

Why Diversity in Research is Important and How to Overcome Subject Barriers to Participation

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MEDICINE *of* THE HIGHEST ORDER



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Is the Research Relevant?

“Clinical research is a critical resource for the development of new prevention, diagnosis, and treatment techniques for a number of diseases....The ability to trust and apply the results of a clinical trial, as well as transfer them into clinical practice, is related to the type and number of patients enrolled in that trial. If trials do not include minorities, then there is a question of whether or not the results of the studies are relevant to everyone across the board.”

<http://www.cancer.gov/newscenter/benchmarks-vol6-issue4/page1>



Inclusion of Women and Minorities

- 1986 inclusion of women encouraged
- 1987 inclusion of minorities encouraged
- 1993 NIH Revitalization Act
- 1994 NIH revised inclusion policy to mandate that women & minorities **MUST** be included in all clinical research studies



Race and Ethnicity

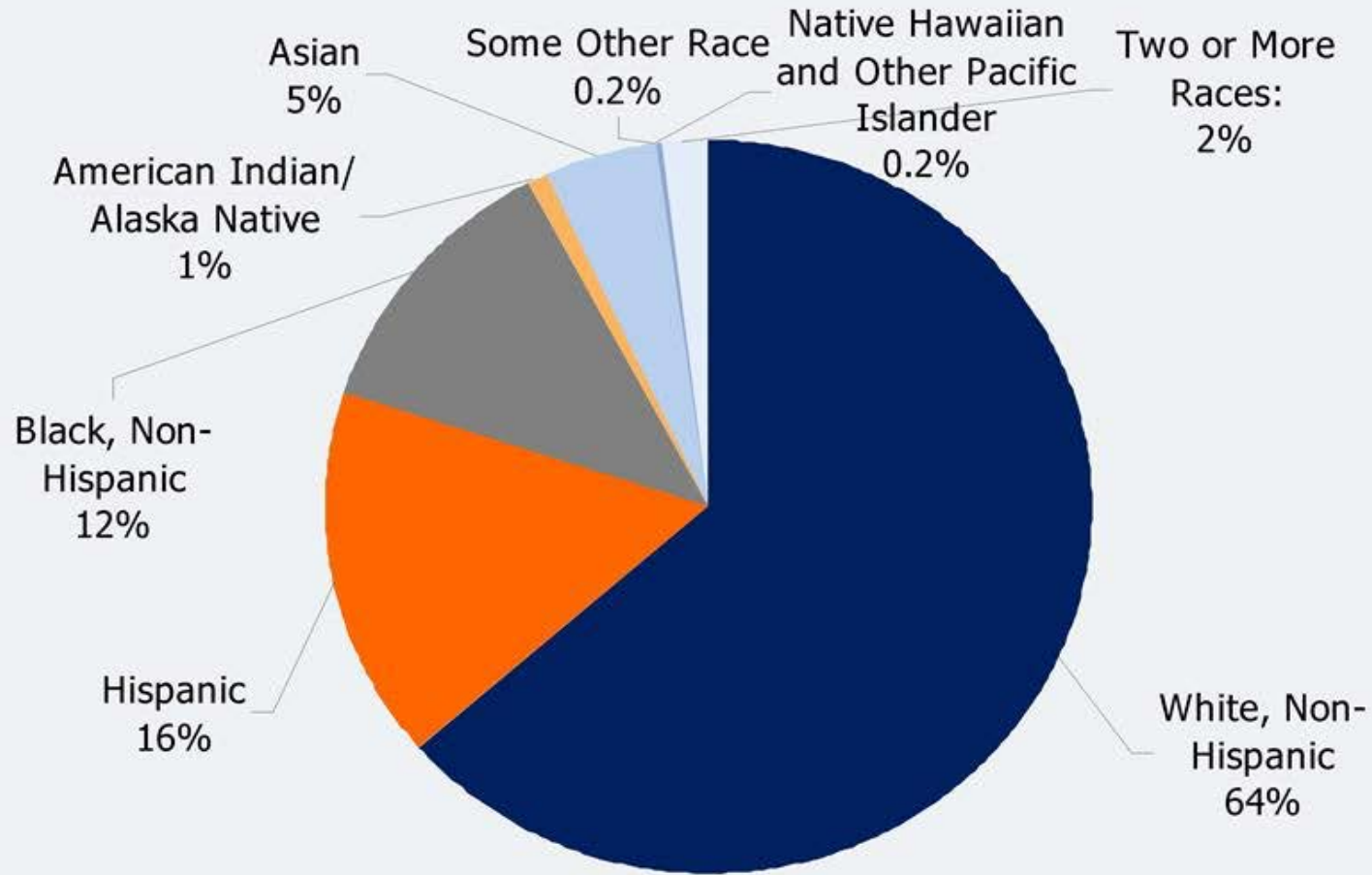
Race, as a social construct, divides people into populations or groups on the basis of various sets of physical characteristics

