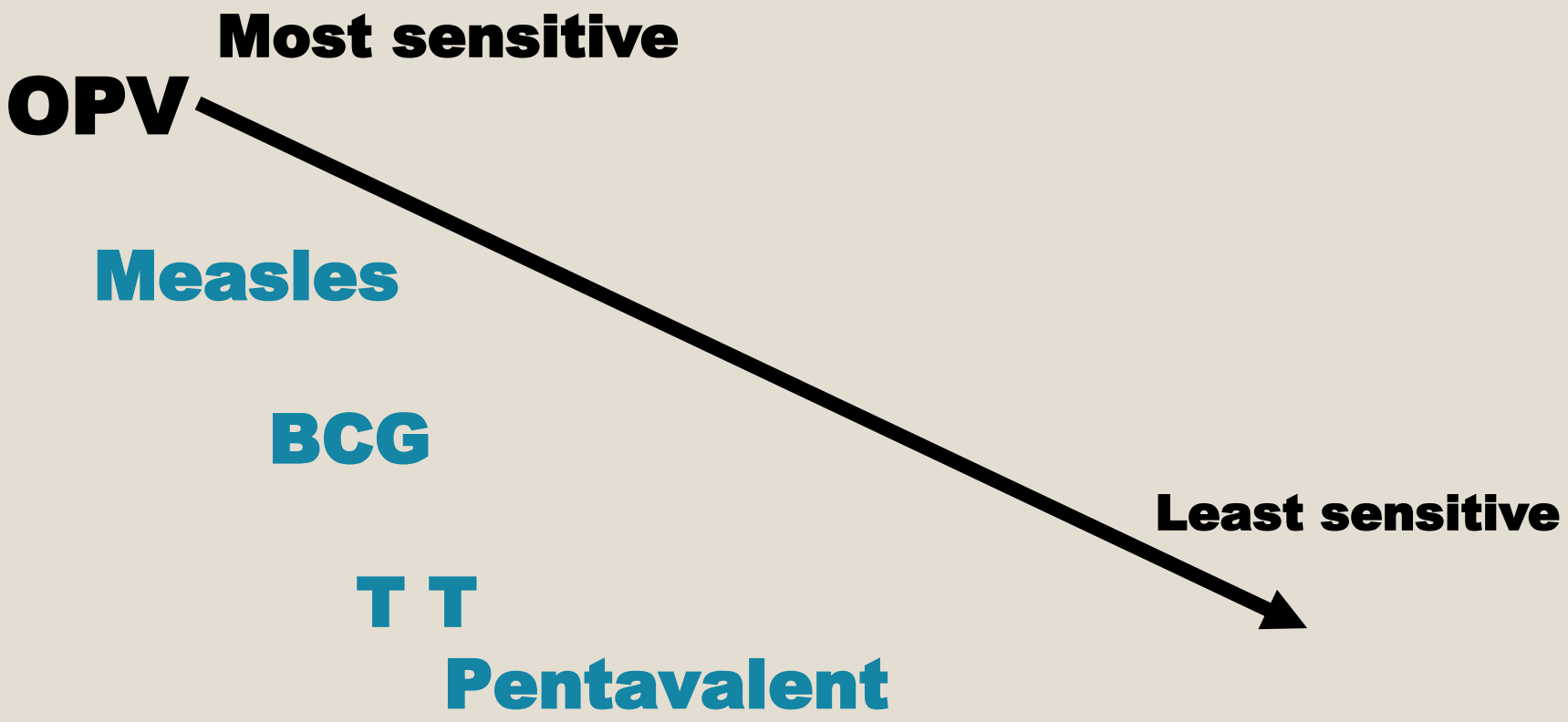
- **Maintaining the cold chain ensures that vaccines are transported and stored according to the manufacturer's recommended temp range +2C to +8C until point of administration**

  - **Polio vaccine is the most sensitive vaccine to heat.**

  - **Live attenuated vaccines are allowed to be frozen (OPV, Measles, MMR and BCG).**

  - **Inactivated vaccines must not be frozen (DPT, DT, dT , TT and HB) .**

Vaccines sensitive to heat



Vaccine sensitivity to freezing

Freeze sensitivity

Most sensitive vaccines

DTaP

DTaP-hepatitis B-Hib-IPV (hexavalent), Hepatitis B

Meningitis C (polysaccharide-protein conjugate)

Pneumococcal (polysaccharide-protein conjugate)

Cautions:

- Never expose these vaccines to zero or subzero temperatures.
- Avoid the use of ice for transport.

WHO recommended vaccine storage conditions

Sensitive to Heat

Most sensitive

- OPV
- Measles
- DTP, yellow fever
- BCG
- Hib,DT

Least sensitive

- Td,TT, Hep B

Sensitive to Cold

Most sensitive

- Hep B
- Hib (liquid)
- DTP
- DT
- DT
- Td

Least sensitive

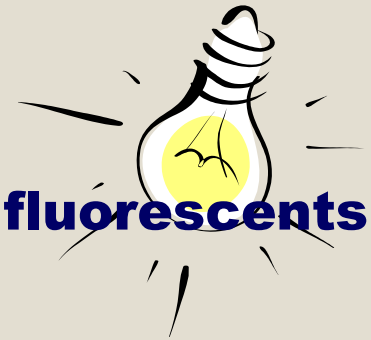
- TT

WHO IVB. Temperature sensitivity of vaccines 2006. *WHO/IVB/06.10*

These vaccines are not damaged by freezing.

Bacillus Calmette- Guérin

Measles, MMR, OPV, Rabies, Rotavirus, Rubella.



