



CHAPTER 5

Epidemiology Study Designs



- Episode 5.4: - Clinical trial
- Field trial
- Community trial

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1

Clinical Trial (การทดลองทางคลินิก)

Clinical Trial (การทดลองทางคลินิก)

- A type of research study, a prospective design that tests how well new medical approaches work in people.
- These studies test new methods of screening, prevention, diagnosis, or treatment of a disease.
- Clinical studies can take place in many locations, including hospitals, universities, doctors' offices, and community clinics. The location depends on who is conducting the study.
- A clinical study is conducted according to a research plan known as the protocol.

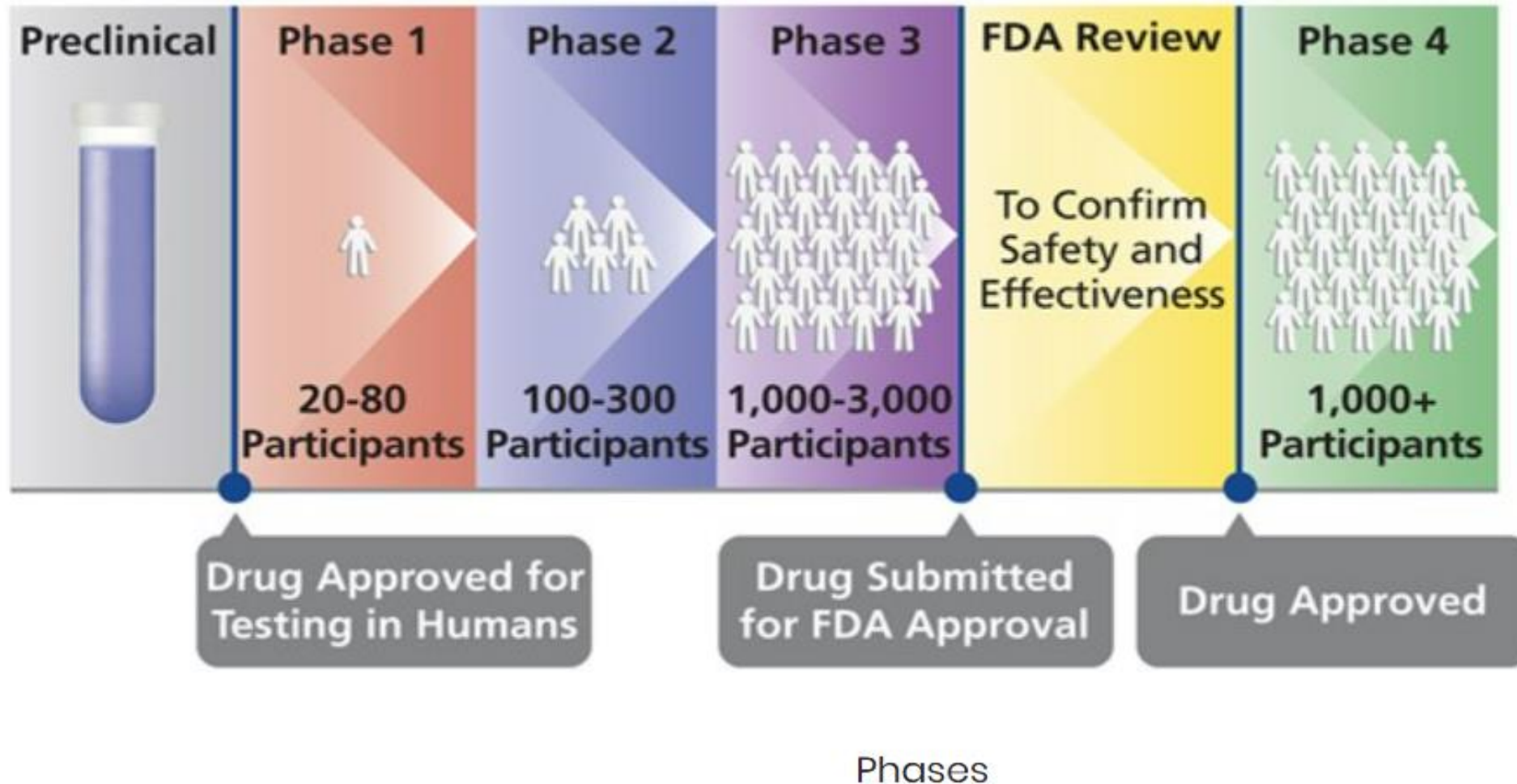
The four phases of clinical trial

- A **Phase I** trial **tests** an experimental treatment on **a small group** of often **healthy people** (20 to 80) to judge its **safety and side effects** and to find the correct drug dosage.
- A **Phase II** trial uses **more people (100 to 300)** **after** the result in Phase I is on safety, the emphasis in Phase II is on effectiveness and continuing to study safety, including **short-term side effects**.
- A **Phase III** trial gathers more information about safety and effectiveness, studying **different populations and different dosages**, using the drug in combination with other drugs. The subjects usually range from several hundred to about 3,000 people. (approve the experimental drug or device)
- A **Phase IV** trial gathers more information about a device or drug's **effectiveness and safety** by monitoring large, diverse populations.

Specific purposes of Clinical Trials



Clinical Trials





