Exploring meaning of participation in a clinical trial in a developing country setting – implications for recruitment

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Background

Increasing body of literature exploring meaning and implications of recruiting participants into clinical trials in a developing country setting:

- Critical bioethics and anthropological perspectives

Range of literature, including systematic reviews, of effective recruitment strategies in developed country settings

- Clinical trials and statistical perspectives

How to incorporate the two?

Study Setting

The *InterACT trial:*

- Clinical observation study in Muheza, Tanzania, to explore efficacy and safety of taking anti-retroviral treatment (ARVs) for HIV concomitantly with artemisinin-based combination therapy (ACT) for malaria
- Recruiting participants presenting with fever at hospital out-patients department or HIV care centre → test for malaria
- Treatment with ACT, plus 9 follow-up assessments over 42 days

Study Outline (1)

Aim:

- To conduct a qualitative case-study among participants and staff engaged with the InterACT clinical observation study, to address two research questions:

1. Perceptions of taking ARVs concomitantly with anti-malarial treatment amongst HIV+ people in Muheza, Tanzania
2. Meaning and experiences of participation in the InterACT study

Study Outline (2)

Methods:

- Qualitative, comparative case-study design, using FGDs and IDIs (n=24)
- Sample included:
  - *Participants of the InterACT trial (HIV+ and HIV-)*
  - *People screened for InterACT trial but non-participating (HIV+)*
  - *InterACT trial staff*
  - *HIV clinic staff*
- Transcription and translation of FGDs/IDIs (ongoing)
- Iterative, meaning-based data analysis, using principles of grounded theory (n=8 to date)

Findings (1)

Recruitment is enmeshed with the clinical encounter

- Narratives of consent process are framed around clinical events and clinical information eg testing for malaria and receiving treatment

- Treatment was identified as the most important reason for consenting

Findings (1)

Recruitment is enmeshed with the clinical encounter

"*When I was coming from the village I told the doctor I am sick and he told me to go for malaria test, when the results were out [the trial nurse] came and she explained to me then we went to the project, they gave me some drugs and became better, so I joined because I... observed what I wanted."* (HIV- female, FGD-C01)

Findings (2)

Disconnect between information given and received

- Poor understanding of the trial and its aims

- Contrasting perceptions of value of information sheet between staff and participants

- Indication that clinical setting influences ability to interpret information about research

Findings (2)

"*... first thing is to make the patient understand that we are here for the project, then [the] general objective of the project which is very important for them to know why we are here and why we ask him to join...*" (Trial Nurse, IDI-01)

"M: what do you think are the advantages and disadvantages of the trial?

R08: I did not totally understand about the advantages since this is my first [time], I went to be treated and I thank God for that.

R11: We were not given any information, there we are checked, if you have malaria you're given the drugs but no more information." (HIV+ females, FGD-A02)

Findings (3)

Enacting the trial

• Despite limited comprehension of information delivered through the recruitment process, both staff and participants implied enactment of trial activities offered space within which to explore understanding of trial

• The developing relationship with trial staff and activities facilitates raising of questions and concerns, eg around blood taking, and in most cases their resolution.

Findings (3)

Enacting the trial

"*Worries had to be there, like me I used to squabble with them the way they were taking the blood, when I meet them I asked not [again]? Why are you taking a lot of blood, my blood will get finished… but they gave me a [good] service until I was getting used [to it]*" (HIV+ female, FGD-A01)

Findings (4)

The trial as a service

• Highly positive perceptions of participation, largely centred on conceptualisation of the trial as ‘receiving a service’

• Value of this ‘service’ for many rooted in opportunity to know ‘health status’ through multiple tests and receive additional treatment, suggesting participants felt their health was the focus of trial activities

• Service frequently recommended to friends, family and colleagues, who were encouraged to be tested

Findings (4)

The trial as a service

"There are no challenges [with participating] because they help us a lot, if you had typhoid problem they solve or any other infections ... they cure, and secondly their service, their servants are kind, they treasure us." (HIV+ female, FGD-A02)

Conclusions & Recommendations

1. Implications for 'informed consent' in recruitment

- Influence of context – particularly clinical – on how information is interpreted and understood
    - *Benefits of clinical setting for increasing recruitment*
    - *But challenging the notion of 'informed consent'*
- Raises questions about how information is used in the recruitment process, to achieve both trial and ethical aims

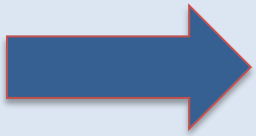
Consider influence of how, where and when information is conveyed to potential participants

Conclusions & Recommendations

2. Viewing the recruitment process as a relationship to be developed

• Engagement with trial activities and staff may facilitate participants' ability to question and understand the meaning of their participation

- *Comprehension arises through enactment of trial experience*
- *Challenging to align with recruitment which must precede*

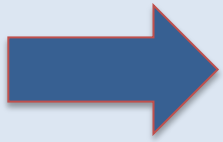


Consider ways in which this relationship can begin earlier in the trial process, eg participatory community engagement

Conclusions & Recommendations

3. Understanding the 'value' experienced by participants

- In this resource-poor setting, access to (free) health care is a motivating factor for consenting to participate
- But real value of *being* in the trial was experiencing being at the centre of care – experiencing a *service*
  - *Gave participants motivation to continue with study*
  - *Influences word-of-mouth recruitment to 'the service'*



Formative/ ongoing qualitative work to understand experienced value of participation, and consider potential for recruitment by word-of-mouth

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