

Racial Disparities in HIV Clinical Trials And Their Consequences

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ABSTRACT

Economic, social, and racial disparities ravage the American health care system, and these issues are as prevalent today as ever. Among these healthcare disparities are those present within HIV clinical trials, particularly the striking underrepresentation of minority groups. More specifically, although Black Americans represent 43% of HIV positive patients in the United States, they account for about 5% of patients in HIV clinical trials. In order to understand why there are racial disparities within HIV clinical trials, I explored HIV transmission and biological processes, and discussed the disparities that HIV positive Black Americans face. Literature on the biological process of HIV transmission definitively demonstrates that HIV is transmitted primarily through the spread of bodily fluids (e.g., blood, semen, vaginal fluid, or breast milk) from person to person, or from mother to child. Therefore, since HIV is spread through bodily fluids, which every human being has, a person's race is an irrelevant factor in the pathobiology of HIV transmission. However, these findings directly conflict with the data that shows that HIV- positive Black Americans are a small percentage in HIV clinical trials, resulting in increased risk of HIV transmission amongst Black Americans and increased rates of mortality. The underrepresentation of HIV Positive Black Americans in HIV clinical trials is not only detrimental in the medical field, but also socioeconomically. Studies show that HIV transmission and risks are high in Black Americans due to the American justice system arresting a high population of Black Americans. The prevalence of HIV/AIDS in Black Americans is about 3-5 times that of the general population, imprisoned Black Men are 6.6 times more likely to be infected with HIV than White Men and imprisoned Black Women are 3.8 times more likely to be infected with HIV than White Women. HIV transmission is high amongst incarcerated folks, in large part, because substance abuse is prevalent amongst the incarcerated population. Suggestions for improving the high mortality rates amongst HIV positive Black Americans are to create programs that focus on targeting predominantly Black neighborhoods about HIV clinical trials and offering free medical services to affected HIV positive populations in those HIV-impacted neighborhoods. Furthermore, to reduce the prevalence of substance abuse, it is essential to establish drug policies that protect drug users, rather than criminalize them to aid in their rehabilitation. In addition, 50 year-old policies for drug offenses should be abolished in favor of rehabilitating drug users. These changes would aid in the decrease of mortality rates amongst HIV positive Black Americans.

METHODS

- Analyzing primary articles about the biological processes of HIV transmission and HIV mechanisms in the body
- Researching primary articles on HIV Clinical Trials about how minority groups were underrepresented
- Focused on researching the disparities that HIV
 Positive Black Americans face, as they account for about 43% of HIV positive community and about 5% of HIV Clinical Trials
- Researched additional socioeconomic factors of high mortality rates in HIV Positive Black Americans
 - War on Drugs
 - Substance abuse/drug policy
 - Increased incarceration rates

RESULTS

HIV invasion site	Anatomical sublocation	Type of epithelium	Transmission medium	Transmission probability per exposure event	contributior to HIV case worldwide
Female genital tract	Vagina	Squamous, nonkeratinized	Semen; blood	1 in 200-1 in 2000	12.6 million
	Ectocervix	Squamous, nonkeratinized			
	Endocervix Other	Columnar, single layer Various			
Male genital tract	Inner foreskin	Squamous, poorly keratinized	Cervicovaginal and rectal secretions; blood	1 in 700-1 in 3000	10.2 million ^a
	Penile urethra	Columnar, stratified			
	Other	Various			
Intestinal tract	Rectum	Columnar, single layer	Semen; blood	1 in 20-1 in 300	3.9 million ^b
	Upper GI tract	Various	Semen; blood	1 in 2500	1.5 million
			Maternal blood, genital secretions (intrapartum)	1 in 5-1 in 10	960,000°
			Breast milk	1 in 5-1 in 10	960,000°
Placenta	Chorionic villi	Two-layer epithelium (cyto- and syncytiotrophoblast)	Maternal blood (intrauterine)	1 in 10-1 in 20	480,000°
Bloodstream		, , ,	Blood products, sharps	95 in 100-1 in 150	2.6 million ^d

Figure 1. Transmission routes of HIV -1 Infection (Hunter & Shaw, 2012)

