



*“In diversity there is beauty and there
is strength”*

—Dr. Maya Angelou

A Community Call to Action to Prioritize Inclusion and Enrollment of Women in HIV Cure-related Research

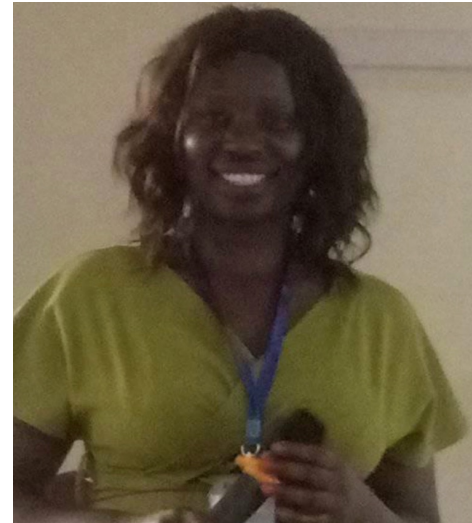
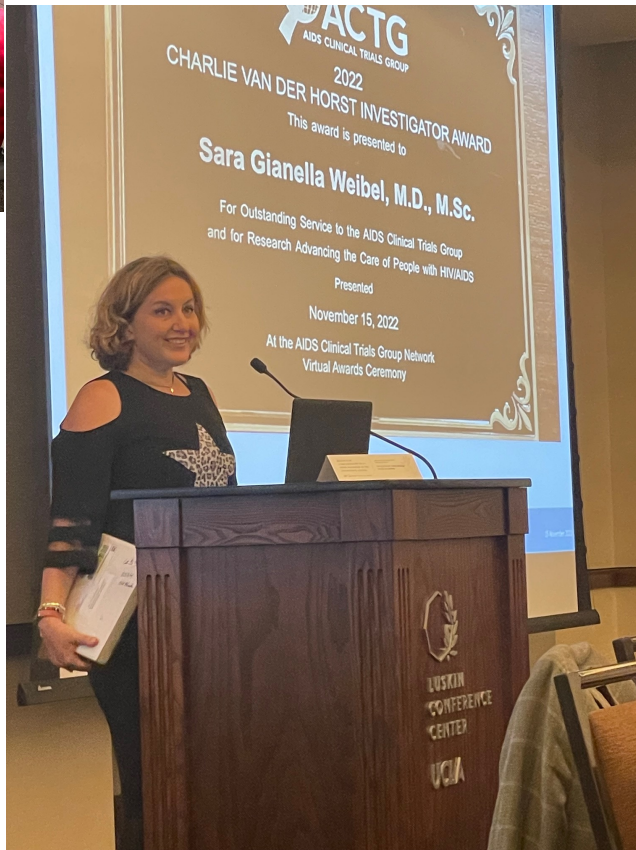
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2023 Pre-CROI Community HIV Cure Research Workshop

February 18, 2023

With respect.



First Woman Has Been ‘Cured’ of HIV Using Stem Cells

The novel treatment using umbilical cord blood could help dozens of people with both HIV and aggressive cancers

IMPAACT P1107 Team Presents First Known Case of a Woman with HIV Remission

A Woman Is Cured of H.I.V. Using a Novel Treatment

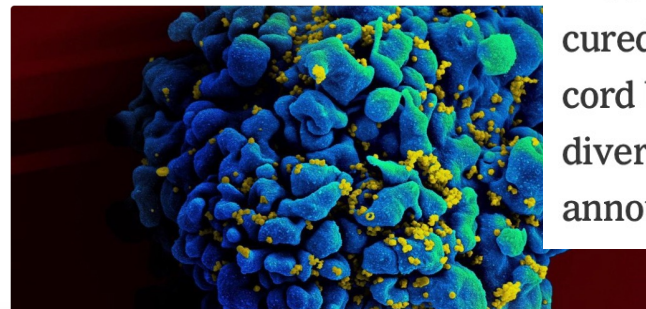
She’s the third person ever to be cured. Researchers announced that the new approach holds the potential for curing more people of racially diverse backgrounds.

FEBRUARY 2022

STUDY RESULTS

SHARE 

The [IMPAACT P1107](#) protocol team presented the **first known case of a woman with HIV remission** following a stem cell transplant for treatment of acute myelogenous leukemia (AML) at CROI 2022 on 15 February. The transplant consisted of cord blood stem cells with the CCR5Δ32 genetic mutation and haploidentical peripheral blood stem cells from a relative. Since having the stem cell transplant, the participant has been in remission for AML.