Light Sensitive

Sensitive to strong light, sunlight, ultraviolet, fluorescents (neon)

BCG

MMR

Varicella

Meningococcal C Conjugate

Most DTaP containing vaccines

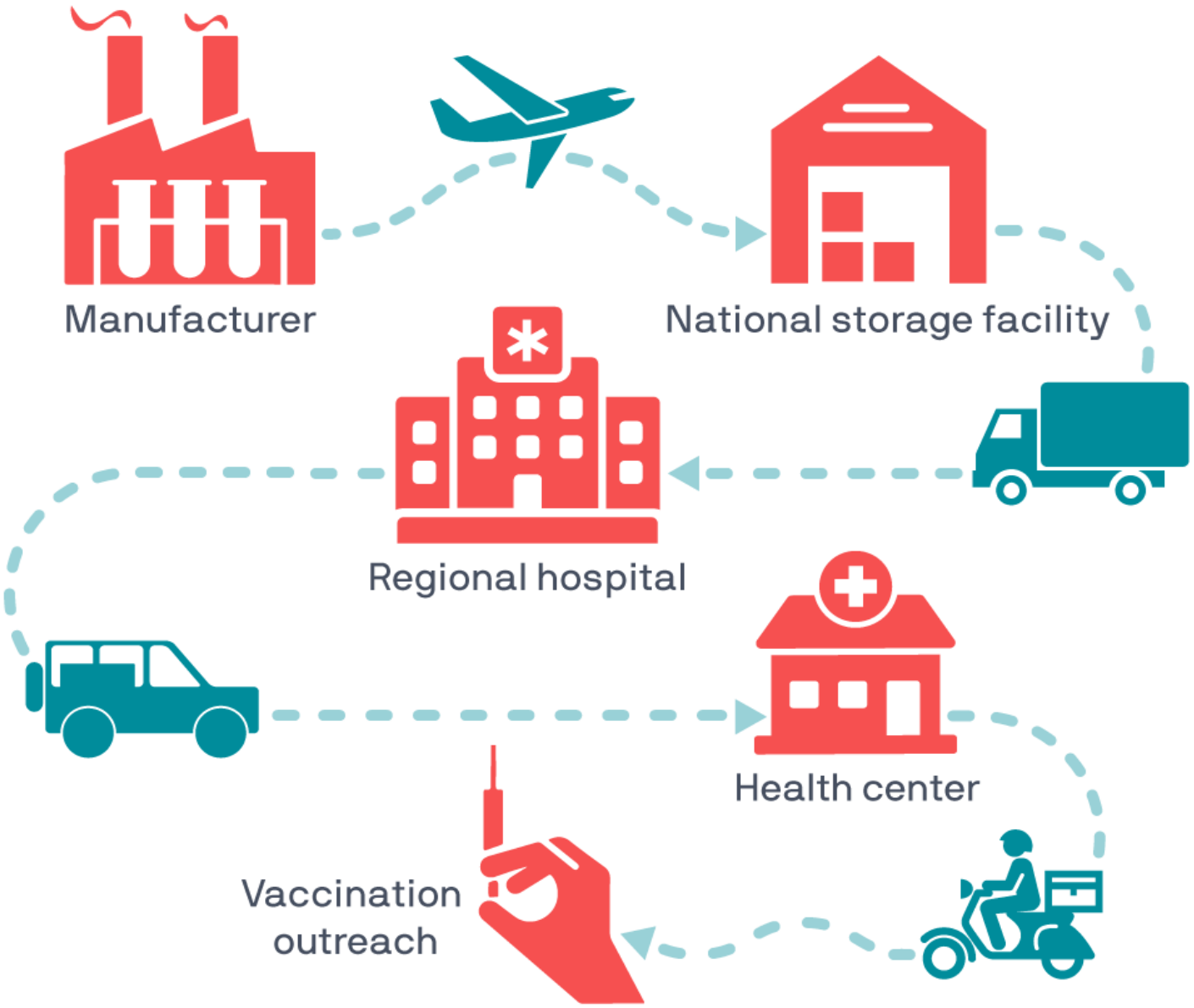
Vaccines should always be stored in their original packaging until point of use to protect them from light.

Serum Institute of India Ltd., India

BCG VACCINE (FREEZE-DRIED) - 20 DOSES

How long is the cold chain?

- Manufacturer to airport; cold storage at airport
- Transport at the correct temperature from airport to storage in central, regional and district stores and in health centers
- Transported at the correct temperature to outreach sites
- Kept at correct temperature during immunization sessions


Manufacturer
National storage facility
Regional hospital
Health center
Vaccination outreach


+2°C to +8°C
URGENT VACCINES
STORE BETWEEN +2°C AND +8°C
°C
+8
+2
DO NOT FREEZE
VACUNA URGENTE NO CONGELAR
يحظر تجميده يرسل فورا لقاح
疫苗速运 请勿冰冻

The administrative levels of cold chain according to the duration of the storage and the temperature required to keep the vaccine potent

The administrative level	Storage period	Temperature	The vaccines
Central & regional stores	Maximum three months	- 20° to- 30°C	OPV, Measles, MMR,BCG
		+2° to +8°C	DPT, DT, dT, TT& HB,Hib
Districts stores& local immunization centers	Maximum one month	0°C to+8°C	OPV, Measles, MMR, BCG
		+2° to +8°C	DPT, DT, dT, TT& HB,Hib

The components of the cold chain

The equipment and tools

The health staff

The procedures

What is the optimum Temperature of the refrigerator in the health center?