- Black or African American
- White
- Asian
- Native Hawaiian or other Pacific Islander
- American Indian or Alaska native

Ethnicity is a broader construct based on cultural tradition, common history, religion, and often a shared genetic heritage

- Hispanic or Latino
- Not Hispanic or Latino

US Population by Race and Ethnicity, 2010



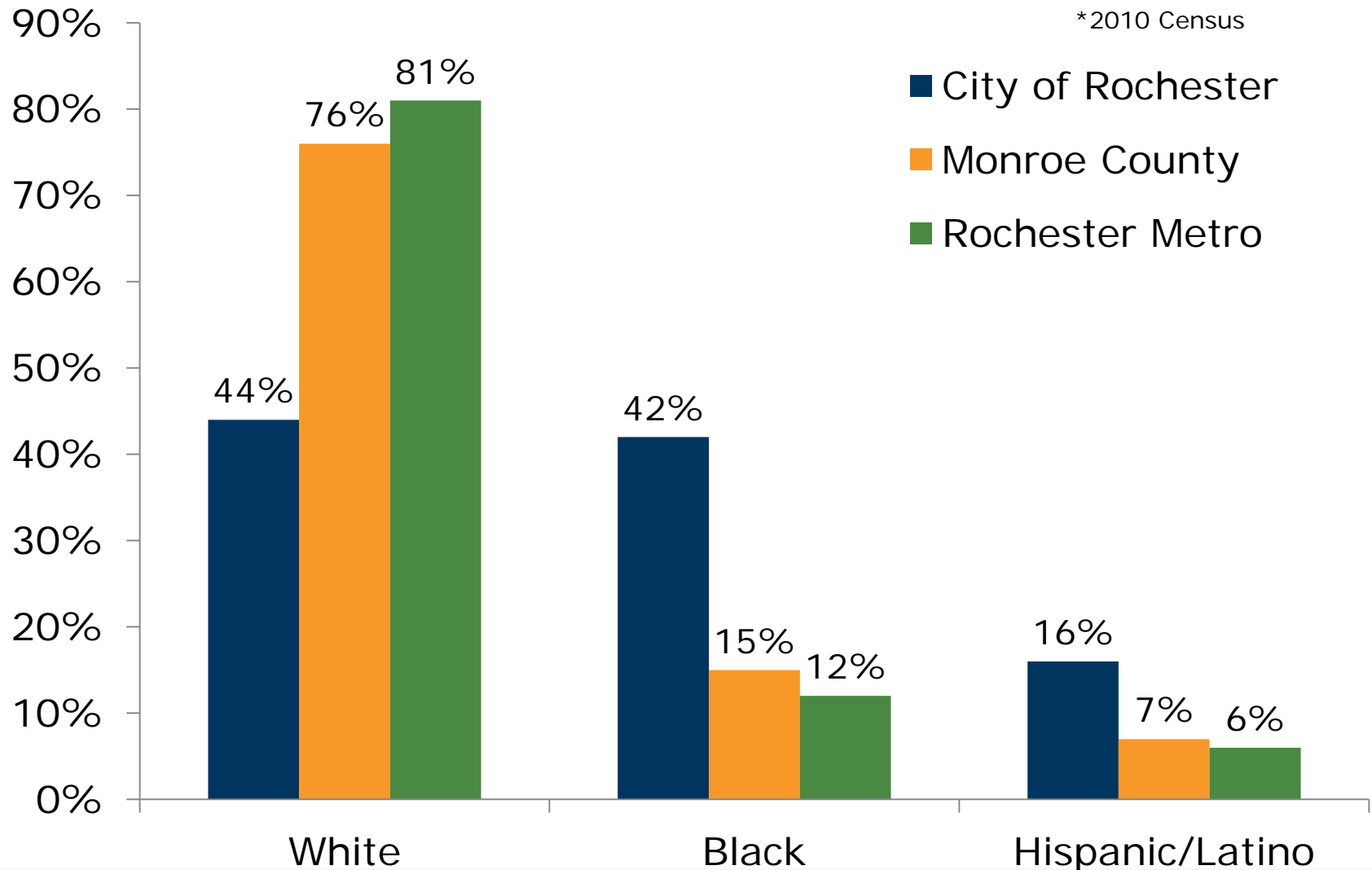
Total U.S. Population = 308.7 million

SOURCE: 2010 U.S. Census



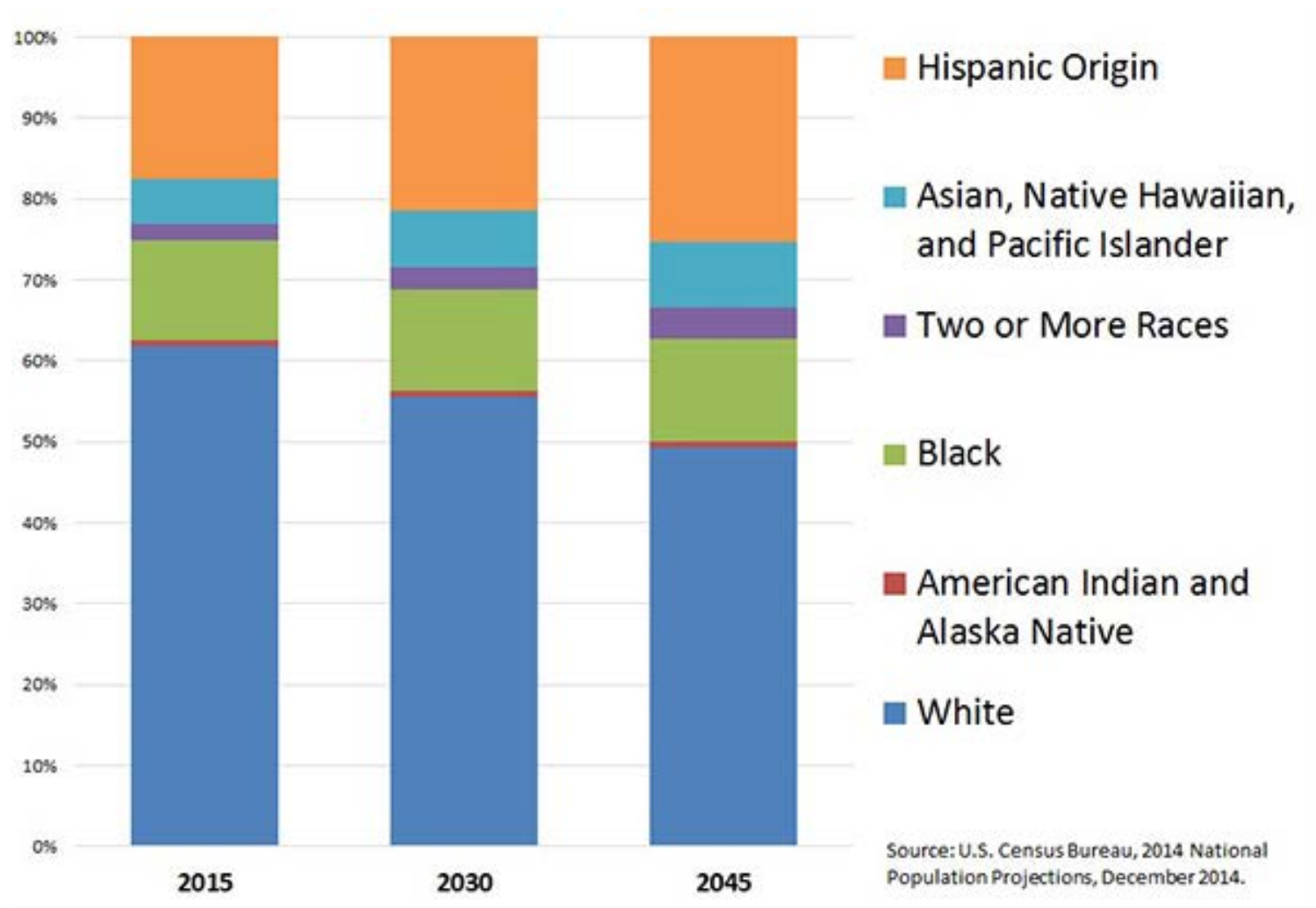
General Population Distribution by Race and Ethnicity, 2010