A woman of mixed race appears to be the third person ever to be cured of H.I.V., using a new transplant method involving umbilical cord blood that opens up the possibility of curing more people of diverse racial backgrounds than was previously possible, scientists announced on Tuesday.

Summary of the global HIV epidemic, 2021

People living with HIV in 2021 People acquiring HIV in 2021 People dying from HIV-related causes in 2021

	People living with HIV in 2021	People acquiring HIV in 2021	People dying from HIV-related causes in 2021
Total	38.4 million [33.9–43.8 million]	1.5 million [1.1–2.0 million]	650 000 [510 000–860 000]
Adults (15+ years)	36.7 million [32.3–41.9 million]	1.3 million [990 000–1.8 million]	560 000 [430 000–740 000]
Women (15+ years)	19.7 million [17.6–22.4 million]	640 000 [480 000–870 000]	240 000 [180 000–320 000]
Men (15+ years)	16.9 million [14.6–19.7 million]	680 000 [500 000–920 000]	320 000 [250 000–430 000]
Children (<15 years)	1.7 million [1.3–2.1 million]	160 000 [110 000–230 000]	98 000 [67 000–140 000]

Source: UNAIDS/WHO estimates

Updated: July 2022



Gendered and racialized global epidemic:

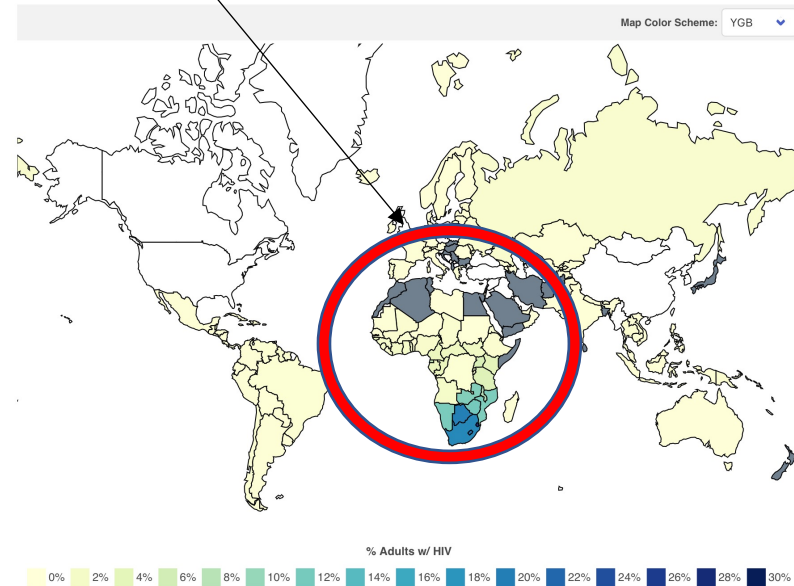
>50% burden among women

African descent

Top 10 Countries with the Highest HIV Rates (% of 2020 Population):

1. Eswatini — 26.8%
2. Lesotho — 21.1%
3. Botswana — 19.9%
4. South Africa — 19.1%
5. Zimbabwe — 11.9%
6. Namibia — 11.6%
7. Mozambique — 11.5%
8. Zambia — 11.1%
9. Malawi — 8.1%
10. Equatorial Guinea — 7.3%

HIV Rates by Country 2023



Paucity of diversity in HIV cure research

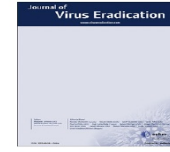
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A landscape analysis of HIV cure-related clinical research in 2019

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ORIGINAL RESEARCH

Journal of Virus Eradication 2019; 5: 212–219

A landscape analysis of HIV cure-related clinical trials and observational studies in 2018

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Full Access

Short Communication: Population Representation in HIV Cure Research: A Review of Diversity Within HIV Cure Studies Based in the United States