+2° C to +8°C


Cold Chain Box
Cold Chain Bag
Vaccine

Refrigeration equipment:

- **Refrigerator**
- **Cold boxes**
- **Vaccine carriers**
- **The ice packs retained in the freezer:**

- To stabilize the temperature of the refrigerator at the optimum level.

- Fully frozen ice-packs are used for lining the vaccines carriers and the cold boxes during storing the vaccines

1-The refrigerator :

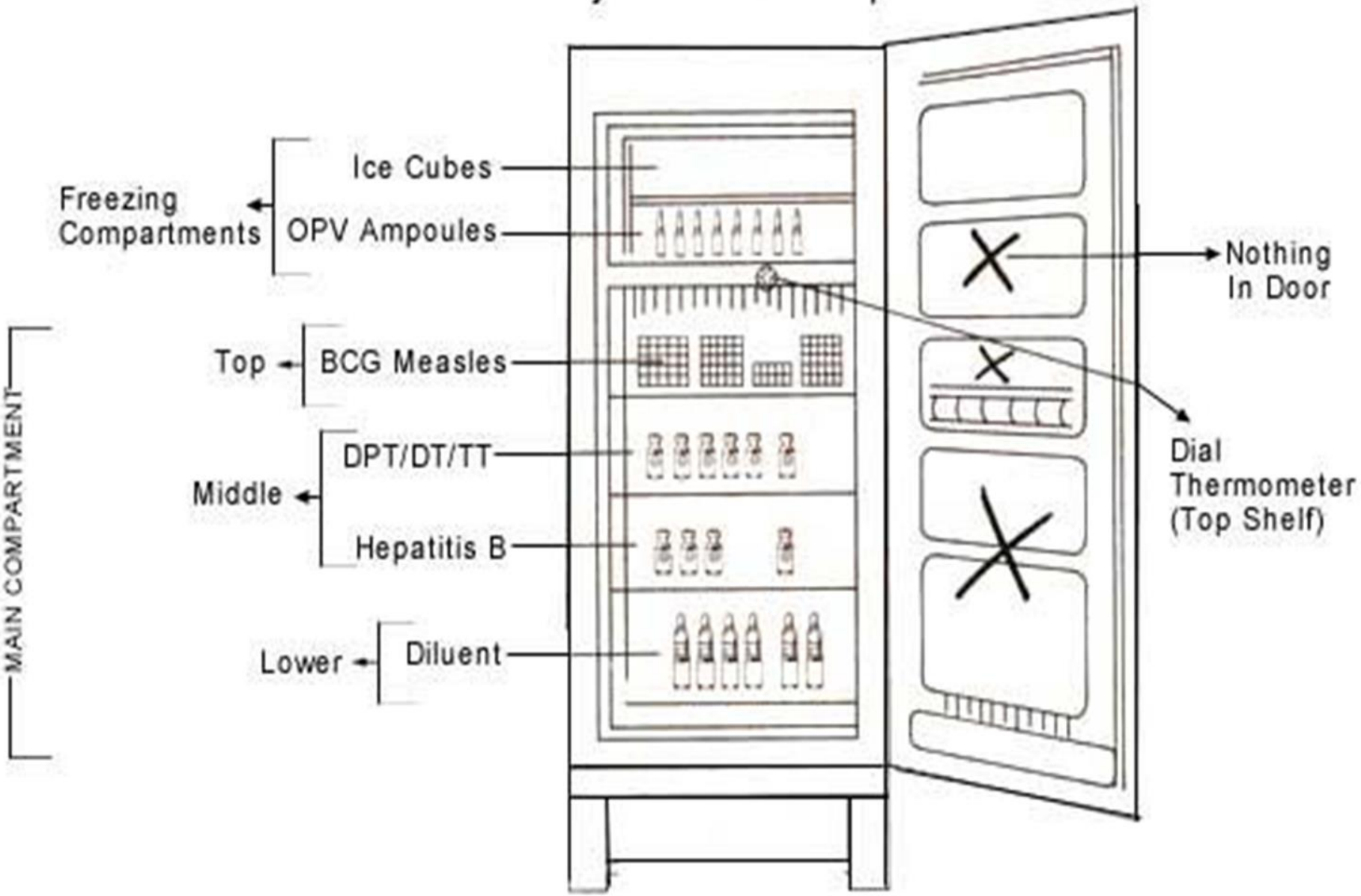
- Placed in the coolest place of the health centers away from sunlight
- Well ventilated and adequate air circulation around it .
- Kept locked and open only when necessary.
- Defrosted regularly .
- Ice packs are kept in the freezer.
- Its temperature is recorded twice daily.
- Drugs, drinks or food must ***not be*** stored in the refrigerator.
- Both the monitor and thermometer are placed in the refrigerator.
- The temperature chart is stuck on the door outside the refrigerator.
- The diluents should be kept on the lowest shelf.

Type of Vaccine Thermometer

Dial type Thermometer

Bar type Thermometer

Refrigerator Showing vaccines Stored Correctly in Clinic Setup



Tools for monitoring the cold chain:

1- Cold Chain Monitor Card.

2- Freeze Watch Indicator

3- Cold Chain Refrigerator Graph

4- Vaccine Vial Monitors

5- Shake Test

Cold Chain Monitor Card: is used to show cumulative exposure to Temp. above the safe range during storage& transportation .

