



Clinical Trials: Do participants understand consent?: The case of Misisi Township in Lusaka - Zambia



Bornwell SIKATEYO

Ministry of Health – Zambia

London School of Hygiene & Tropical Medicine - UK

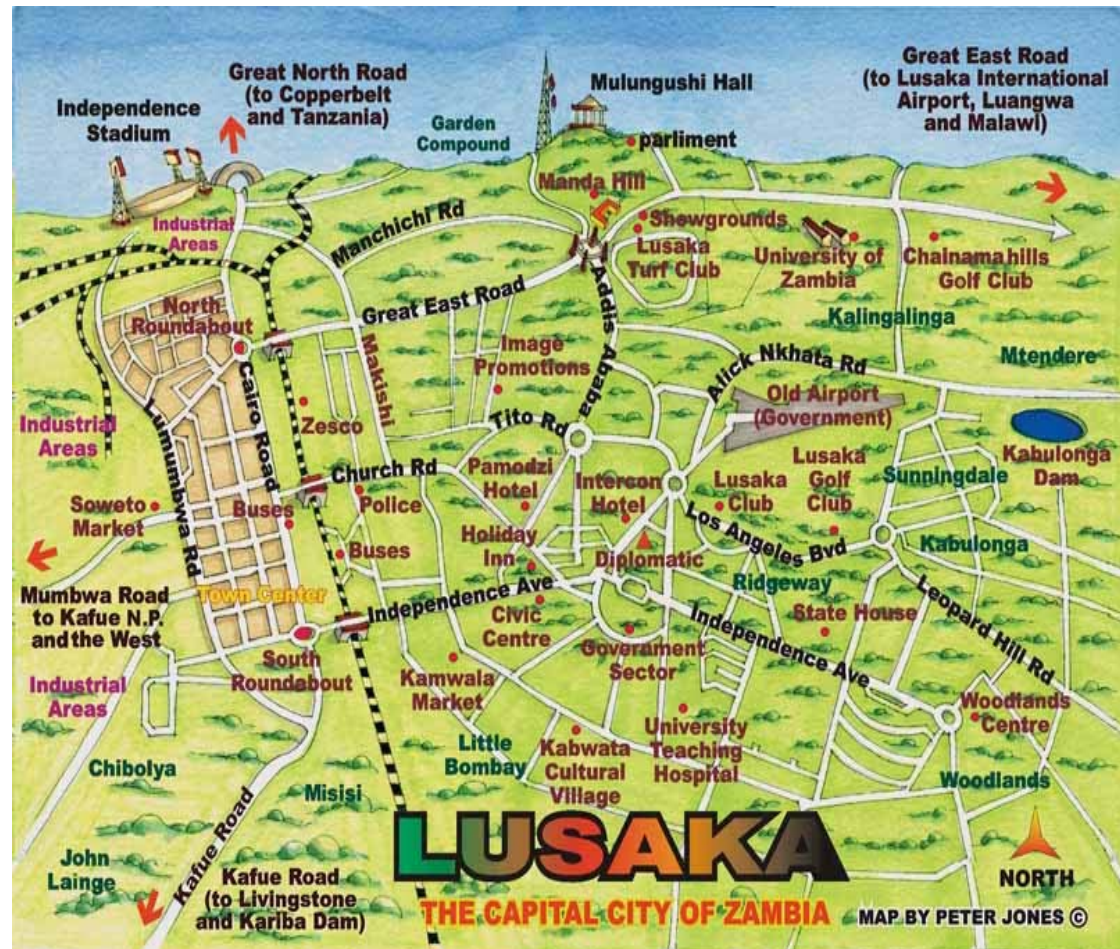




Background



- Misisi
- Squatter Township
- Overcrowded
- Poor sanitation
- Low literacy
- Cohort of participants from longitudinal study





General Aim



- To identify and explore factors that affect participants' ongoing consent to participate in an Entero-Toxigenic vaccines trial in Misisi Township in Lusaka, Zambia
- Participation → Context–Individual–Trial



Objectives



- To understand the interactions between researchers and participants in which 'consent' is negotiated and maintained
- To explore participants' social and economic characteristics, everyday life and situations as they impact the 'consent process'
- To assess how negotiations of participant consent evolve over the course of the trial in view of the complex procedures



Methods



- Literature review
- Four additional types of data collection methods were used to generate 'empirical' data on informed consent:
 - Participant observations
 - Individual in-depth interviews
 - Group discussions
 - Ethnographic observations and visits



Results (1)



- Data was collected from 34 in-depth interviews , 4 Group Discussions, several ethnographic visits and participant observations
- People do not participate in research for altruistic reasons
 - They do not participate out of therapeutic misconception either
 - Rather they participate for other ulterior motives and money for economic survival



Results (2)



- Access to free healthcare was the major motivating factor to participation
- Participants enrolled more out of trust than understanding of the consent process
- Illiteracy was not a barrier to participant comprehension of the research process
- Lack of understanding of the distinction between research and healthcare
- Long term engagement reduces suspicions of research



Discussion & Conclusions



- The findings would seem to be somewhat contradictory of the assumptions upon which informed consent is founded
 - Culture, literacy, competence
 - Understanding, disclosure
 - Participants had previous experience from the 10 year epidemiological study
- However, despite the apparent contradiction participants still sustain their enrollment throughout the trial



Future perspectives



- Strengthening the coordination of the national research ethics framework to enhance its effectiveness
- Further research into how communities receive research programs and how they are reorganised in the process
- Use of more ethnographic approaches to examine consent in medical research in poor-resource settings



Thank you very much for your attention