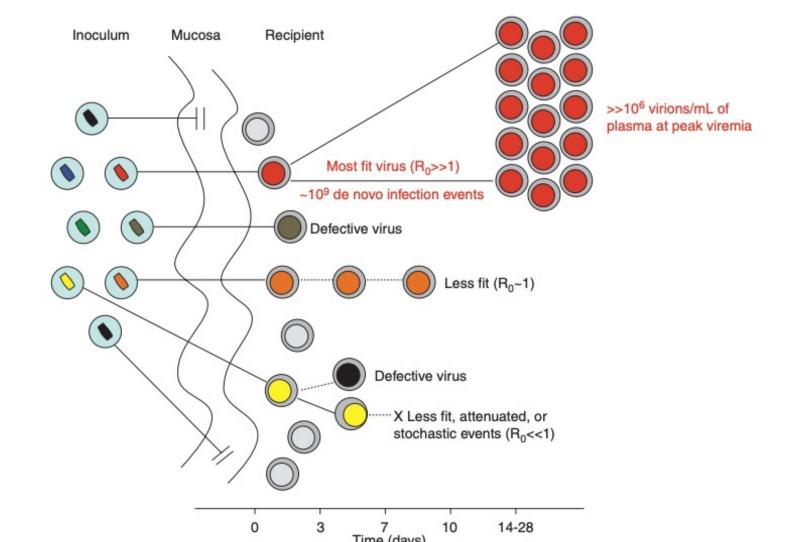


Figure 2. HIV-1 Transmission via breaching of mucosa, with varying outcomes of transmission (Hunter & Shaw, 2012)

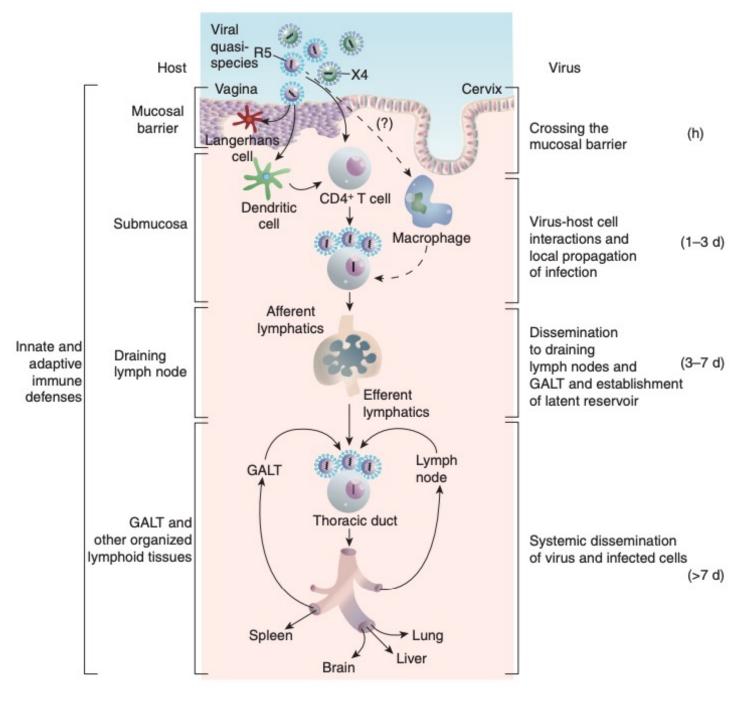


Figure 3. HIV-1 Transmission Model on Cervicovaginal model (Hunter & Shaw, 2012)

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RESULTS

Figure 4. Summary of barriers related to HIV Clinical Trial (CT) participation in minority patients (Bass et al., 2020)

Barriers to CT Participation

		2008			2009			2010			2011			2012	
Race/Ethnicity	No.†	Rate per 100,000 pop.	Rate per 1,000 PLWH [§]	No.†	Rate per 100,000 pop.	Rate per 1,000 PLWH [§]	No.†	Rate per 100,000 pop.	Rate per 1,000 PLWH [§]	No.†	Rate per 100,000 pop.	Rate per 1,000 PLWH [§]	No.†	Rate per 100,000 pop.	Rate per 1,000 PLWH [§]
Black/African American	9,920	33.1	28.4	9,596	31.7	26.5	8,682	28.3	23.3	8,444	27.2	21.9	8,165	26.0	20.5
Hispanic/Latino	2,949	8.5	18.5	2,913	8.2	17.5	2,809	7.4	16.3	2,799	7.2	15.6	2,586	6.5	13.9
White	5,662	3.3	20.8	5,545	3.2	19.8	5,395	3.2	18.8	5,307	3.1	18.1	5,426	3.2	18.1
Other races	890	5.5	22.8	998	6.1	24.6	1,003	5.5	23.9	946	5.0	21.8	989	5.1	22.0
Total	19,421	7.7	23.7	19,052	7.5	22.5	17,890	7.0	20.5	17,496	6.8	19.4	17,166	6.6	18.5

* Data include persons with diagnosed HIV infection regardless of stage of disease at diagnosis. Deaths of persons with a diagnosis of HIV infection might have resulted from any cause.