It has an indicator that responds to two different Temps: the first part marked as **ABC**, responds to **Temp above +10ºC**; the **2nd part** marked as **D responds to Temps. above +34ºC.**

Cold Chain Monitor (CCM)

Vaccine Cold Chain Monitor

Date in	Index	Location	Date out	Index

	If A all blue	If B all blue	If C all blue	If A & B & C & D all blue
Polio	Use within 3 months	TEST VACCINE BEFORE USE		
Measles & Yellow Fever	These vaccines may be used	Use within 3 months	TEST VACCINE BEFORE USE	
DPT & BCG			Use within 3 months	TEST VACCINE BEFORE USE
TT & DT & Hepatitis B				TEST VACCINE BEFORE USE

SUPPLIER
FOURNISSEUR

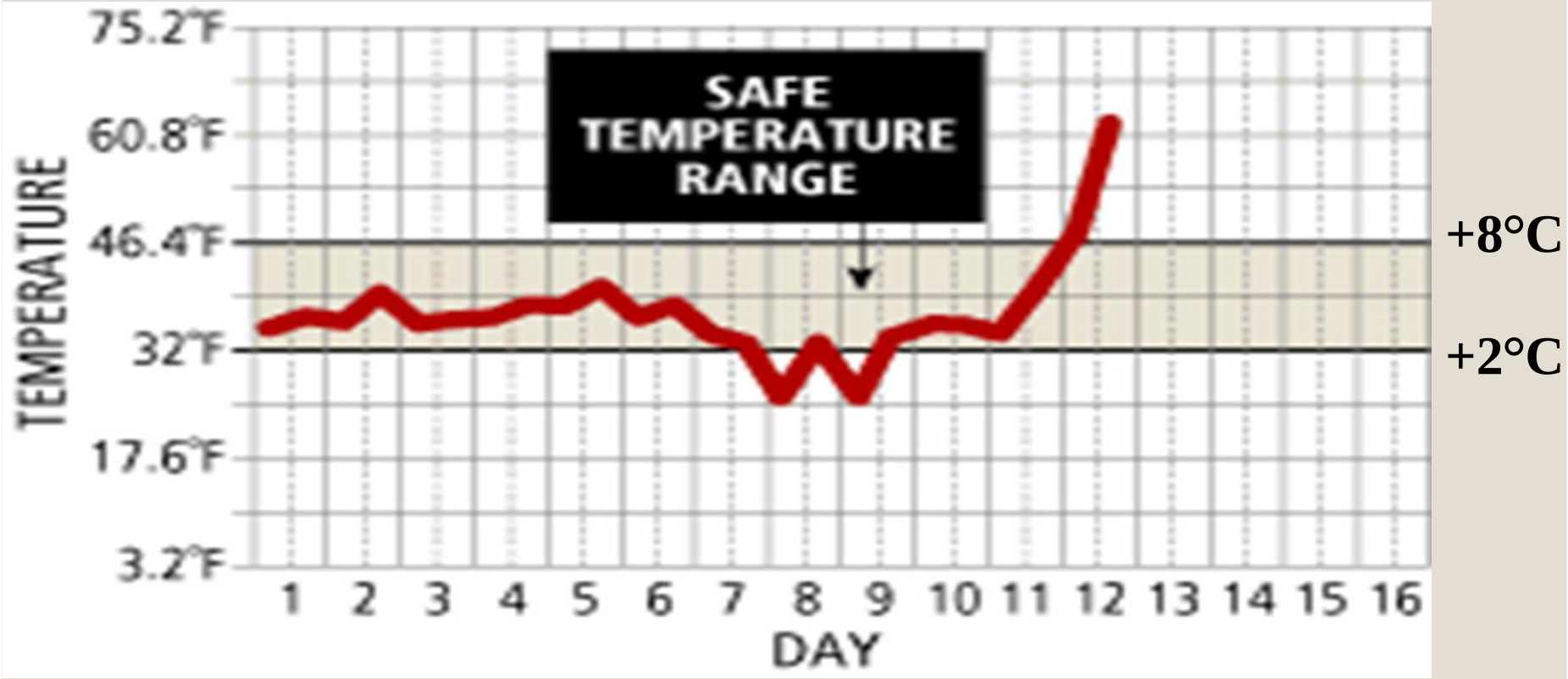
Name: _____
Nom:
Date of dispatch: _____
Date d'expédition:
Vaccine: _____
Vaccin:

Cold Chain Refrigerator Graph

The vaccines are stored in refrigerators, they are monitored twice a day and readings are recorded on a chart to ensure a safe temperature is maintained.

Emergency provisions made.

Vaccines moved to cold storage for 48 hours.



Vaccine vial monitors:

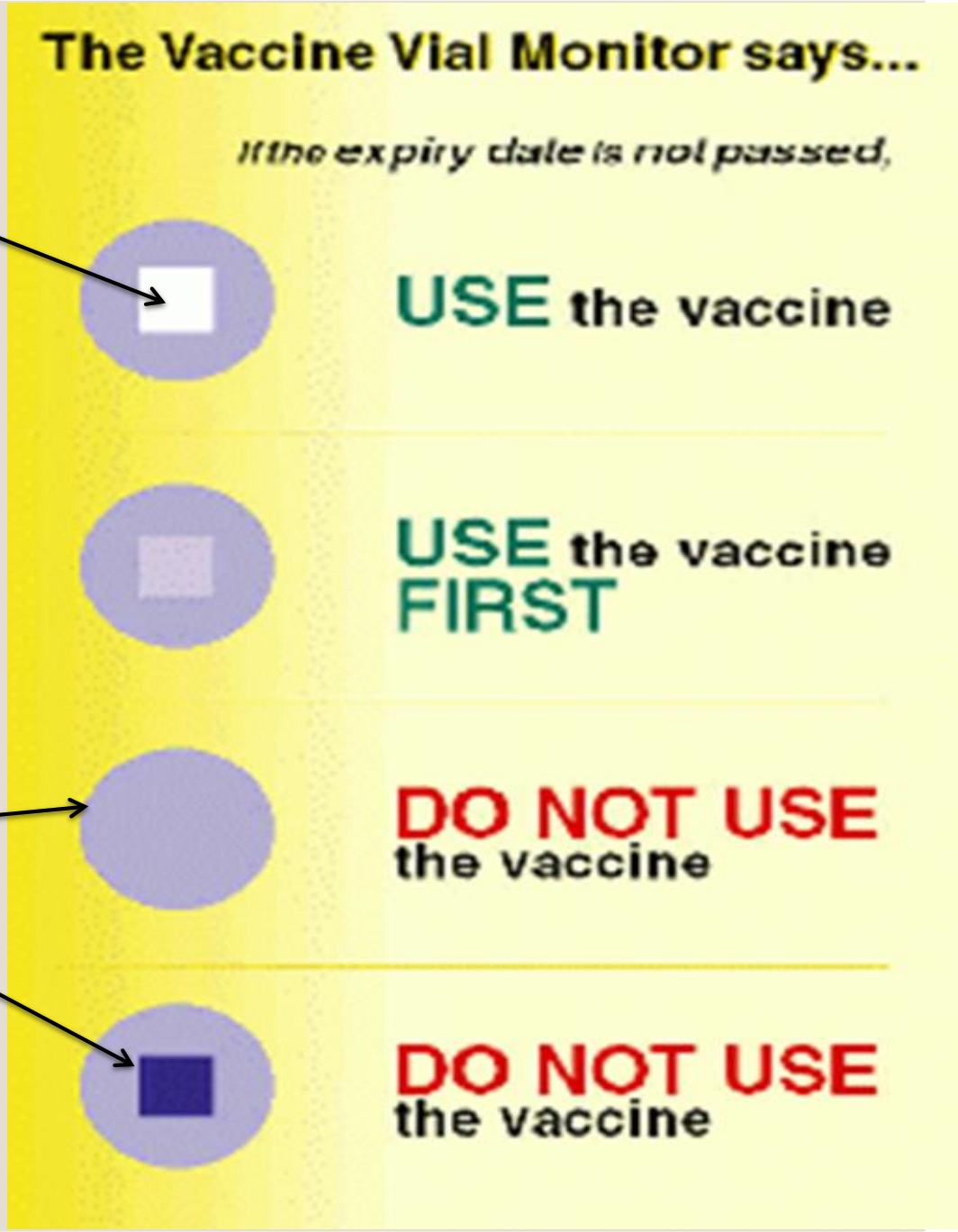
Every vial is also shipped with a temperature-sensitive label, that health workers monitor during vaccination sessions.

SAFE

If the inner square is lighter than the outer ring and the expiration date is valid, the vaccine is usable

SPOILED

If the inner square matches or is darker than the outer ring, the vaccine must be discarded.



The shake test

The “shake test” was designed to detect freeze damage in aluminum-based, adsorbed, freeze sensitive vaccines such as DTP, DT, Td, TT, typhoid, and hepatitis B. These vaccines must never be frozen as this reduces their immunogenicity

By shaking two vials, side-by-side, one that might have been frozen and one that has never been frozen, health workers can determine if a vaccine has spoiled.

Fig. 4.10: Shake Test Passed - Vaccine usable

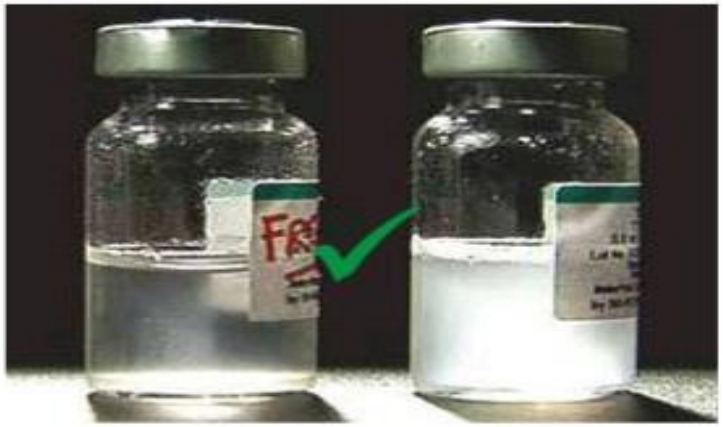


Fig. 4.11: Shake Test Failed - Do not use Vaccine

What damage the Vaccines?

1. Any defect in the cold chain.
2. Out date expiry.
3. Using skin antiseptic at the site of injection (e.g. BCG).
4. Using the reconstituted vaccine (MMR, measles, BCG) after the recommended period (6 hours).
5. Exposure of the vaccine to unacceptable temperature during the immunization session.
6. Exposure of the vaccine to direct sunlight.

HERD IMMUNITY

Herd immunity', also known as 'population immunity', is the indirect protection from an infectious disease that happens when a population is immune either through vaccination or immunity developed through previous infection.

WHO supports achieving 'herd immunity' through vaccination, not by allowing a disease to spread through any segment of the population, as this would result in unnecessary cases and deaths.