*2010 Census



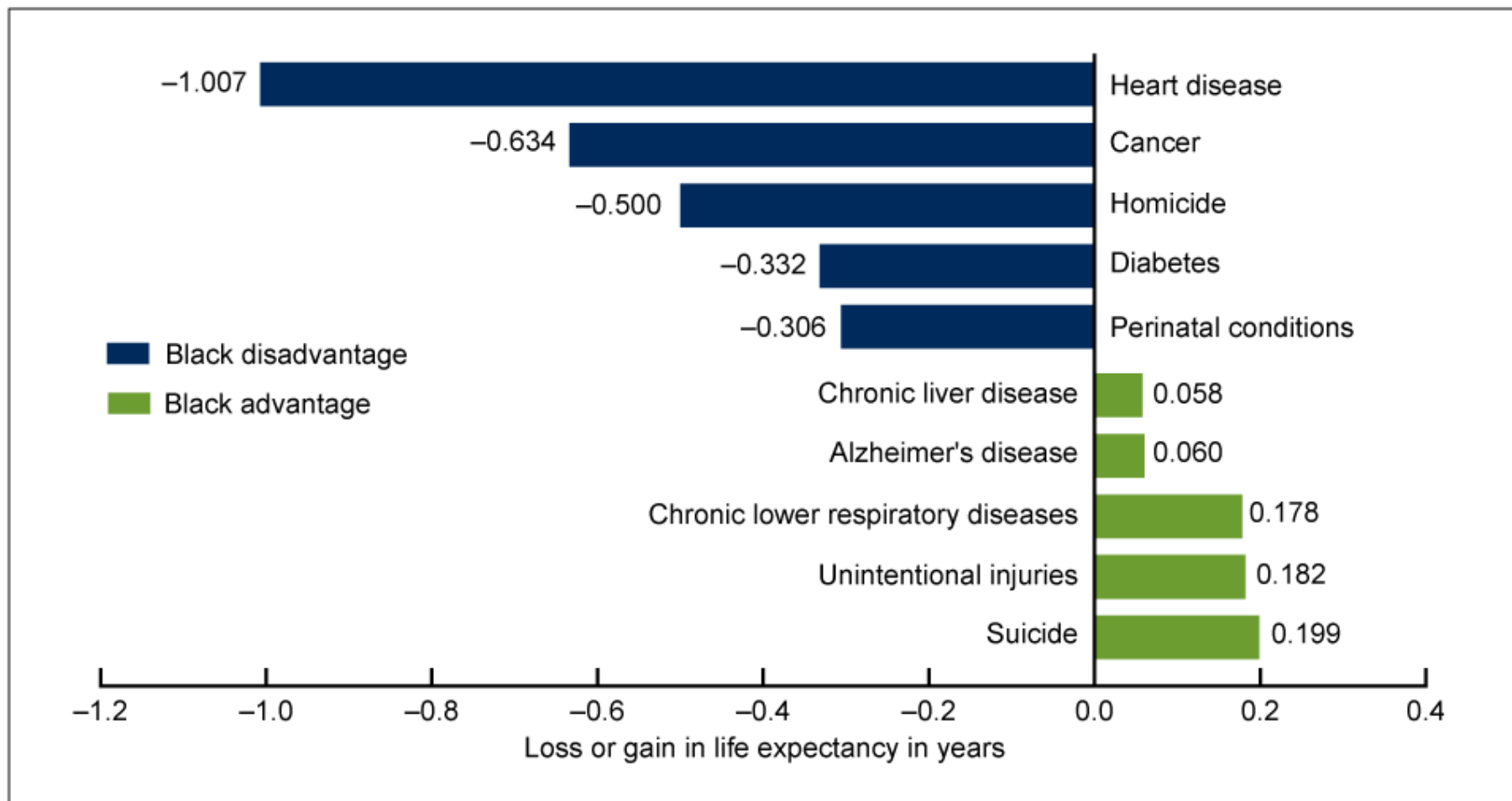


U.S. Population Becoming More Diverse



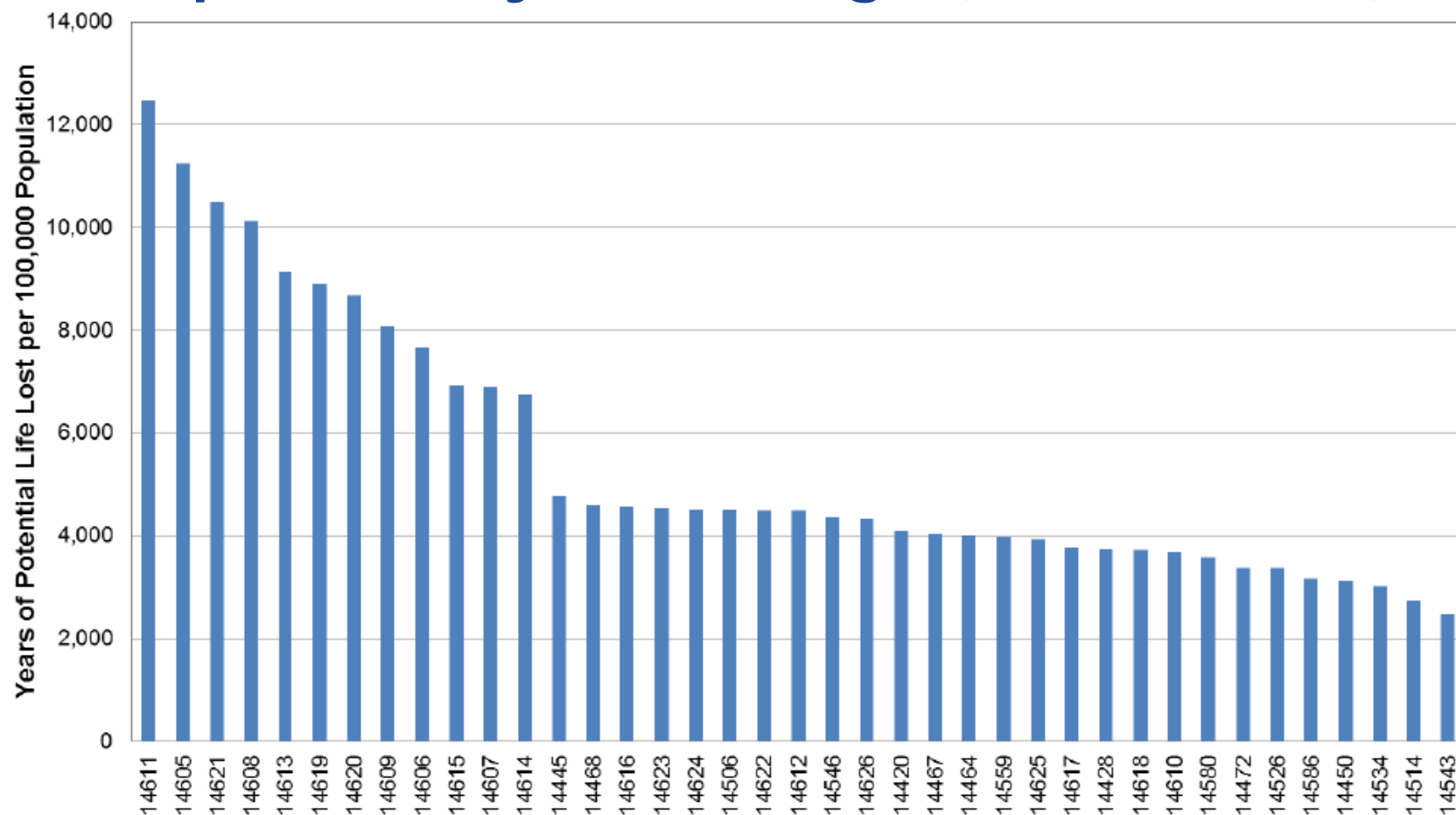
What's Killing Americans?

