

Community Perspectives

HIV Cure Trials

Cipriano Martinez
May 2019



napwha national association of
people with HIV australia

**I acknowledge we are on the land of
the Turrbal & Jagera peoples and
give my respect to their elders, past
present and emerging.**



Thank you people living with HIV
Many of you have generously shared your time, talent,
experiences, and bodies for the purposes of research.
I acknowledge, appreciate, honor and respect
your acts of love
to & for us

Thank you to many health professionals and allies of people
with HIV, to you in this room, for your generous & full efforts
I acknowledge, appreciate, honor and respect
your acts of love
to & for us



Our HIV journey is a love story



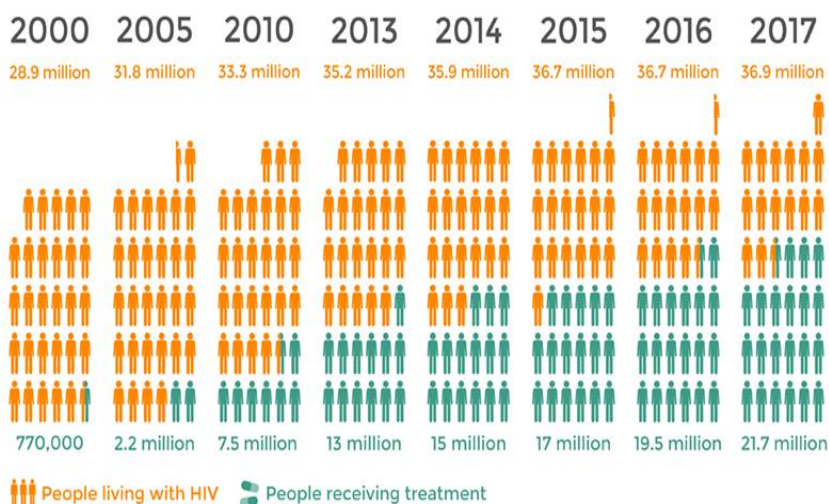
Pic source – Ken Crosswell, The lives of Stars



