

**TOPIC 3. STUDY
ALLOCATION AND
RANDOMIZATION:
HOW TO ENSURE ALL
RESEARCH PARTICIPANTS
HAVE EQUAL CHANCES,
WITHOUT BIAS?**

How to explain it to the people interested

Study Allocation/ Randomization

Course Objective:

- ❖ Demonstrate understanding of the randomization process and how to discuss it with study participants
 - Identify intervention vs. comparator group
 - Discuss the importance of randomization
 - Proficiently explain the randomization process to study participants and its implications



Put a ★ where a CHW can assist:

PLANNING THE STUDY: How patient and stakeholder partners like **CHWs can participate in study planning and design.**

Developing the research question and relevant outcomes to be studied

- To ensure that the project and its results will be useful and important to patient and stakeholder communities.

Defining the characteristics of study participants

- To minimize the risk that certain patients will be included or excluded due to criteria that are not relevant/biased

Designing the study to minimize disruption to patient and stakeholder study participants

- To promote retention of study participants

Engagement Guidelines

PLANNING THE STUDY: How patient and stakeholder partners like CHWs can participate in study planning and design.

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Medical Studies/Clinical Trials

- ❖ Research involving new drugs, devices (e.g. catheter, pacemaker), vaccines, or therapies attempting to answer specific questions.
- ❖ Who receives what or when is important, CHWs help bringing in/recruit participants when **they minimize the risk** that certain patients will be included or excluded due to criteria that are not relevant/biased.



Who receives What/When: Study Allocation/ Randomization

- ❖ Assigning individuals to a group or treatment not using specific reason, but as a **random process**, like **a lottery**, giving everybody the same chance!
- ❖ Identify **intervention group** (*the one receiving the treatment, what is different in this particular study*) **vs. comparator** (*the one doing standard, the usual*)



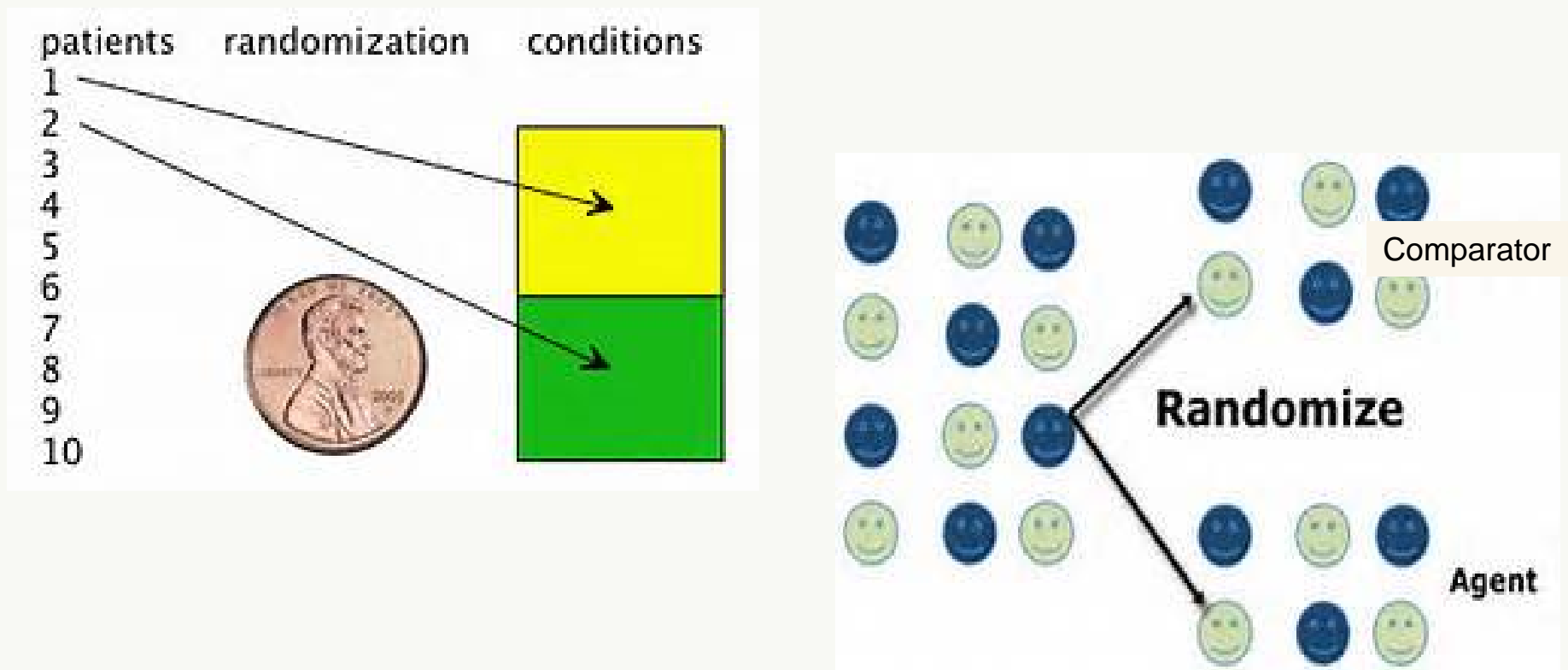
Let's Play!