Field Trial (การทดลองสนาม)



Features of Field Trial (การทดลองสนาม)

- One type of interventional study is designed to evaluate prevention strategies (Prospective study)
- Carried out with people who are at risk, free of disease
- Carried out on the field in people not admitted to a hospital or an institution
- Field trials can be carried out among individuals or groups of people
- The group may be a household, a block of houses, a school, or a workplace.
- To test health education methods, training procedures, or other public health programs.



➤ *Prevention interventions:*

- vaccine effectiveness studies;
- nutritional interventions
- interventions in maternal and neonatal health
- education (campaigns against tobacco, exclusive breastfeeding, improvement of excreta disposal methods)
- vector control and disease transmitters (measures to control insects, larvae, or elimination of breeding grounds)

Strengths

- Helpful in assessing the value of new strategies to prevent the risk of certain diseases.
- It can evaluate a single variable in a precisely defined group of people.
- Eliminates bias by comparing two otherwise identical groups.
- Able to control selection, confounding, and measurement biases.

Limitations of Field Trial

- ❑ Field trials usually **require a greater number** of subjects than clinical trials and therefore are usually much more expensive.
- ❑ A field trial often necessitates visiting subjects in the field or establishing centers from which the study can be conducted and to which subjects are urged to report.
- ❑ Field trials are often logistically complicated.
- ❑ Ethical and practical limitations.



3

Community Trial/Community Intervention Study (การทดลองในชุมชน)