Figure 3. Contribution of the leading causes of death to the difference in life expectancy between black and white persons: United States, 2010



SOURCE: CDC/NCHS, National Vital Statistics System, Mortality.

Years of Potential Life Lost by Monroe County Zip Code, 5 year Average (2006 – 2010)



Years of Potential Life Lost based on deaths before age 75
Data Source: NYS Vital Statistics

Finger Lakes Health Systems Agency



Diversity in Clinical Trials

- Greater diversity offers an opportunity to recruit more volunteers into clinical trials
- Demographics are changing – minority populations will become the majority in the future
- Safety and efficacy of drugs and devices should be evaluated in stratified populations
- Address the concerns of the public and policymakers



Diversity in Clinical Trials

African Americans 13% of population – 5% of CT participants

Hispanics 17% of population – 1% of CT participants

Clopidogrel

Lancet 1996; **348**: 1329-39



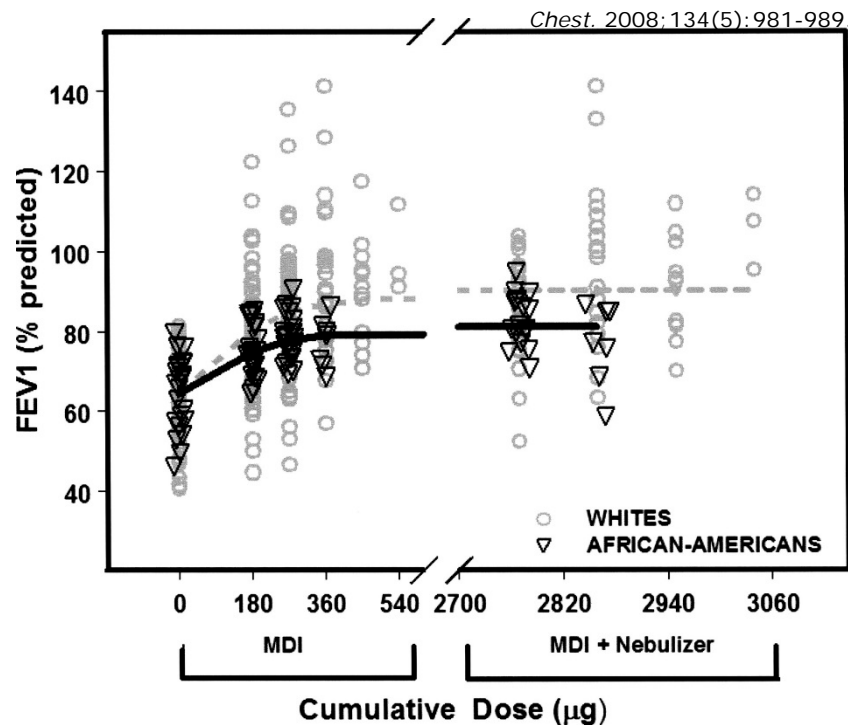
Ineffective in the 50 percent of Asians who lack the enzyme to activate it.

