Understanding motivations for participation undertaken by research participants in a vaccine trial in Lusaka - Zambia

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HIV VACCINE TRIAL

- 3 year multi-sited trials centrally controlled study: 1st year for assessments and 2 years for the interactions study

- Testing the hypothesis that micronutrients can enhance innate immunity in response to colonisation by live, attenuated oral vaccines

  – Micronutrient and vaccine interactions on innate and secretory immunity in the intestinal mucosa

  – Supplementation reduced severe episodes of diarrhoea, reduced mortality in HIV infected participants, and enhanced intestinal α-defensin expression in malnourished individuals

  – 4 live, attenuated oral vaccines will be used in the study
    - **Orochol**
    - **Vivotif**
    - **Rotarix**
    - **ACAM2010**

VACCINE TRIAL DETAILS (2)

- **Study will be divided into three parts**
  - 1st part will only involve helminth negative participants
  - Determine whether basic nutrition has an impact on the potency of vaccines
  - Each vaccine will be tested in a separate trial in order to determine the time course of any effects on antimicrobial peptide and cytokine expression
  - Each vaccine will involve 28 participants
  - Total of 160 endoscopies on 80 volunteers

VACCINE TRIAL DETAILS (3)

2nd stage

- Will look at interactions with innate immunity in two
- 4 groups, each with 20 participants
- Are 2 vaccines given together are more effective than when given individually?
- Are the potencies of the vaccines affected by the order with which they are given?
- Individually then in sequence, for example:

a) Ty21a, then ACAM2010/2017;

b) ACAM2010/2017 then Ty21a;

c) Rotarix, then Orochol;

d) Orochol, then Rotarix.

LOCATION & STUDY POPULATION

- Misisi township, Lusaka
  - One of Lusaka's poor squatter townships
  - Overcrowded housing conditions
  - Contribute to the high morbidity and mortality levels at UTH
- Both sexes of cohort aged between 18 and 78 years,
  - 35% are HIV seropositive
- Infants in the cohort (for Rotarix)

ETHICS CONCERNS

- Resource poor setting
- Access to health care
- HIV prevalence
- Social and ethical implications of vaccine trials
  - Ethics concerns related to power and wealth differentials
  - Northern public research grants focus mainly on vaccine and drug trials
  - Other important areas such as epidemiology and health systems are neglected
  - Pharmaceutical industry has little interest in diseases of poverty
  - Study populations bare burden of trials, but accessibility of post trial products is problematic

- Literacy, understanding issues
  - Trust/Mistrust of trials in situations of poverty and exploitation

- Zambian health research conducted to a large part by transnational organizations
  - Ignoring national health research agenda priorities
  - Ethics concerns related to power and wealth differentials

CRITICAL COMPONENTS OF CONSENT

- Disclosure of adequate information
- Understanding
- Trust

REVIEW OF STUDIES

- While several studies have addressed issues of information, understanding (Horng & Grady 2003, Pace, Grady & Emanuel 2003, Joubert et al 2003, Joffe et al 2001, Lynoe et al 2001, Fitzgerald et al 2001, Leach et al 1999, Karim et al 1998, Pitisuttithum et al 1997), and trust (Tindana et al 2006, Dawson & Kass 2005, Molyneaux 2004, 2005, Fairhead et al 2004, Karlawish, Fox & Pearlman 2002, van der Geest 2000, Leach 1999, Birungi 1998, Préziosi 1997), the social relations in the research process have not

- I therefore, would like to take the social grounding of consent in the research process by looking at the social relations, which make the trial process function

- I will do this by looking at the **everyday interactions** making trial implementation and agreements between research staff and participants.

SOCIAL RELATIONS

- Gender
- Lack of health care and medical benefits
- Relations of trust or mistrust of research
- Economic and medical situation
- Autonomy is NOT central to decision-making
  - Look at interactions as ongoing activities
  - Elicit a range of viewpoints from various actors
  - Understand what elucidates successful negotiations in the everyday interactions
  - Documentation of process happens after a series of events over time

ACTUAL CONSENT PRACTICES

- Social, economic and healthcare contexts
  - Influence understanding and agreement
  - Can participation be voluntary, ethically sound?
  - Close relationship between health care and research
- Consent as a socially grounded agreement between agents, rather than individual choice
  - Ethical nature of the interchange becomes more grounded in social interactions
- Consent as an evolving, processual relationship
  - Not just a moment of information exchange and agreement
  - Offers new avenues to make consent more robust

MY APPROACH TO INFORMED CONSENT

- Proposed Definition
  - Broad social consensual agreement to participation between agents
- How
  - Examine person-to-person-interactions in the consent process and during implementation of trial procedures
- What to use
  - Everyday interactions in the long-term relationships, e.g. consent form activities, expectations, rights, etc

