Evolving Vaccine Trials

Adaptive Informed Consent in the Global Context

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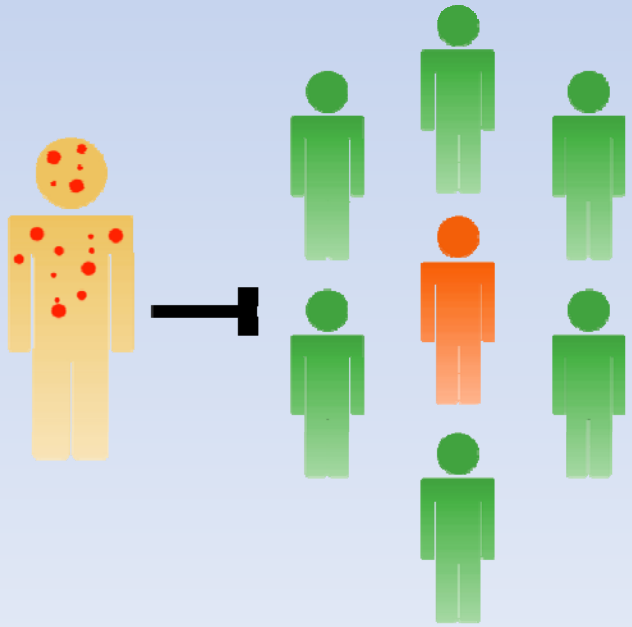
Vaccine Clinical Trials Go Global

Raises questions about informed consent in new research contexts

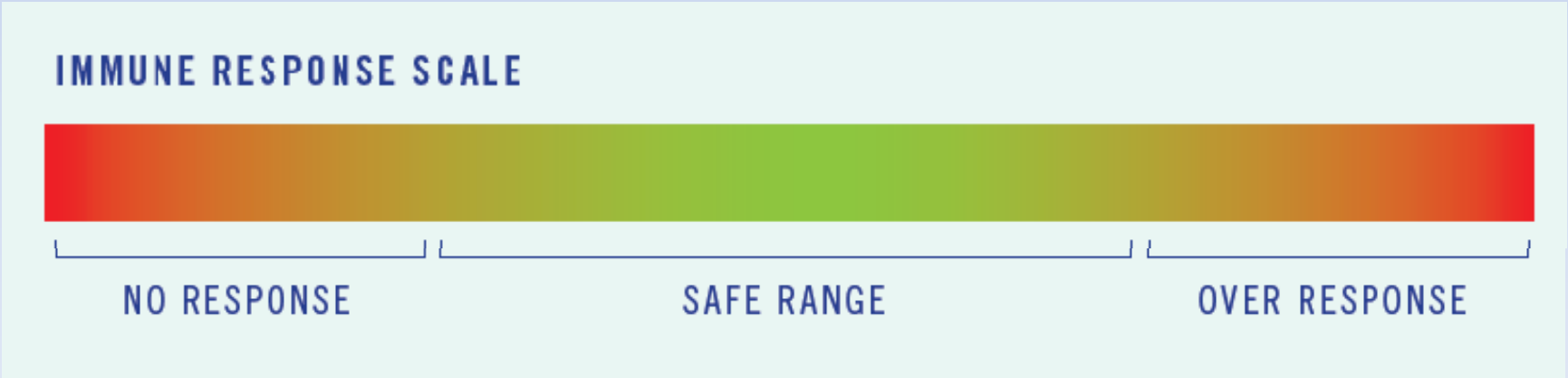
Why Do We Need Vaccines?

- Vaccines prevent disease by introducing a weakened version of the disease-causing agent to a person's immune system
- They can target specific strains of a given disease



How Do Vaccines Work?

- Vaccines introduce harmless antigens (part of the pathogen used for recognition by our bodies) into a patient
- People respond to vaccines differently
- Therefore, we must run clinical trials to ensure safety & efficacy



Vaccine Trial Design

- Different phases of the trial serve different purposes
- Placebos – which do not include the vaccine – are used as controls
- Currently, most vaccine trials adapt and adhere to the ICH Good Clinical Practice Manual

Necessary Information for Consent to Participate

- Possibility of no response to vaccine
- Possible overreaction of the immune system
- Alternatives to new vaccine
- Possibility that participant receives a placebo (i.e. not a vaccine)
- Possibility that dose is not adequate for full vaccination

Barriers to Adequate Comprehension of Information

- Medical terms cannot be easily translated
- Comprehension level of the potential participant
- Societal structure/decision making
- Consent is given in different ways
- Researcher pressure

What is Autonomy and How is it Taken Away by Inadequate Informed Consent?