- ❖ Sampling Techniques – An Activity with candy to use as a “treatment/intervention”
- ❖ **Randomization:** Assignment by lottery, determined totally by chance, not predictable at all.

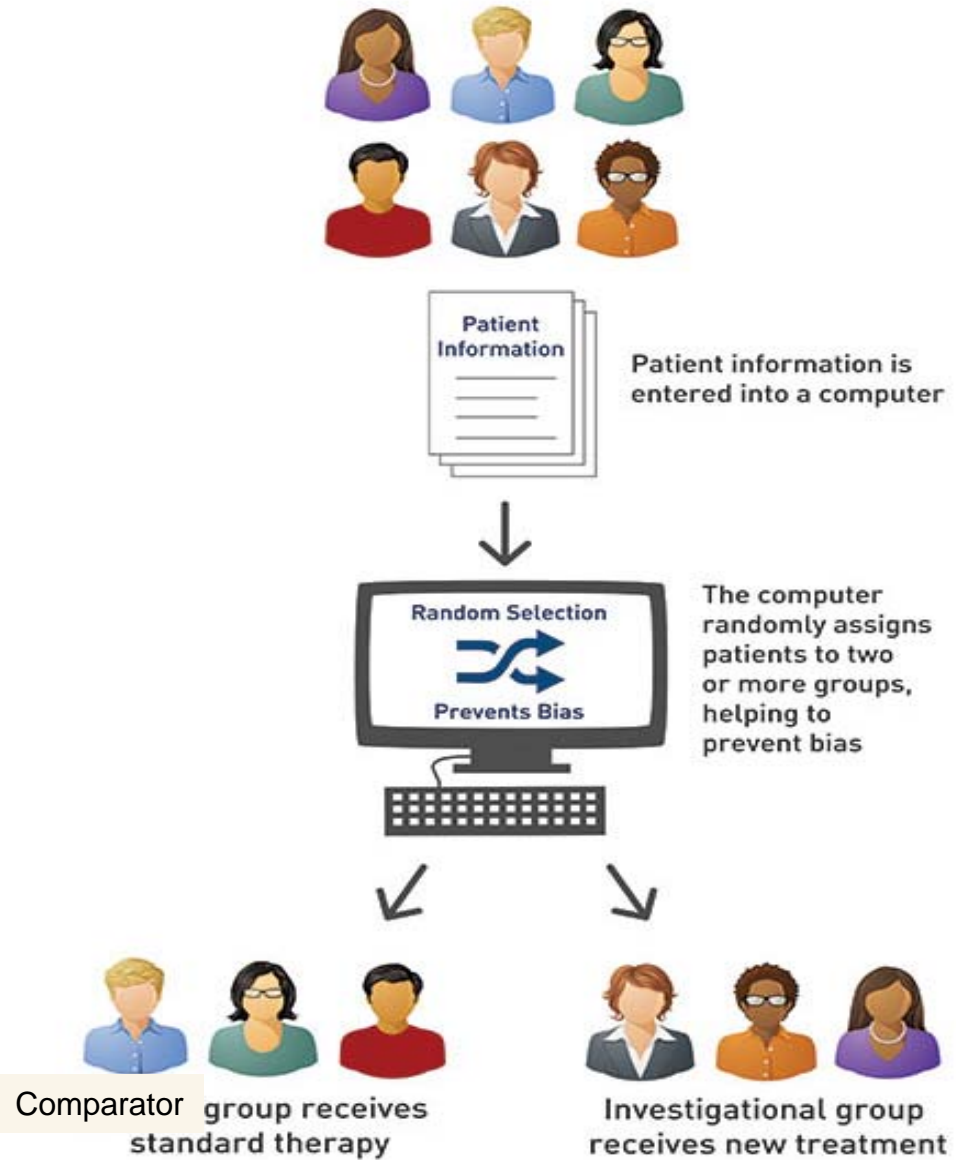


Randomization: Why is important?

- ❖ To give everybody the same shot, without inappropriate preferences, to be fair to all!



Example – Clinical Trial Randomization



Bias

- ❖ Inappropriate interference or factors other than the treatment or intervention that may explain/might affect the study results.



Open Discussion

- ❖ How we can ensure all research participants have equal chances, without bias, to be included in a study?



Questions?



❖ Next topics:

- What are the different ways to collect research data; how can CHWs collect data for research studies?
- What is the process of informing the participants about their rights and risks associated with a study?
- How does one track data and report data collected?
- How to report study results and to whom?