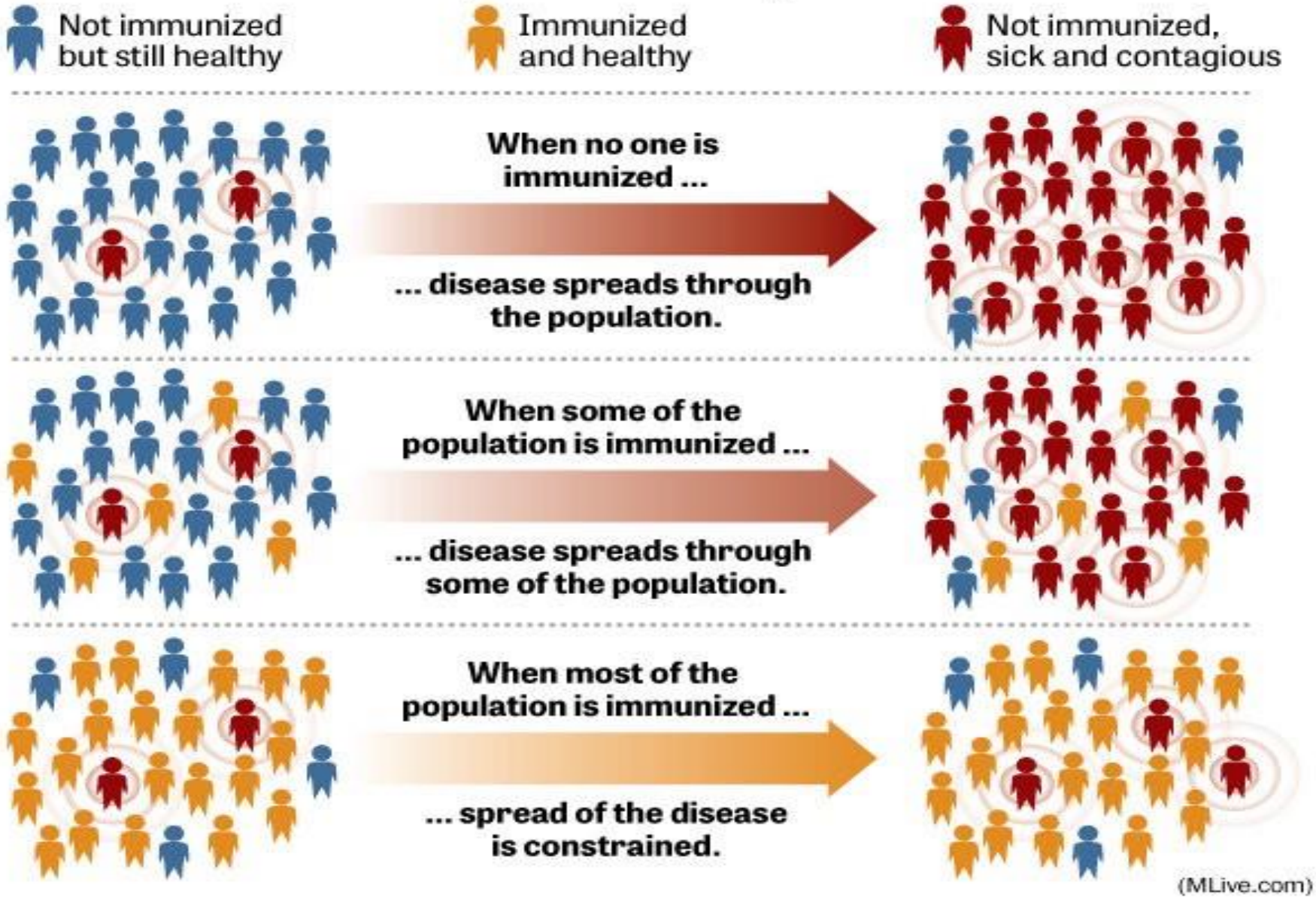
Herd immunity (or community immunity) describes a form of immunity that occurs when the vaccination of a significant portion of a population (or herd) provides a measure of protection for individuals who have not developed immunity.

Herd immunity theory proposes that, in contagious diseases that are transmitted from individual to individual, chains of infection are likely to be disrupted when large numbers of a population are immune or less susceptible to the disease.

The greater the proportion of individuals who are resistant, the smaller the probability that a susceptible individual will come into contact with an infectious individual

WHY DOES MY CHOICE MATTER TO OTHERS?

It matters because of the concept of "herd immunity." Here's how it works:



Herd immunity can effectively stop the spread of disease in the community. It is particularly crucial for protecting people who cannot be vaccinated.
These include children who are too young to be vaccinated, people with immune system problems, and those who are too ill to receive vaccines (such as some cancer patients).

Mechanism

Vaccination acts as a sort of firebreak or firewall in the spread of the disease, slowing or preventing further transmission of the disease to others.

Unvaccinated individuals are indirectly protected by vaccinated individuals, as the latter are less likely to contract and transmit the disease between infected and susceptible individuals.