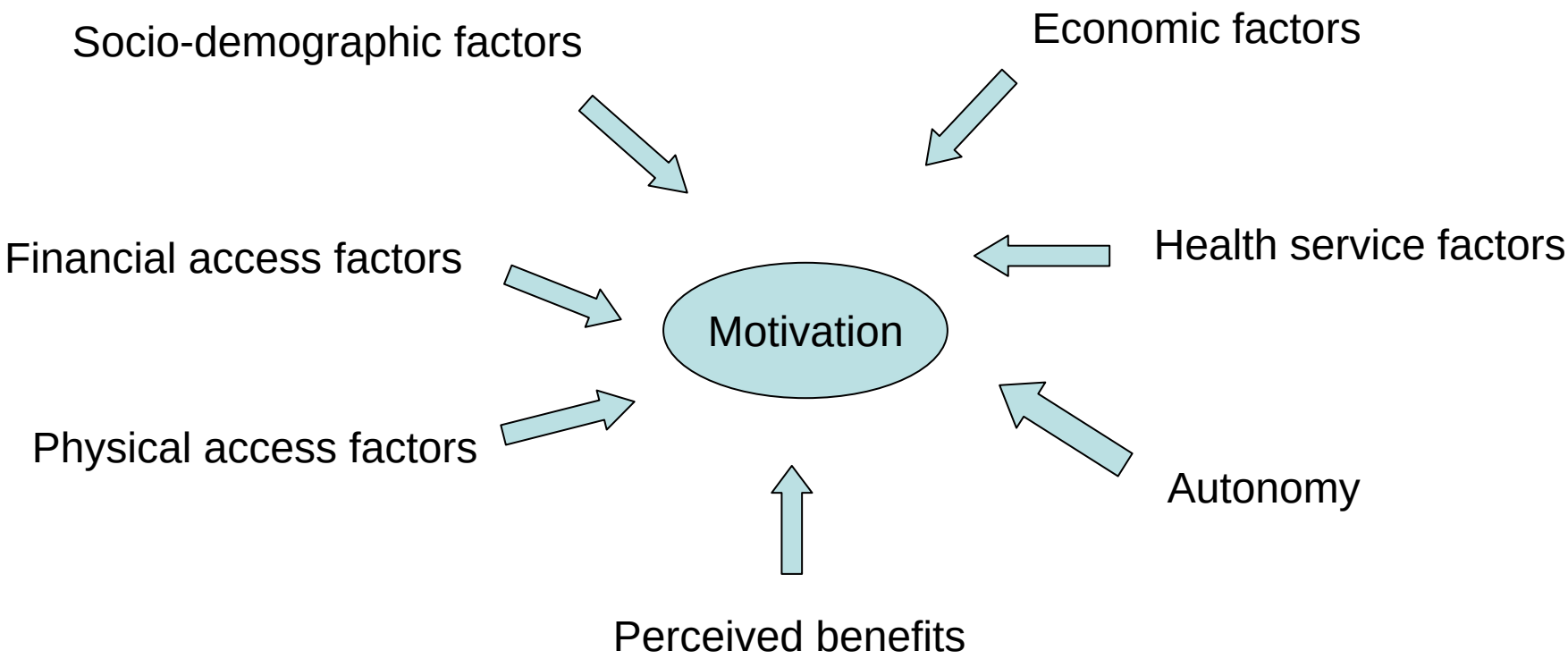
STUDY AIM

To understand the motivations for participation undertaken by research participants in this complex and challenging vaccine trial

STUDY OBJECTIVES

- To determine and explore factors that motivate people to enrol in the vaccine trial
- To determine and explore factors that inhibit people from enrolling in the vaccine trial
- To assess how the consent relationships evolve and change over the course of the trial

Conceptual Framework



DATA COLLECTION & ANALYSIS

- Triangulate interdisciplinary tools
- Participant observations
- In-depth interviews
  - Field notes
  - Transcripts
  - Discourse or narrative analysis of textual data
- Group discussions
  - Transcribing
  - Translating (and back translation)
  - Inductive analytic techniques
  - Data verification
- Literature and document review

LIMITATIONS / BIAS

- Affiliation to MoH
  - Position as national research focal point person
  - Gender
  - Researcher bias – familiarity with people working with
  - Location of study
  - Length of enquiry

ETHICAL CONSIDERATIONS

- LSHTM Ethics Committee
- Zambian Research Ethics Committee
- Minimal risks to participants
  - No immediate benefits to participants (incentives)
  - Access to participants will be through the trial process
- Participatory methods will only be done after verbal and written information
  - Nature, purpose, confidentiality and data protection issues
- Participants in audio recording will be given both oral and written information
  - Aims of the study, informed consent will be sought and taped

WHAT WILL THE STUDY ADD?

- Data on the application of ethics guidelines for consent as it unfolds in the course of a research process to better inform academia, policy makers, and the public

- Data on the everyday interactions making informed consent between research staff, regulators and participants in a resource-poor setting

- Inform national policy on development of vaccine trials in Zambia and Sub-Saharan Africa

Thank you very much for your attention!!