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
VACCINE TRIAL PROCESS

LEADERS:
- RELIGIOUS
- POLITICAL
- COMMUNITY

RESEARCHER
WHO
COMMUNITY
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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