Carly Roberts, Emma Creamer, Cheriko A. Boone, A. Toni Young , and Manya Magnus

Published Online: 5 Aug 2022 | <https://doi.org/10.1089/aid.2021.0127>

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CLINICAL SCIENCE

A Systematic Review of the Inclusion (or Exclusion) of Women in HIV Research

From Clinical Studies of Antiretrovirals and Vaccines to Cure Strategies

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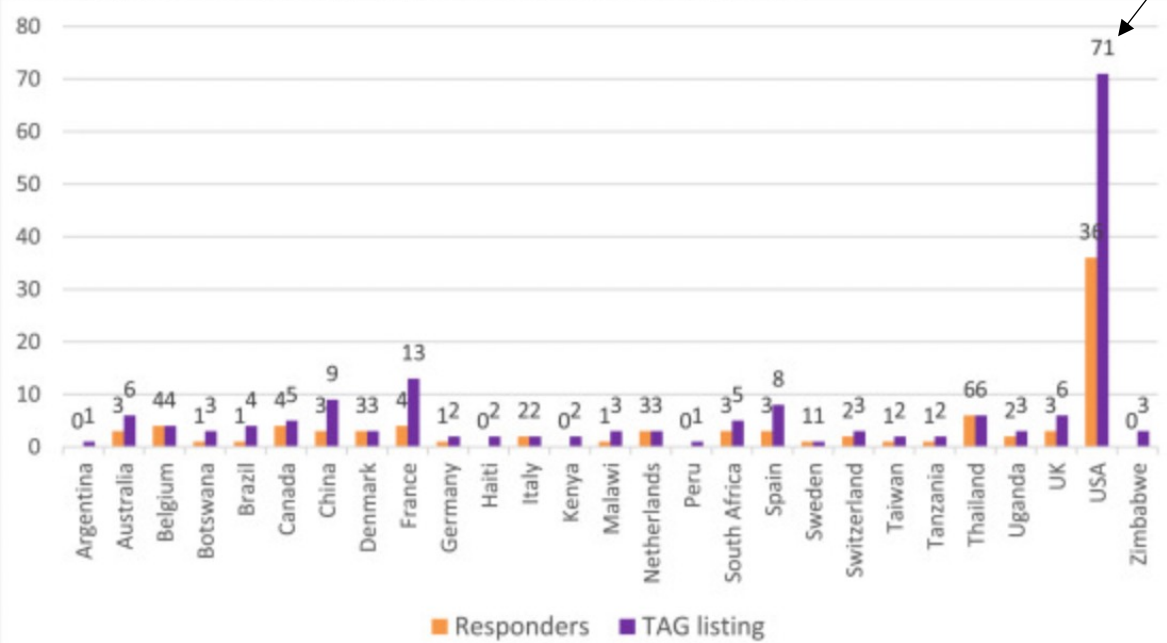
[Author Information](#)

JAIDS Journal of Acquired Immune Deficiency Syndromes 71(2):p 181-188, February 1, 2016. | DOI:

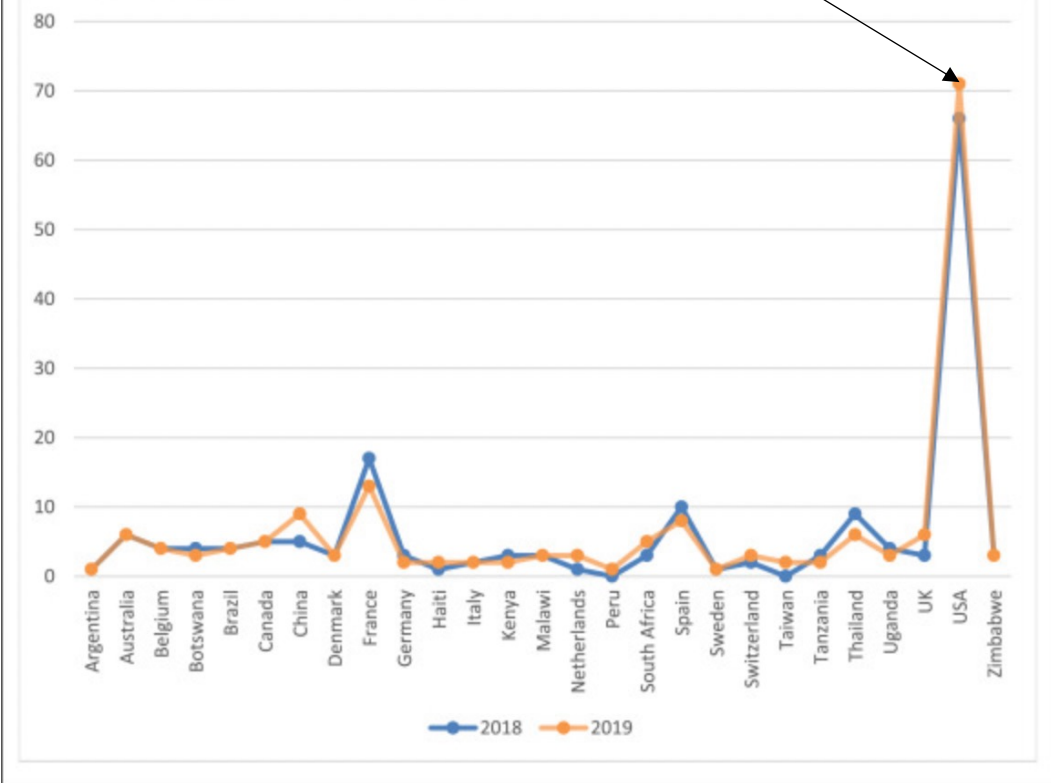
10.1097/QAI.0000000000000842

Lack of geographic equity

1A: Study locations, survey responders and TAG listing, 2019



1B: Study locations, TAG listing 2018-2019



Ethical Conundrum: Access to scientific progress derived from research is a human right

WHERE DOES THE RIGHT TO THE BENEFITS OF SCIENTIFIC PROGRESS COME FROM?

The right to the benefits of scientific progress was first recognized internationally in the Universal Declaration of Human Rights (UDHR) (1948) and later as Article 15 in the legally binding International Covenant on Economic, Social and Cultural Rights (ICESCR) (1966). The right to the benefits of scientific progress is also mentioned in a number of other regional and international human rights instruments and statements ([Read more](#)).

... Not for women

- Limited participation-> desire future pregnancies, ongoing breastfeeding, and strict contraception requirements
- Unwillingness to participate -> sociostructural barriers that include stigma and limited logistical support from sites including childcare, inconvenient transportation, and site hours of operation

Women MUST be part of HIV cure research

- Population informed scientific research-> Previous research highlighted the effects of sex assigned at birth on HIV pathogenesis, persistence, and treatment response and how sex differences may affect the HIV reservoir and immune response to therapeutic approaches being investigated as cure strategies
- Sex-based analyses are imperative at all stages of clinical research to understand the crucial differences in HIV reservoir dynamics

Policy frameworks to inform a just research enterprise

- NIH Revitalization Act of 1993 provided a federal level mandate that all NIH supported research must include women and minority populations.
- Universal Declaration of Human Rights (UDR) (1948) and Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) (1996) affords the right to the benefits of scientific progress to all people.
- Consensus Study Report by the National Academies of Science, Engineering, and Medicine, “Improving Representation in Clinical Trials and Research.”
- APHA Policy Statement 20226- “Support for Women’s Inclusion in HIV-Related Clinical Research”

We as Community offer several action steps to support an HIV cure research infrastructure that is inclusive of women.

We call for:

- Full support of women's bodily autonomy and decision-making processes to freely decide whether to participate in an HIV cure study
- Consideration of women's sexual and reproductive freedoms that intersect with their ability to meaningfully participate in research
- The end of overly restrictive contraception requirements and documentation as part of inclusion criteria for HIV cure studies
- Provide no-cost, easily accessible contraception as part of study participation
- Targeted representation and enrollment of women in HIV cure research at all phases, not only those in phase 2b or higher
- Engagement of community and other women early in study development
- Meaningfully involve women from resource-limited settings to lead HIV cure research and advocacy related efforts
- Conduct of HIV cure trials in resource-limited settings for women from resource-limited settings, where the burden of the HIV epidemic lies
- Inclusion of sociobehavioral sciences research to understand and address barriers to women's enrollment and retention in clinical trials
- Clinical trial protocols to specifically state the minimum percent enrollment for women; clinical research sites should be given adequate time, resources, and support to enroll women
- Clinical trial protocols to be written to include sex-based comparisons, when appropriate, so that necessary information can be collected as trials are conducted
- Scientific conferences and journals to enforce requirements for the inclusion of sex and gender data or at least a concrete plan to collect these data in a future follow-up study
- Accurately report sex and gender (ie, to avoid misclassifying transgender women and/or nonbinary individuals)
- Publications to report numbers of women enrolled, even when it is zero
- Identification of the sex of cell lines and animals (in preclinical studies), in addition to sex and gender of human participants.

Thank you!