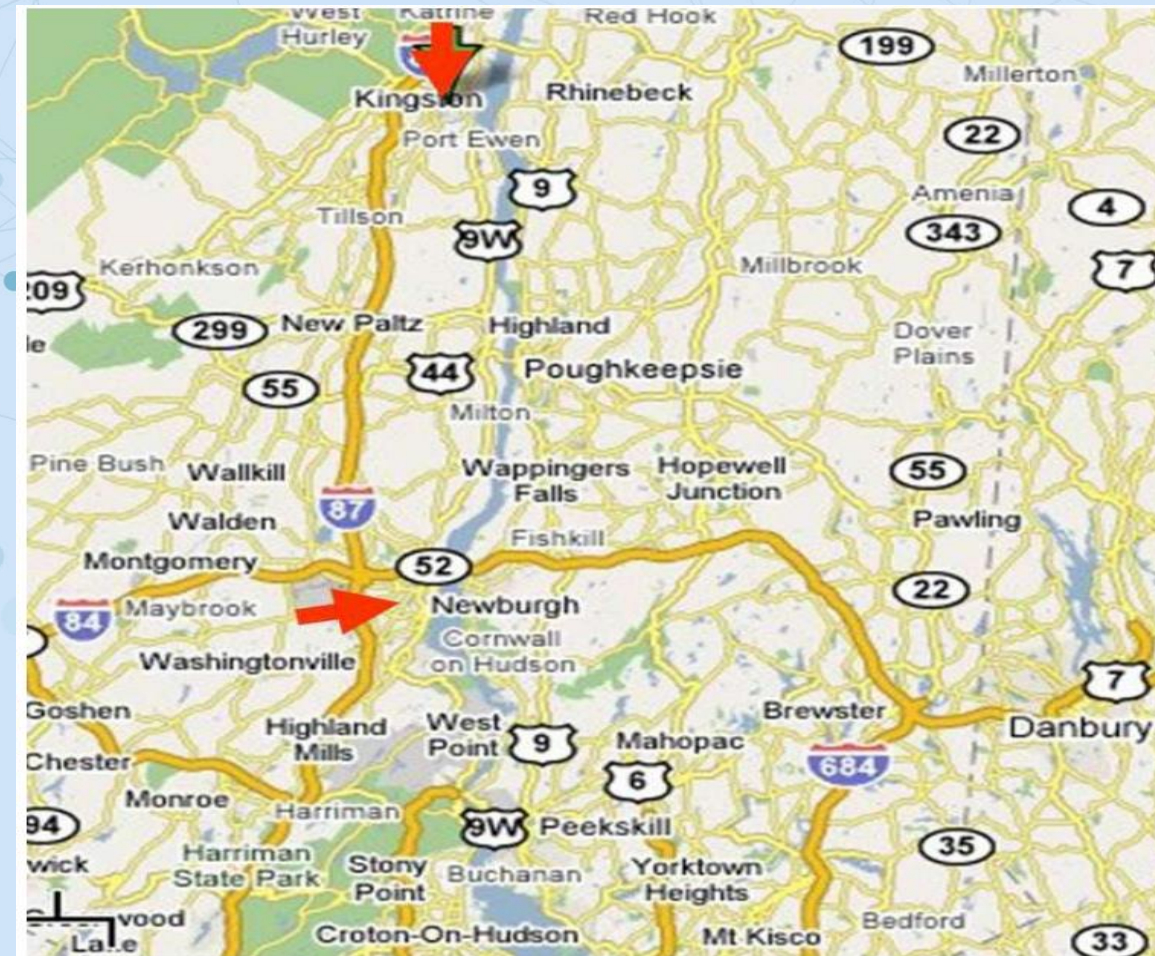
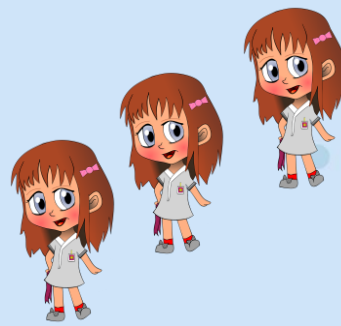
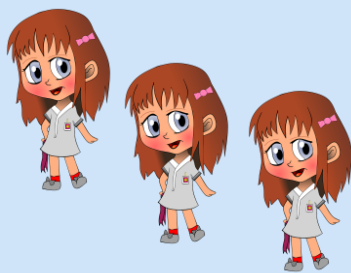


- Community trials, also called community intervention studies, are (mostly preventive) experimental studies with whole communities (such as cities or states) as experimental units; that is, interventions are assigned to all members in each of a number of communities.



Sample of Community Trials: fluoride in preventing dental caries

- The effectiveness of **fluoride in preventing dental caries** was tested by comparing the frequency of caries in the children in Kingston and Newburgh. (In the 1940s)



Source:

https://sphweb.bumc.bu.edu/otlt/mphmodules/ep/ep713_clinicaltrials/EP713_ClinicalTrials2.html

Phuket: A case study on the possibility of living with COVID-19

- During Thailand's second wave last year, inbound international tourists must be vaccinated and stay on the island for 14 days before traveling to other parts of the country.
- Within three months, over 75% of Phuket residents were fully vaccinated
- Severe cases are reported very low in Phuket, allowing tourism activities to carry on despite the spread of Omicron.

"Phuket has proved to the world that living with COVID-19 is possible and safe."

- ✓ The community trials provide important information for making public health decisions and optimizing national health programs.

Summary



Clinical trial

It is a study of “patients” in a hospital or clinic. The exposure factor is treatment, i.e. treatment or no treatment. Usually, compare the “recovery rate” in each sample group.

Field trial

- ✓ It is a study with In the general population, exposure is often a means of preventing disease, such as vaccination to provide protection.
- ✓ The condition that is expected to be an outcome is usually a disease of high severity or a disease that affects public health problems.

Community trial

- ✓ It is an education with a “community” rather than an individual person.
- ✓ Exposure is often a preventative measure, such as providing health education to the community or providing protection compare with no protection.
- ✓ The outcomes are often diseases with a complex etiology.

Summary

- ✓ Clinical, field, and community trials are experimental study, a prospective design.
- ✓ Field trials differ from clinical trials in that they deal with subjects who have not yet gotten the disease and therefore are not patients.
- ✓ Field trials in which whole communities are the unit of allocation are called community trials.



Thank you

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