Characteristic	All patients	
	Clopidogrel (n=9599)	Aspirin (n=9586)
Mean (SD) age in years	62.5 (11.1)	62.5 (11.1)
% male	72	72
% white	95	95
Percentage of patients with a history of:		
Ischaemic stroke*	9	9
TIA/ RIND	10	10
Diabetes mellitus	20	20
Hypertension	52	51
Hypercholesterolaemia	41	41
Angina (stable)	22	22
Angina (unstable)	9	9
Myocardial infarction*	17	16
Congestive heart failure	6	5
Cardiomegaly	5	4
Atrial fibrillation	4	4
Intermittent claudication*	5	4
Current cigarette smoker	29	30
Ex cigarette smoker	49	49

*Not including the qualifying event; MI=myocardial infarction; PAD=peripheral artery disease

Table 4: **Baseline characteristics**

Albuterol



Absolute improvement in percentage of predicted FEV₁ was 16.6% in AA patients vs 26.7% in white patients

Carbamazepine



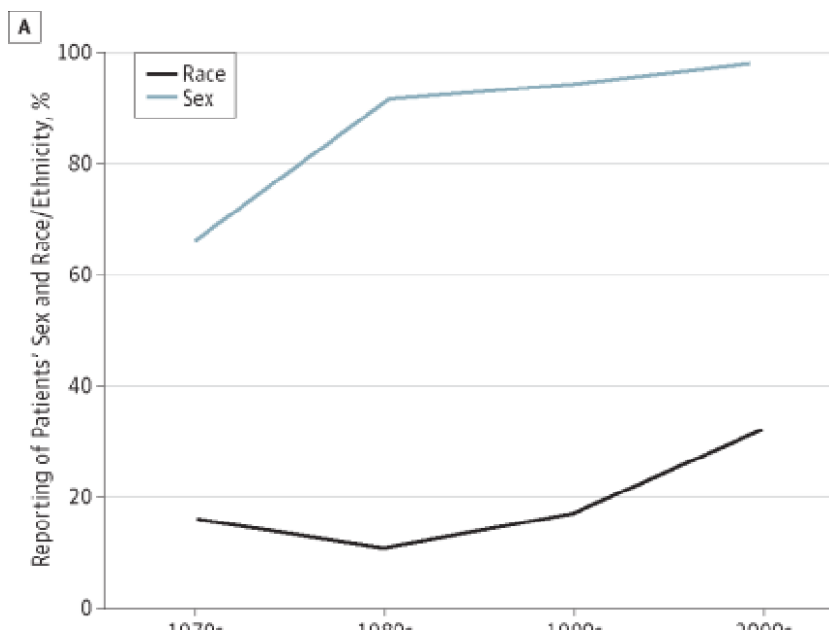
Risk of Stevens–Johnson syndrome:
White: 1-6 per 10,000
Asian: 10-60 per 10,000

Genetic Differences in Disease Among Racial and Ethnic Groups

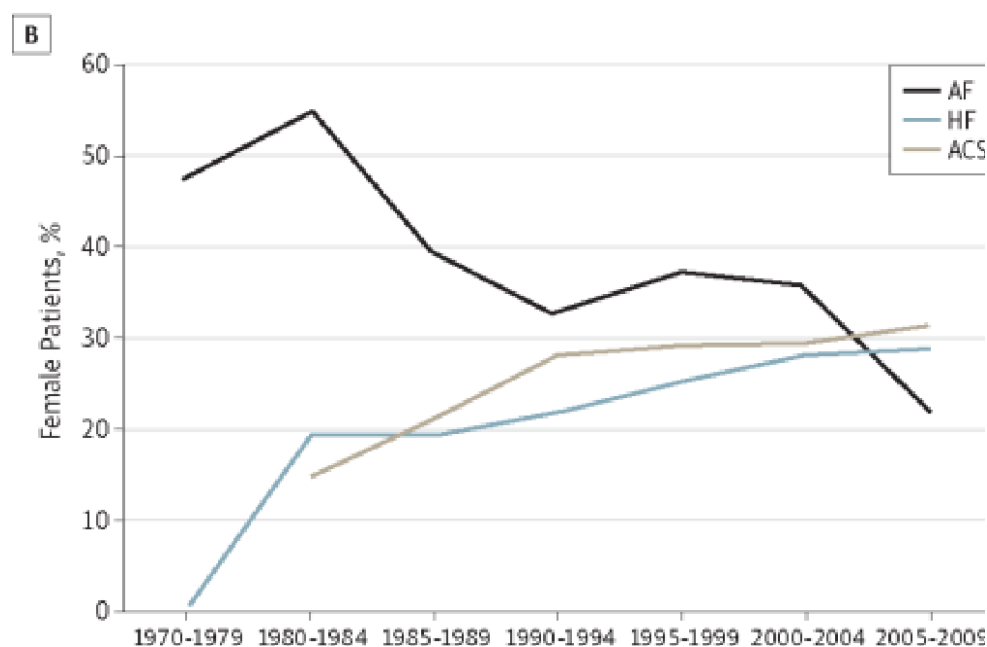
- CCR5 – receptor used by HIV to enter cells. 25% of white people are heterozygous for the CCR5delta32 variant – protective against HIV infection and progression. This variant virtually absent in other groups – racial and ethnic differences in protection against HIV

