Ethical considerations in a community-based vaccine trial in Nepal: a socio-medical perspective

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Speaker's Profile

Current Position: Public Engagement Manager

Highest Educational Attainment: Master of Public Health

Short bio:

Ashata Dahal is a public health professional and is employed as Public Engagement Manager at Oxford University Clinical Research Unit since 2018. She is currently pursuing her PhD at The University of Oxford and her major research interest is exploring social aspects towards clinical trials and understanding the behavior of people that can have an impact on their health. Ms. Dahal has been actively involved around vaccine engagement, antimicrobial resistance and climate change. Her commitment to public health and community empowerment is underscored by her dedication to bridging research with impactful, inclusive public service.

INTRODUCTION

- Double burden of diseases in developing nations
  - High prevalence of diseases like malaria, HIV/AIDS, tuberculosis
  - Growing burden of cardiovascular diseases, diabetes, cancers
- Results in strain on health care system
- Efforts require strengthening healthcare systems through evidence-based, cost-effective healthcare interventions informed by successful community-based clinical trials.
- Ethical considerations are critical in this case to protect participants' rights, ensure equitable distribution of benefits, a uphold the integrity of the research.

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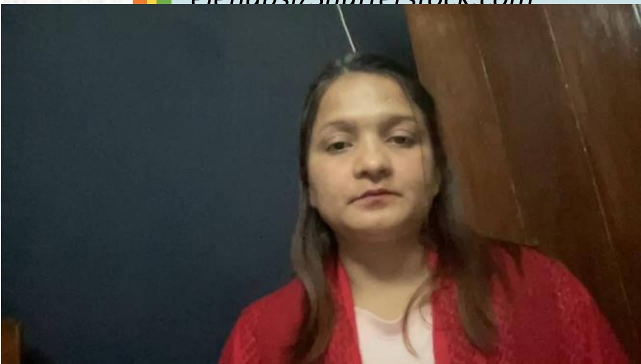

OBJECTIVE

- To explore the ethical tensions in community-based clinical trials in Nepal.

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METHODOLOGY

- **Research Design:** Qualitative research
- **Data collection method:** 17 Focus Group Discussion (FGD), 88 semi-structured interviews (SSI)
- **Data collection tool:** FGD guide, SSI guide
- **Data analysis:** Content analysis

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spartanglobalfund.org

RESULT 1: KEY ETHICAL CONCERNS

Theme 1: Therapeutic Misconception

- Participants believed the trial provided free medical treatment.
- Many were unaware of the research nature, despite study explanations.

Implication: Gaps in research literacy and understanding of trial purposes.

"We definitely need to do blood draw. It helps to diagnose infection."

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RESULT 2: KEY ETHICAL CONCERNS

Theme 2: Undue Inducement

- Free healthcare, reimbursements, and incentives (e.g., toys) influenced participation.

Challenge: Voluntariness of consent may be compromised.

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“We come here because we don’t have to queue for ticket. Plus, you provide us free health services as well.”

RESULT 3: KEY ETHICAL CONCERNS

Theme 3: Kinship and Trust

- Decisions influenced by trust in healthcare professionals and community volunteers.
- Hierarchical dynamics and social trust overshadowed voluntary decision-making.

"Doctors are like God. We trust whatever they say. They have studied s
much so we need to trust."

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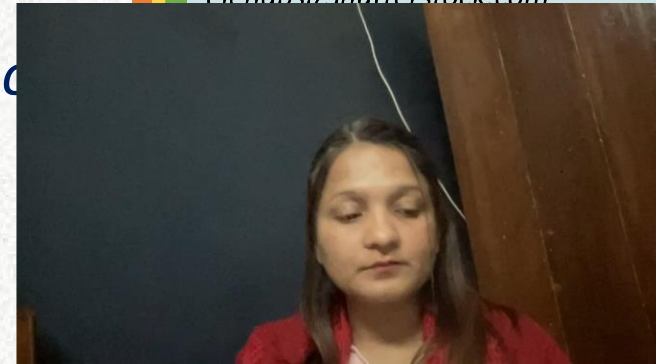

CONCLUSION

- Ethical challenges are subtle yet significant in community-based trials, often rooted in socio-cultural and economic contexts.
- Research ethics must adapt to the complexities of resource-limited and culturally diverse settings.

RECOMMENDATIONS

- Enhance Research Literacy
- Refine Consent Processes
- Empower Communities
- Strengthen Ethical Oversight

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THANK YOU!!!

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REFERENCES

Beaglehole, R., & Yach, D. (2003). Globalization and the prevention and control of non-communicable disease: The neglected chronic diseases of adults. *The Lancet*, 362(9387), 903-908.

CIOMS Guidelines: International ethical guidelines for health-related research involving humans, by the Council for International Organizations of Medical Sciences.
Accessible at: https://cioms.ch

Declaration of Helsinki: Ethical principles for medical research involving human subjects, developed by the World Medical Association. Accessible at: https://www.wma.net

Gautam, R., et al. (2018). Communicable Diseases in Developing Countries. *International Journal of Health Policy and Management*, 7(6), 503–511.

Jamison, D. T., et al. (2013). *Disease Control Priorities in Developing Countr*
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