Unanticipated participant benefits in HIV cure clinical research:
A qualitative analysis

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Background

• HIV cure research involves risks; lacks direct benefits

• Participants are made aware of the lack of benefits
  (Henderson 2015 AIDS Res Hum Retroviruses)

• Inclusion benefits well known; sometimes mentioned in consent, not always

Aims

• Determine perceptions of benefits and risks associated with participating in HIV cure research

• Use multiple stakeholder data to inform the development of consent tools for HIV cure research
Why should we care?

• Therapeutic or ‘curative’ misconception (Lo and Grady 2013 *Curr Opin HIV AIDS*)

• Risk vs. benefit ratios (Eyal 2016 *JME*)

• Participant motivation? (Peay and Henderson 2015 *J Virus Erad*)

• Debates about the language of HIV cure (Dubé et al. 2014 *Trends Microbiol*)

• Very little research on participants’ perceptions of cure research (McMahon et al. 2015 *AIDS*)
Methods

• In-depth, semi-structured interviews

• Studies: (1) Therapeutic vaccine (ARGOS), (2) latency reversal (Vorinostat), (3) HIV-1 Expanded Specific T Cell Therapy (HXTC), and (4) cell donation

Research participants: 16  Researchers: 11
Median age: 49 (28-62)  Clinical research staff: 6
14 White, 1 Black, 1 Latino  Research scientists: 5
14 with some college
12 MSM

Interviews transcribed, coded, and then analyzed using MAXQDA12
### Benefit categories and examples

- **Psychological benefits**
  - Positive outlook, sense of purpose

- **Improved care**
  - Quality of providers, improved access

- **HIV knowledge**
  - Information about cure linked to hope

- **Personal relationships**
  - Opportunities for support, brought ‘closer together’

- **Behavioral changes**
  - Drugs/alcohol, improved diet/exercise

- **Financial benefits**
  - $25-300/hr, lunch, overnight hotel stays
Risks and burdens

- Quality of life (12/16)
- Cancer (5/16)
- Side effects (3/16)
- Status disclosure (3/16)
- Undue inducement (1/16)
- Latency reversal risks (1/16)
- Conflict with partner (1/16)
- Therapeutic misconception

'I’d be lying if I didn’t say… I’m closer than somebody else sitting on their hands, just taking their ARTs and getting their blood checked every 3 months. I’m closer to a cure if I’m involved in the research....'
Conclusions

• Inclusion benefits are recognized and valued, not common in consent (Henderson 2015 AIDS Res Hum Retroviruses)

• Participation is meaningful; personal relationship effects; changed behaviors; learning to live with HIV

• May increase study retention; serial participation?

• The potential for inclusion benefits should be addressed in HIV cure consent documents
Limitations

• Study was exploratory (no quant. data)
  – Benefit themes emerged

• Data from few interviews not generalizable

• Very little diversity

• Social bias?

• Benefits of participation or HIV cure participation?
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