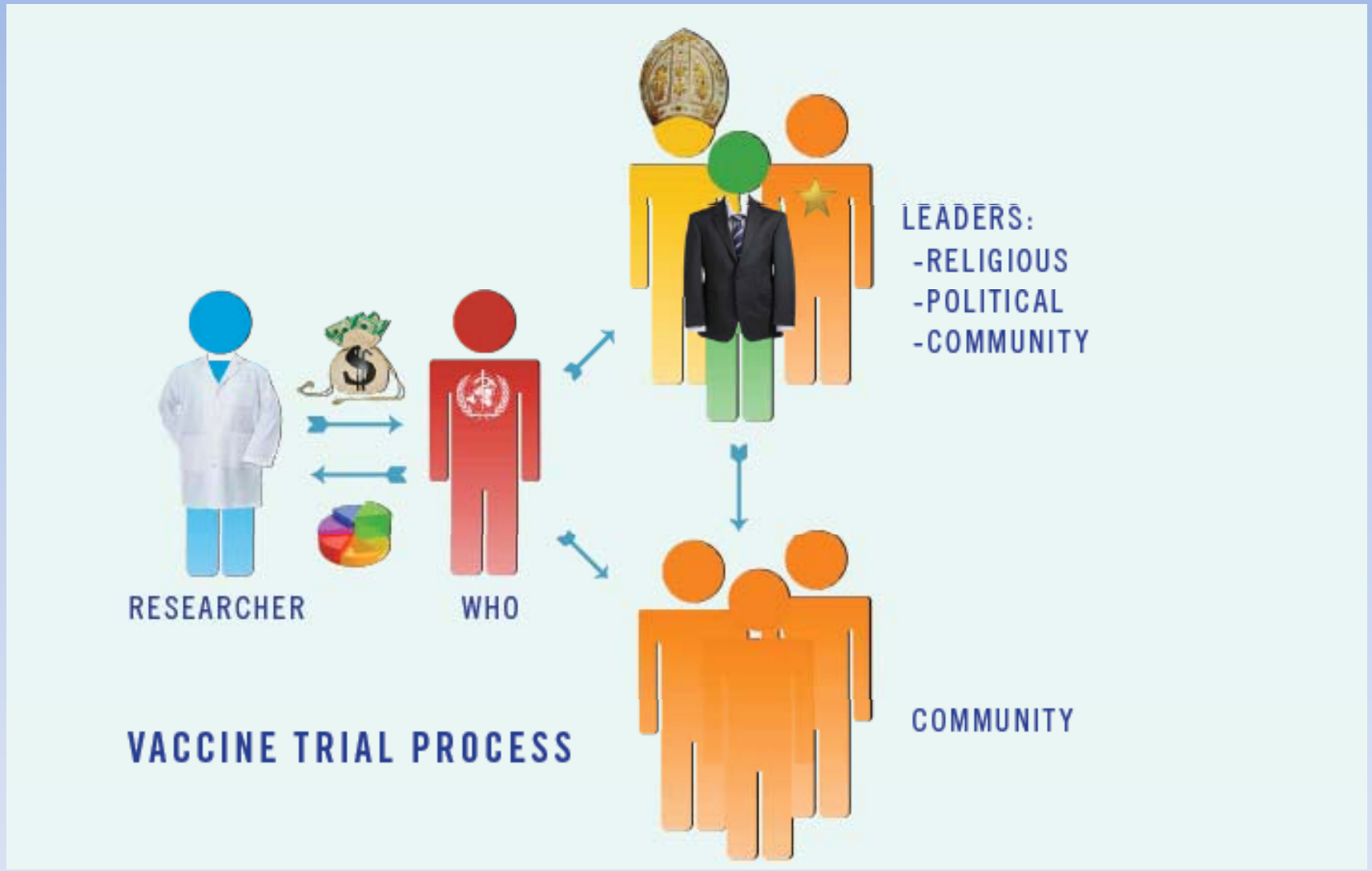
- An autonomous decision requires that people know enough information to make a decision for themselves without outside influence
- Undermining autonomy affects an individual's rights
  - Right to know
  - Right to noninterference

Adaptive Informed Consent

- Cultural sensitivity
- Will ensure specific and appropriate cultural constructs are used in trial process
- Conducted through third party such as the World Health Organization (WHO)

Steps for Adaptive Informed Consent

- Prepare clinical infrastructure and train WHO trial investigators
- Structure informed consent based on cultural and societal norms
  - Test adaptive informed consent against the original to ensure better understanding


LEADERS:
-RELIGIOUS
-POLITICAL
-COMMUNITY
RESEARCHER
WHO
COMMUNITY
VACCINE TRIAL PROCESS

WHO Responsibilities Throughout the Trial

- Gathering participants and administration of Adaptive Informed Consent process
- Confirmation of continued understanding by trial participants
- Data to be returned to the researchers
- Administration of the vaccine or placebo

Solution Summary

- Pre and post-studies will ensure participant understanding both prior to and throughout the trial
- Will prevent researcher bias from influencing study participants or results
- Will help preserve a greater degree of participant autonomy

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