Enrollment in RCTs for Cardiovascular Guidelines

Reporting

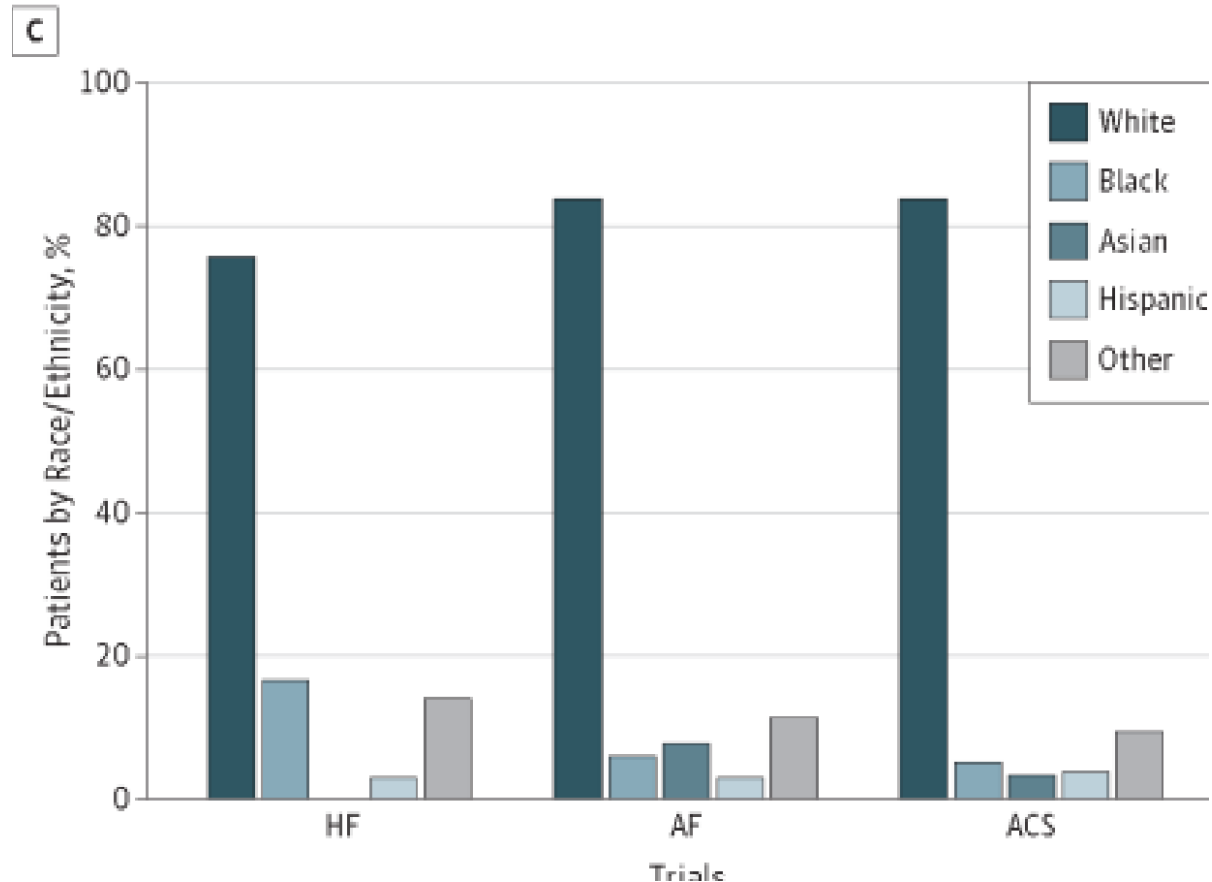


Female Patients



JAMA Intern Med. 2014;174(11):1868-1870. doi:10.1001/jamainternmed.2014.4758

Race/Ethnicity in RCTs for Cardiovascular Guidelines



JAMA Intern Med. 2014;174(11):1868-1870. doi:10.1001/jamainternmed.2014.4758



General Barriers to Participation in Clinical Trials

- Many do not know what a CT is
- Fear of research – historical abuses
- Fear treatment will be withheld
- Poor access to CTs
- Personal and practical obstacles (language)
- Cultural influences
- Study design eligibility criteria (i.e. co-morbidities)
- Low health literacy
- Not a top priority

Distrust as a Barrier to Participation

- Distrust of scientific investigators and of academic institutions are often major barriers among African Americans
- Signing consent forms was reported as relinquishing rather than protecting rights
- Research volunteer is considered a “guinea pig”
- Knowledge of the Tuskegee Syphilis Study was not necessarily negatively associated with willingness to participate

Tuskegee Syphilis Study

- Longest running study in the U.S. PHS; ran from 1932 to 1972
- Studied the natural history of syphilis in 400 African American males
- Participants were promised free treatments for “bad blood.” Participants were not told they had syphilis
- Syphilis untreated, even when penicillin became available in the late 1940s





Healthcare Provider Barriers

- Unaware of clinical trials
- Fear of “losing control” of patient’s care
- Administrative responsibility
- Believe that current treatment is the best
- Insufficient time to discuss option with patients
- Assume that patient would not be interested



