

EXPERIENCES AND EXPECTATIONS OF PARTICIPANTS COMPLETING HIV CURE FOCUSED CLINICAL TRIALS

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Background

- Expectations of the eventual outcomes of HIV cure research potentially differ between investigators and people living with HIV¹
- Understanding expectations and experiences of PLHIV participating in 'cure-focused' clinical trials, particularly the risks of participation, will improve the design of future studies and the process of informed consent
- Particularly important as currently these do not have a curative intent so involvement is essentially altruistic²



1 Verdult, IAS, Washington, DC. 2012. 2 Tucker, AIDS , 2014



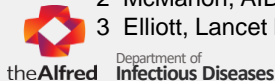
Background

- Recent surveys published on the broader PLHIV community:¹
 - Willingness to participate in HIV cure trials
 - Perceived risks of participation
- We have previously reported on participants completing one cure focused trial² and this study extends that work to include people completing 2 additional trials testing HIV cure focused interventions³

1 Simmons HIV Med 2017; 18: 73-79. Dube, J. Virus Erad 2017; 3:40-50

2 McMahon, AIDS 2015, 29:248–250, Elliott, PLoS Pathogens. 2014 Nov;10(11):e1004473;

3 Elliott, Lancet HIV 2015.2(12): 520-9, clinicaltrials.gov/ct2/show/NCT02500446



Methods

- Participants were receiving antiretroviral therapy (ART) and had completed one of three studies
 - Two examined the effects of adding Vorinostat (VOR) or Disulfiram (DSF) on latent HIV¹
 - One examined if the addition of Dolutegravir (DTG) impacts residual HIV viral replication²
- Trials were intensive - minimum 8-9 visits over a 1-3 month period with clinical assessment and blood draws
 - In addition two rectal biopsies were performed in the vorinostat trial
- Motivation for involvement was largely altruistic

1 Elliott, PLoS Pathogens. 2014 Nov;10(11):e1004473; Elliott, Lancet HIV 2015.2(12): 520-9; 2 clinicaltrials.gov/ct2/show/NCT02500446



Methods

- Design - Paper survey provided to all subjects at the conclusion of the trial (typically last study visit) focused on:
 - Experiences and satisfaction with trial participation
 - Desirability of two potential HIV cure scenarios
 - ‘sterilising cure’ [completely cured / stop ART / no doctor visits] and ‘functional cure’ [HIV still present / stop ART / doctor visits required]
 - Ranking the importance of 5 potential benefits of HIV cure
 - stopping ART, stopping doctor visits, cannot transmit HIV, cannot be re-infected with HIV and being considered someone without HIV
- Analysis - Compared by Wilcoxon signed-rank (sterilizing vs. functional cure) and Kruskal–Wallis (five potential benefits) tests

If an HIV cure could be achieved in the future how desirable to you are these two different scenarios - please circle your response

You are completely cured. So you no longer need to take HIV medications or see doctors about HIV.

Very Desirable	Somewhat Desirable	Somewhat Undesirable	Very Undesirable
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The virus is still in your blood, but your body is able to keep the virus in check on its own. You no longer need to take HIV medications but you still need to visit your doctor for testing to monitor HIV.

Very Desirable	Somewhat Desirable	Somewhat Undesirable	Very Undesirable
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If an HIV cure could be achieved how important are these 5 possible scenarios Please rank the following different scenarios 1 to 5. Where Number 1 would be the most important and number 5 the least important.

<input type="text"/>	Stopping HIV medications
<input type="text"/>	Stop visiting the doctor for regular visits to monitor HIV
<input type="text"/>	Not passing the virus on to others
<input type="text"/>	Not getting HIV again for a second time
<input type="text"/>	Being considered as a person who is not infected with HIV

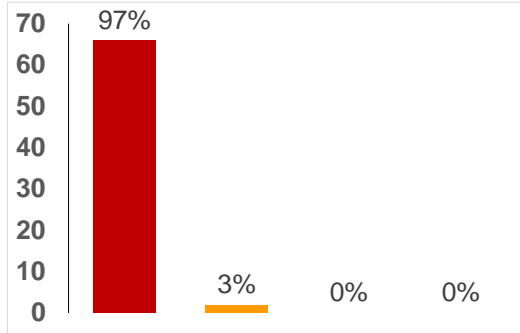
Demographics

- N=68 completed the survey
- 20/20 (100%) VOR, 10/15 (66%) DSF, 38/40 (95%) DTG
- 65 male, 2 female, 1 transgender
- Mean (+/- SD) age 47.7 +/- 9.3 years
- Transmission risk category
 - MSM 40, Heterosexual 5, Bisexual 10, IVDU 2, Unknown 11
- All had viral load <50 copies/mL for a minimum 3 years and CD4 > 350 cells/ μ L