† Estimates include statistical adjustment that accounted for reporting delays, but not for incomplete reporting.

§ Rate per 1,000 population aged ≥13 years living with diagnosed HIV infection (PLWH). Denominator was estimated as (no. PLWH at the end of [year X-1]) + (no. new diagnoses during year X).

Figure 5. Estimated number and rates of deaths of persons aged \geq 13 years with diagnosed HIV Infection by ethnicity/race in the United States (CDC, 2021)

	Race (n=1,993) ^a						
	White (n=677)	African American (n =871)	Hispanic (n=445)	<i>P</i> value*			
December he in study	(1-011)	(11 – 01 1)	(11-440)	value			
Reasons to be in study	E00 (000/)	704 (000/)	200 (700/)	- 001			
Help fight HIV/AIDS	582 (86%)	721 (83%)	320 (72%)	<.001			
Better health care	221 (33%)	349 (40%)	215 (48%)	<.001			
Might get money	212(31%)	277 (32%)	102 (23%)	.002			
Learn about HIV/ AIDS	349 (52%)	509 (58%)	235 (53%)	.012			
Get medications	211 (31%)	232 (27%)	116 (26%)	.08			
Represent gender	120 (18%)	269 (31%)	116 (26%)	<.001			
Represent race	71 (10%)	311 (36%)	140 (31%)	<.001			
MD recommended	315 (47%)	281 (32%)	150 (34%)	<.001			
Family/friend recommendation	71 (10%)	113 (13%)	45 (10%)	.2			
Reasons to avoid study							
Not friendly to my race	27 (4%)	147 (17%)	44 (10%)	<.001			
Not friendly to my gender	31 (5%)	94 (11%)	30 (7%)	<.001			
Not friendly if I use drugs	30 (4%)	102 (12%)	26 (6%)	<.001			
Not friendly if I use alcohol	32 (5%)	74 (8%)	22 (5%)	.004			
Worry of being hurt	147 (22%)	201 (23%)	99 (22%)	.8			
Worry about placebo	163 (24%)	96 (11%)	65 (15%)	<.001			
Worry about confidentiality	99 (15%)	195 (22%)	80 (18%)	<.001			
Worry medications will not work/ hurt me	226 (33%)	273 (31%)	127 (29%)	.2			
Do not understand the studies	26 (4%)	91 (10%)	40 (9%)	<.001			
Do not have time	115 (17%)	126 (14%)	71 (16%)	.4			
Do not want to be "guinea pig"	43 (6%)	133 (15%)	43 (10%)	<.001			

- Excluded individuals who responded other race (n=102), mixed race (n=23), or become a Excluded individuals who responded other language (n=31) or had no response.
- Excluded individuals who responded other language (n=31) or had no response Excluded individuals who had no response (n=54).
- * Chi-square test.

Figure 6. Factors that influence HIV Clinical trials separated by race (Castillo-Mancilla et al., 2015)

CONCLUSIONS

- The lack of access to healthcare, insured or uninsured treatment, and treatment of Black Americans in the healthcare system are all contributing factors of increased exposure of HIV/AIDS.
- The lack of access to healthcare results in untreated or mistreated HIV/AIDS which can increase the progression of HIV dramatically, resulting in death.
- HIV/AIDS research shows a lack of data amongst Black Americans in that they comprise of approximately 48% of all PLHA (Persons living with HIV/AIDS) Only 30% of ACT (AIDS clinical trials) participants (Gwadz et al., 2010).
- Black Americans face a higher risk in contracting HIV due to their incarceration status and the aftermath of their incarceration.

FUTURE DIRECTIONS

- HIV Clinical Trial outreach programs should be focused in predominantly Black neighborhoods
- HIV Clinical Trials should include higher percentages of Black Americans
- Increased opportunity for affordable access to healthcare in predominantly Black neighborhoods will decrease mortality rates
- Increased lobbying for change in drug policy is necessary that will aid in regulation of substance abuse and rehabilitation
- Increased diversity and nondiscriminatory policies In healthcare/research fields that protect Black Americans from experiencing discrimination