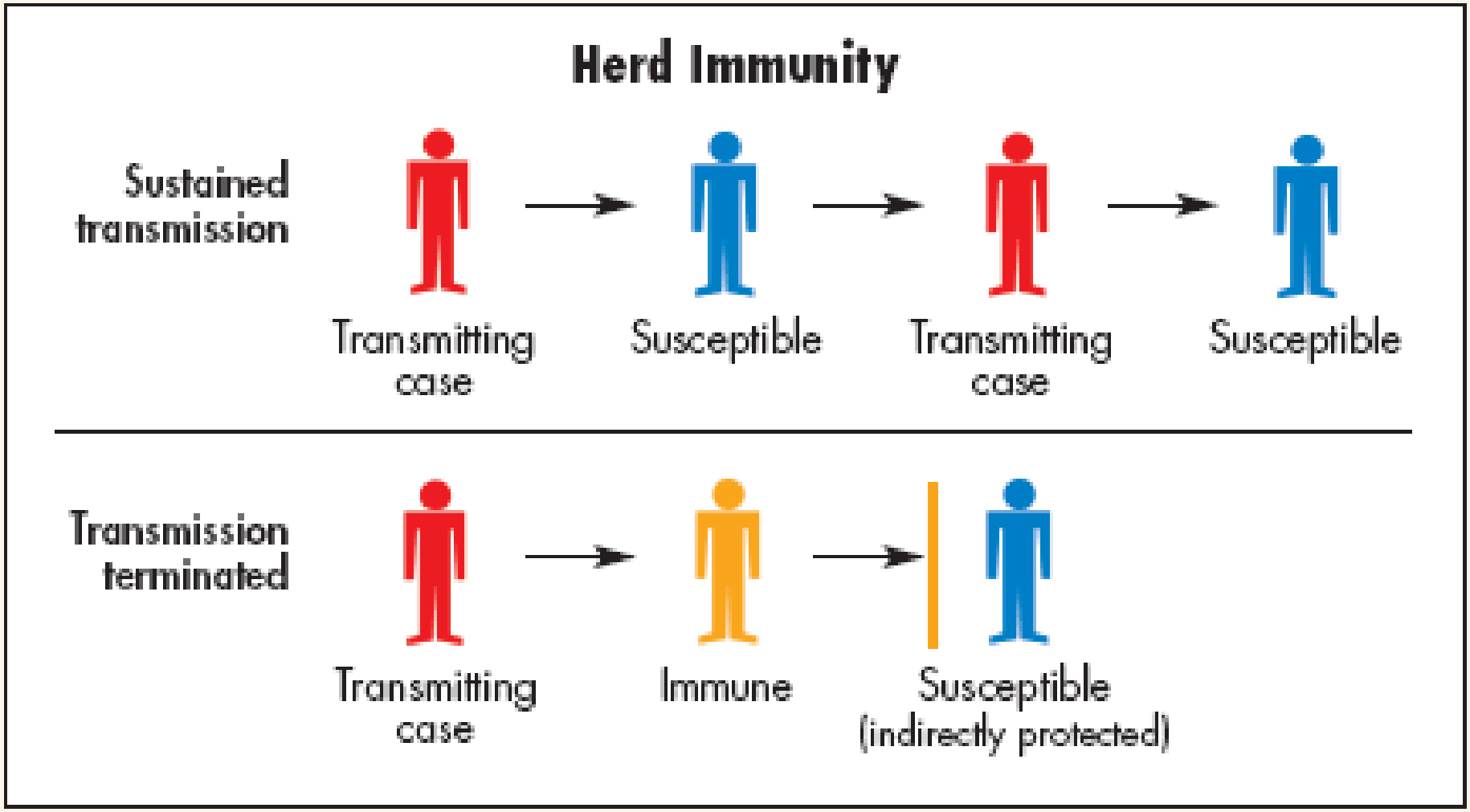
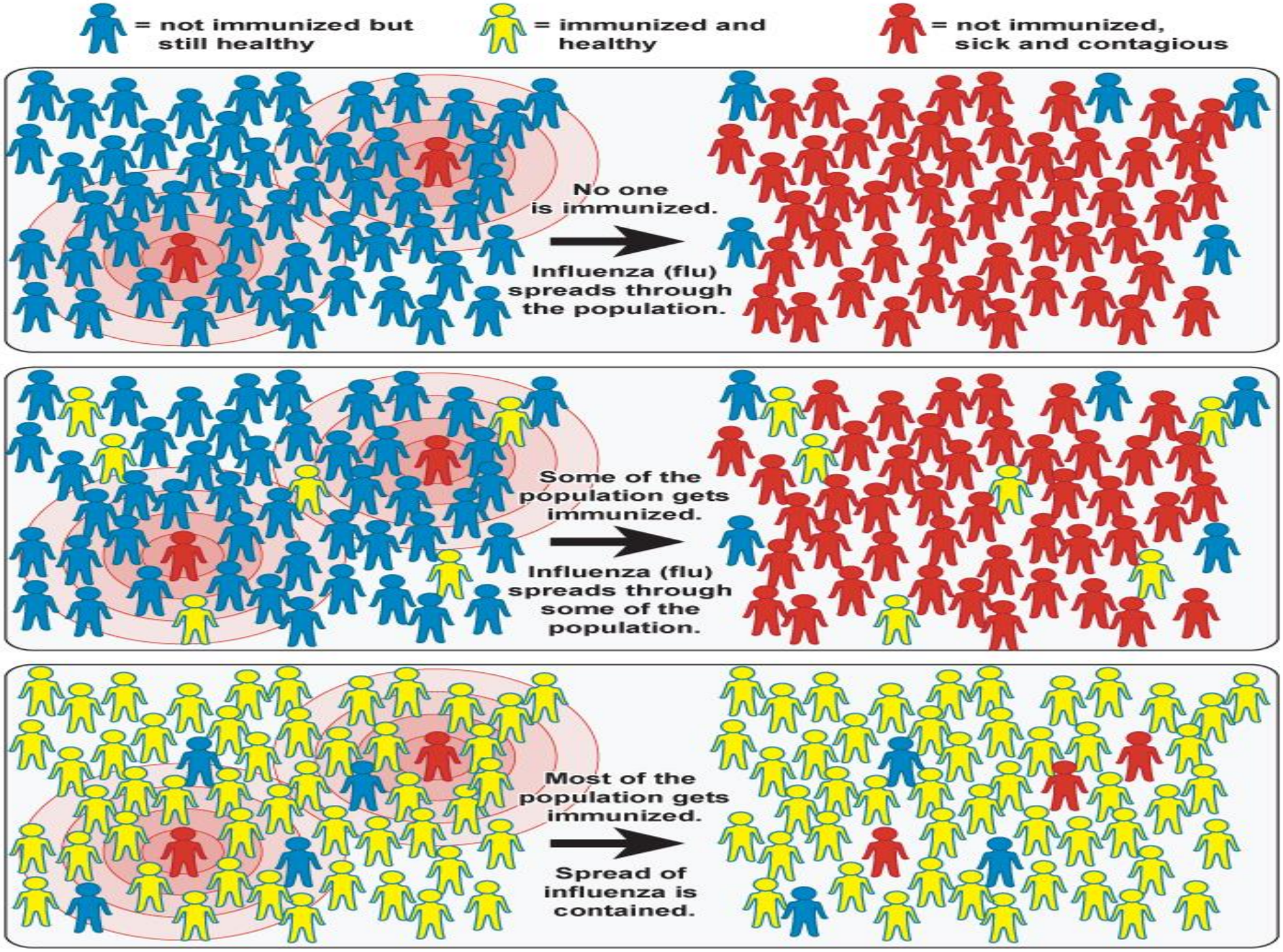