Satisfaction and Motivation

- Motivation – why participants entered the study
 - Most significant responses
 - “to contribute to research” 65/68 (96%), “to help others” 60/68 (88%)¹
 - Less significant responses
 - “to effect control on my HIV” 34/68(50%), “to improve my own health” 35/68 (51%)¹
- High levels of satisfaction with the studies:
 - Using a scale of 0 to 100 median satisfaction with the overall study experience was 90 (IQR: 90-100)
 - > 85% subjects would definitely consider enrolling in a similar study focused on HIV cure if approached

You are completely cured. So you no longer need to take HIV medications or see doctors about HIV



97% rated 'sterilising cure' very desirable compared to 57% for 'functional cure' (p<.01)

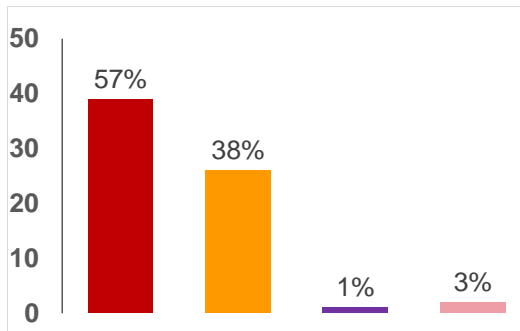
Very Desirable

Somewhat Desirable

Somewhat Undesirable

Very Undesirable

The virus is still in your blood, but your body is able to keep the virus in check on its own. You no longer need to take HIV medications but you still need to visit your doctor for testing to monitor HIV



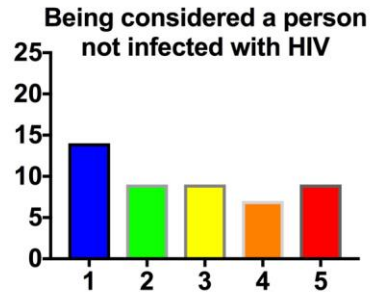
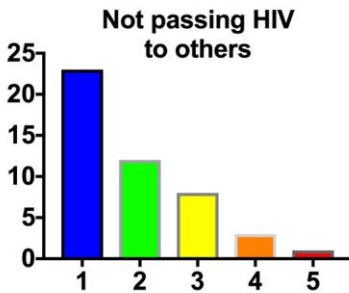
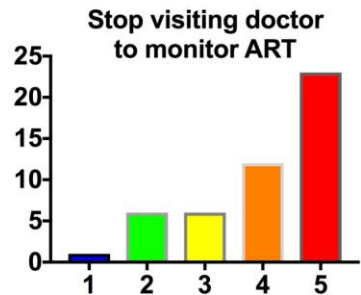
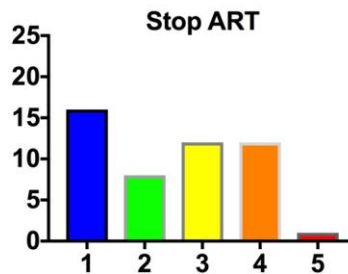
Ranking of 5 potential cure scenarios (n=68)

Ranking scenarios from:

Most important (1)

TO

Least important (5)



Most Important Scenario n=68

Potential cure scenarios ranked most important n (%)					P value
Not passing HIV on to others	Stopping HIV medications	Being considered as a person who is not infected with HIV	Not getting HIV again for a second time	Stop visiting the doctor for regular visits to monitor HIV	
31 (46%)	22 (32%)	21 (31%)	13 (19%)	2 (3%)	<0.01

Conclusions

- High levels of participant satisfaction were achieved during intensive clinical trials focusing on HIV cure
- Motivations to participate in cure studies mirror recent US and UK studies where PLHIV prioritised benefits such as¹:
 - “helping other people with HIV in the future”
 - “helping find a cure for HIV”
 - “(not) passing HIV to sexual partners”

1 Simmons HIV Med 2017; 18: 73-79. Dube, J. Virus Erad 2017; 3:40-50

Conclusions

- Overwhelming majority of participants in cure-focused studies rated a 'complete' or 'sterilizing' cure as more desirable than a scenario of HIV remission
- Potential benefits of not transmitting HIV considered most important
- This research highlights the importance of understanding the expectations of people who enter and complete these altruistic cure focused trials to:
 - More clearly discuss the rationale for these studies (consent)
 - Improve study design



<http://hivcure.com.au/2017/09/22/interrupt-treatment-hiv-cure/>

2 Surveys (For PLHIV and Providers) about acceptability and parameters for analytical treatment interruption in the cure research

napwha national association of people with HIV australia

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HIV CURE

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PAUSE THE PILLS: WOULD YOU INTERRUPT TREATMENT FOR HIV CURE RESEARCH?

TWITTER

🐦 Rowena Johnston from @amfAR will join us to discuss #HIV remission next Tuesday 1pm AEDT at

Acknowledgements

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