Our HIV journey is a love story

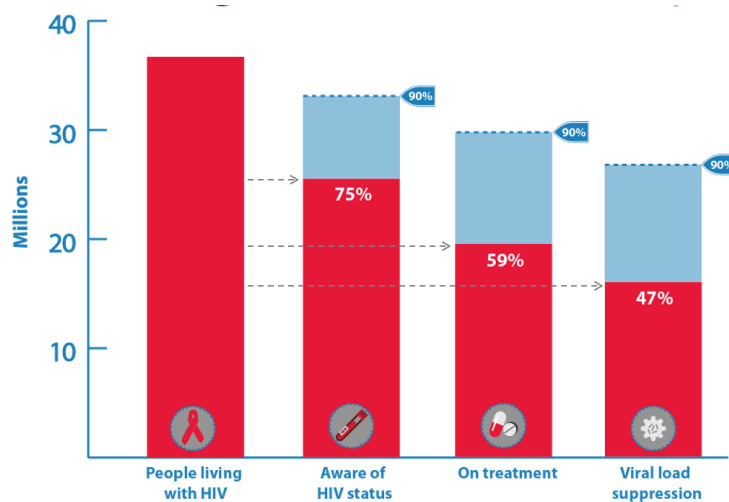


People Living With HIV and Accessing Treatment Globally

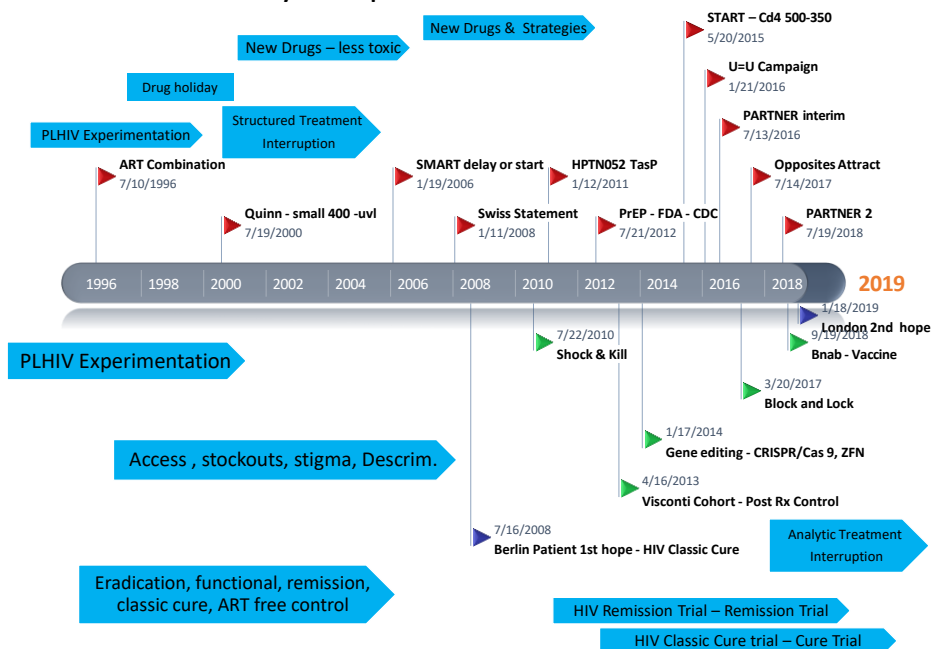


Source: UNAIDS Data 2018

HIV Testing & Care Continuum 2017



Community Perspective – Context Matters



HIVcure.com.au

Community and Provider Attitudes Towards ATI

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HIV CURE

FIND OUT ABOUT CURRENT STUDIES

GET INVOLVED

Home Science Clinical Trials **Community** Media Video

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

12 months ago

Doherty Institute

TWITTER

RT @ASHMMedia: Don't miss Prof of Microbiology and Immunology, Dr Barbara Shacklett @UCDavisMed, presenting perspectives on HIV-specific T-

theAlfred

Doherty Institute

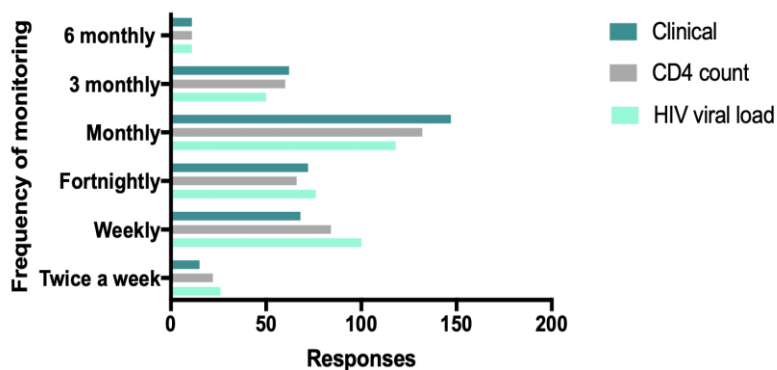
living positive victoria

napwha national association of people with HIV australia

Australian Research Centre in Sex, Health & Society

AUSTRALIAN HIV Cure Community Partnership

PLHIV preferred monthly monitoring

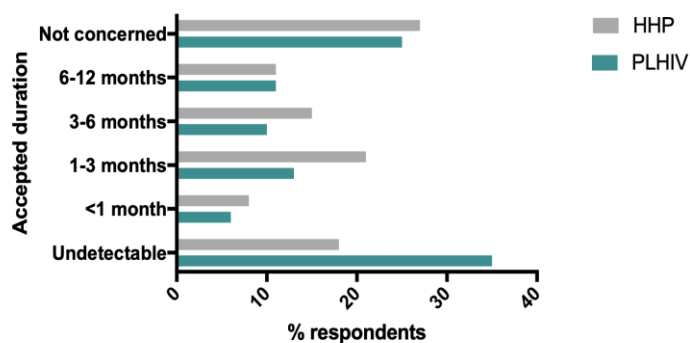


Jillian Lau -

Community and provider perspectives on Treatment Interruptions in the landscape of HIV cure focused studies

Jillian SY Lau¹, Miranda Z Smith², Brent Allan³, Cipriano Martinez⁴, Jennifer Power⁵, Sharon R Lewin^{1,2}, James H McMahon¹

PLHIV less accepting of sustained viremia during ATI



Acceptable period of time off ART during ATI for PLHIV and Providers

U=U

UNDETECTABLE
=
UNTRANSMITTABLE

A PERSON LIVING WITH HIV
WHO HAS AN UNDETECTABLE
VIRAL LOAD DOES NOT
TRANSMIT THE VIRUS TO THEIR
PARTNERS.



The International AIDS Society is proud to endorse the U=U consensus statement of the Prevention Access Campaign.

- Era of pill free interventions – We need a Rapid VL test.
- Cure interventions, must not jeopardise a return to UVL.
- UVL essential to many, health, sex and social lives to reduce stigma and discrimination, boosts resilience , well being, sense of a normal life, control

ATI & Transmission



TREATMENT NEWS

French Man With HIV Transmits Virus While Off Meds During Cure Trial

Many HIV cure trials take participants off antiretrovirals for a period in order to see how well the investigational treatment works.