Figure – The principle underlying herd immunity is that the presence of enough immune persons in a community interrupts the transmission of an infectious agent, thereby providing indirect protection for unimmunized (or "susceptible") persons.


= not immunized but still healthy
= immunized and healthy
= not immunized, sick and contagious
No one is immunized.
Influenza (flu) spreads through the population.
Some of the population gets immunized.
Influenza (flu) spreads through some of the population.
Most of the population gets immunized.
Spread of influenza is contained.

Herd immunity generally applies only to diseases that are contagious.
It does not apply to diseases such as tetanus (which is infectious, but is not contagious), where the vaccine protects only the vaccinated person from disease.

Nor does it apply to the IPV poliomyelitis vaccine that protects the individual from viremia and paralytic polio but does not prevent the fecal-oral spread of infection.

Herd immunity should not be confused with contact immunity, a related concept wherein a vaccinated individual can 'pass on' the vaccine to another individual through contact.

People who depend on herd immunity

Some people in the community rely on herd immunity to protect them. These groups are particularly vulnerable to disease, but often cannot safely receive vaccines:

- **People without a fully-working immune system, including those without a working spleen**
- **People on chemotherapy treatment whose immune system is weakened**
- **People with HIV**
- **Newborn babies who are too young to be vaccinated**
- **Elderly people**
- **Many of those who are very ill in hospital**

The percentage of people who need to be immune in order to achieve herd immunity varies with each disease.

For example, herd immunity against measles requires about 95% of a population to be vaccinated. The remaining 5% will be protected by the fact that measles will not spread among those who are vaccinated.

For polio, the threshold is about 80%.

The proportion of the population that must be vaccinated against COVID-19 to begin inducing herd immunity is not known.

This is an important area of research and will likely vary according to the community, the vaccine, the populations prioritized for vaccination, and other factors.

Elements which contribute to herd immunity

a- Occurrence of clinical and sub-clinical infection in the herd

b-immunization of the herd

c- herd structure. Herd structure is never constant.

It is subject to constant variation because of new births, deaths and population mobility. An on-going immunization programme will keep up the herd immunity at a very high level.

The herd structure includes not only the hosts (population) belonging to the herd species but also the presence and distribution of alternative animal hosts and possible insect vectors as well as those environmental and social factors that

favors or inhibit the spread of infection from host to host.

The herd structure thus plays a critical role in the immunity status of the herd.

If the herd immunity is sufficiently high, the occurrence of an epidemic is regarded as highly unlikely.

Studies have shown that it is neither possible nor necessary to achieve 100 per cent herd immunity in a population to stop an epidemic or control disease, as for example eradication of Smallpox.

Just how much less than 100 per cent is required is a crucial question, for which no definite answer can be given.

Herd immunity may be determined by serological surveys.

PASSIVE IMMUNIZATION

(SEROPROPHYLAXIS)

Passive immunization needed for rapid, but temporary protection of susceptible, either after exposure to infection or before expected exposure (occasionally). The duration of immunity induced is short and variable (1-6 weeks). Passive immunization has a limited value in the mass control of disease, it is recommended for non-immune persons under special circumstances.

Three types of preparations are available for passive immunity

A- normal human immunoglobulin

B- specific [hyper immune] human immunoglobulin

C- antisera or antitoxins

APPLICATION OF IMMUNOGLOBULIN:

1-After exposure ; associated with either

* **Sero prevention ; when given early in incubation period**

* **Sero attenuation ; when given later in incubation period.**

* **Not effective; if given late in incubation.**

2-Before expected exposure; travelers from free to endemic areas can be given seroprophylaxis for expected infection; hepatitis A.

Specific immunoglobulin's are available for seroprophylaxis; antiviral (mumps, hepatitis A,B, measles, rubella, rabies. antitoxic (diphtheria & tetanus), and antipertussis (for exposed susceptible infants).

Serotherapy: tetanus ,diphtheria and rabies have specific antitoxin immunoglobulin that can be used for both prophylaxis & therapy in bigger doses. But there is no antiviral Serotherapy.