February 28, 2019 · By Benjamin Ryan

ANRS LIGHT VRI02 trial, a randomized, multicenter double-blinded placebo-controlled Phase II therapeutic vaccine trial in France

What can be improved?

- Education-Assume VL is high
- Partner on PrEP
- Reduce ATI period where possible
- Develop rapid VL test



Consensus recommendations for ATI

Inclusion criteria

- Stable CD4 counts ≥ 500 cells per μL *
- HIV RNA undetectable on stable ART†
- Otherwise healthy individuals without major comorbidities

Key exclusion criteria

- Active or chronic hepatitis B virus infection, with detectable hepatitis B surface antigen, hepatitis B e antigen, or hepatitis B core antibody

Additional or more stringent criteria might be required based on known toxicities of the study drug(s) or expected risks of the study intervention(s). Inclusion and exclusion criteria, monitoring, and antiretroviral therapy (ART) restart criteria might differ in children depending on age. ART=antiretroviral therapy. *Baseline CD4 counts of ≥ 350 cells per μL might be considered. †Based on FDA-approved HIV RNA quantification assay. ‡Latent tuberculosis infection discussed in the text. §Other malignancies discussed in the text. ¶Defined as single key mutations or an accumulation of minor mutations that result in resistance to entire respective drug classes. ||Symptoms include, but are not limited to, unintentional weight loss (>5 – 10% of the pre-ATI bodyweight), otherwise unexplained persistent fever ($>100.4^\circ\text{F}/38^\circ\text{C}$), persistent night sweats, persistent diarrhoea, oral candidiasis and generalised lymphadenopathy. **Largely dependent on the CD4 entry criteria; a sufficiently large delta between the entry value versus CD4 measurement for ART resumption should be ensured. ††12–16 weeks of uncontrolled viraemia, with HIV RNA of more than 100 000 copies per mL; it might be acceptable in studies in which a stable viral set point is a primary endpoint.

- Women who are pregnant or breastfeeding
- Advanced non-alcoholic fatty liver and advanced nonalcoholic steatohepatitis, if evidence for substantial fibrosis (fibrosis score $\geq \text{F2}$) or evidence of cirrhosis
- HIV-related kidney disease or moderate-to-severe decrease in estimated glomerular filtration rate (<45 – 60 mL/min/1.73 m^2)
- Children younger than 2 years of age when the ATI is planned

Monitoring

- HIV RNA monitoring weekly for 12 weeks, then every other week
- CD4 count monitoring every two weeks
- Monitoring of clinical symptoms, in particular in people who started ART during the trial

Julg, Lancet HIV, 2019

Cure Trials



TAG
Treatment Action Group



- Cure
- Remission
- drug-free long-term control,
- Viral suppression off-ART
- ART-free remission

- Disconnect between, researchers understanding of personal benefit and the participants hope & desire for cure
- Guidelines recommend staying on ART
- No other option to measure intervention



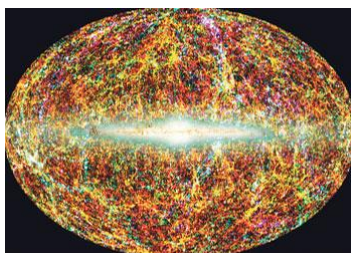
Talking Hope with peers

- Hope is important as it often leads to positive action, like greater efforts toward self care and improved resilience.
- HIV 101 basics may not be understood, so engagement with HIV cure and remission concepts could be misunderstood with negative consequences.
- Too much hope can lead to disappointment when it does not materialise - cynicism and a negative outlook can be detrimental to well being and health.
- Too little hope for the future, can lead to despair if a person perceives the negative impacts of HIV as permanent.
- A balanced hope – A belief that, real & ongoing efforts & advances, even if only small and incremental, will eventually lead to worth while progress.



Every year we have the chance to lovingly
save a million lives, a million points of
loving light.

Yes its worth it!
Yes love is worth it!
Yes I will participate in a cure trial
yes I choose to give love



Australian HIV Cure Community Partnership

Steering Committee:



theAlfred



Kirby Institute



living positive victoria

Members from:



Supported by:



Thanks to our Global Collaborators!

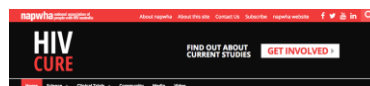


... and all scientific and community leads and partners!



**Thank you
everyone
for being a
part of loving
health care**

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