Barriers to Recruiting Underrepresented Populations in Trials

Barriers to:

- trial awareness
- opportunity to participate (research design, provider attitudes)
- acceptance of enrollment (perceived harms, mistrust)
- additional barriers related to cultural factors



Recruitment Strategy: Community Involvement

- Use lay outreach workers from the targeted population (cultural insider)
- Community-based organizations
- Places of Worship: Although some investigators have identified religiosity as a barrier due to a fatalistic view of disease –others have found religiosity to be positively associated with willingness to participate



Recruitment Strategy: Friendly Informed Consent

- Health literacy - not just about reading and writing, but also the ways health information is communicated eg. speaking, drawing pictures and using technology.
- Majority of consent forms are on a 12th grade reading level
- Provide consent in different languages, use “comfort” words, pictures, diagrams
- Voice-enhanced ICF
- Yates, 2009 developed a 23 page ppt flip chart for an IC-study comparing traditional cardiac rehab vs home-based cardiac rehab-improved participation rate from 22%-54%



Recruitment Strategy: General

- Characterize the target population
- Involve members of the target population in planning efforts
- Give something back to the community
- Use a community spokesperson to enhance credibility
- Identify and remove barriers to participation
- Cultural relevance of materials
- Improve staff sensitivity
- Stress importance of prevention and early detection

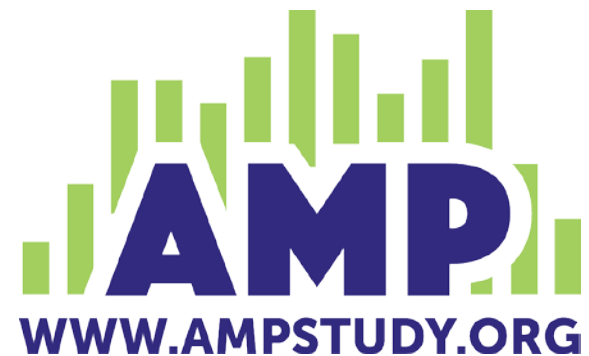


Recruitment Strategy: Research Team

- Incorporate diversity in the Subject Enrollment Plan
- Understand the patient
- Researchers from underrepresented populations
 - More likely to conduct research in underrepresented populations
 - Gain trust of underrepresented communities

Recruitment Strategy: AMP Study

- Antibody Mediated Prevention (AMP) Study
- 19 NIH-sponsored HIV Vaccine Trials Network (HVTN) sites
- Enroll and follow about 3,900 participants
- Young Black MSM and transgender individuals



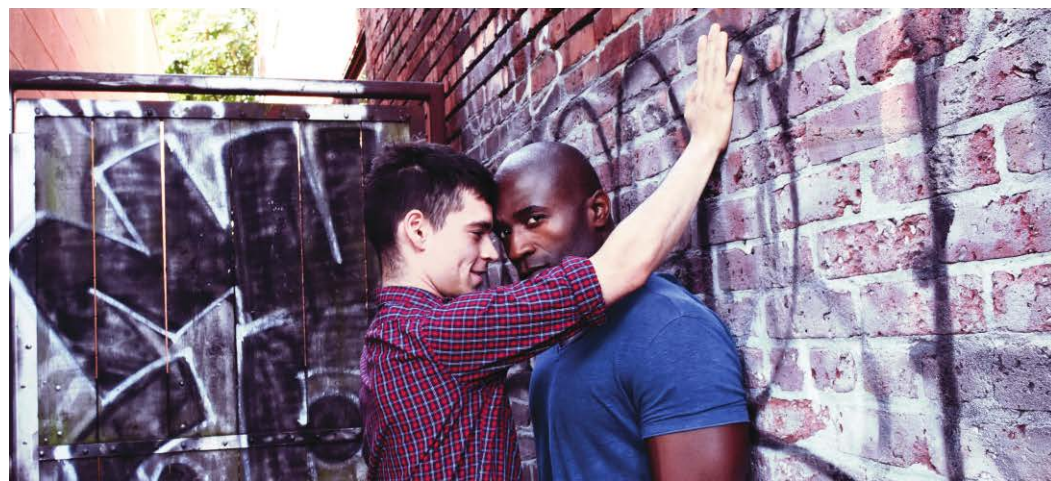
Recruitment Strategy: Criteria

- 18 to 50 years old
- HIV negative
- Men who have sex with men
- Transgender men and women who have sex with men



Recruitment Strategy: Text4Strength

- Automated text messaging system
- Keyword responses
- Commercial SMS service that meets evolving healthcare industry standards
- Data, while not highly sensitive, is stored and backed up on secure, encrypted, dedicated servers and hard drives



TEXT **AMP** TO
(585) 496-0020
FOR MORE INFO



TURN UP
THE VOLUME ON
HIV PREVENTION!

WE'RE RESEARCHING
A NEW WAY
TO FIGHT HIV

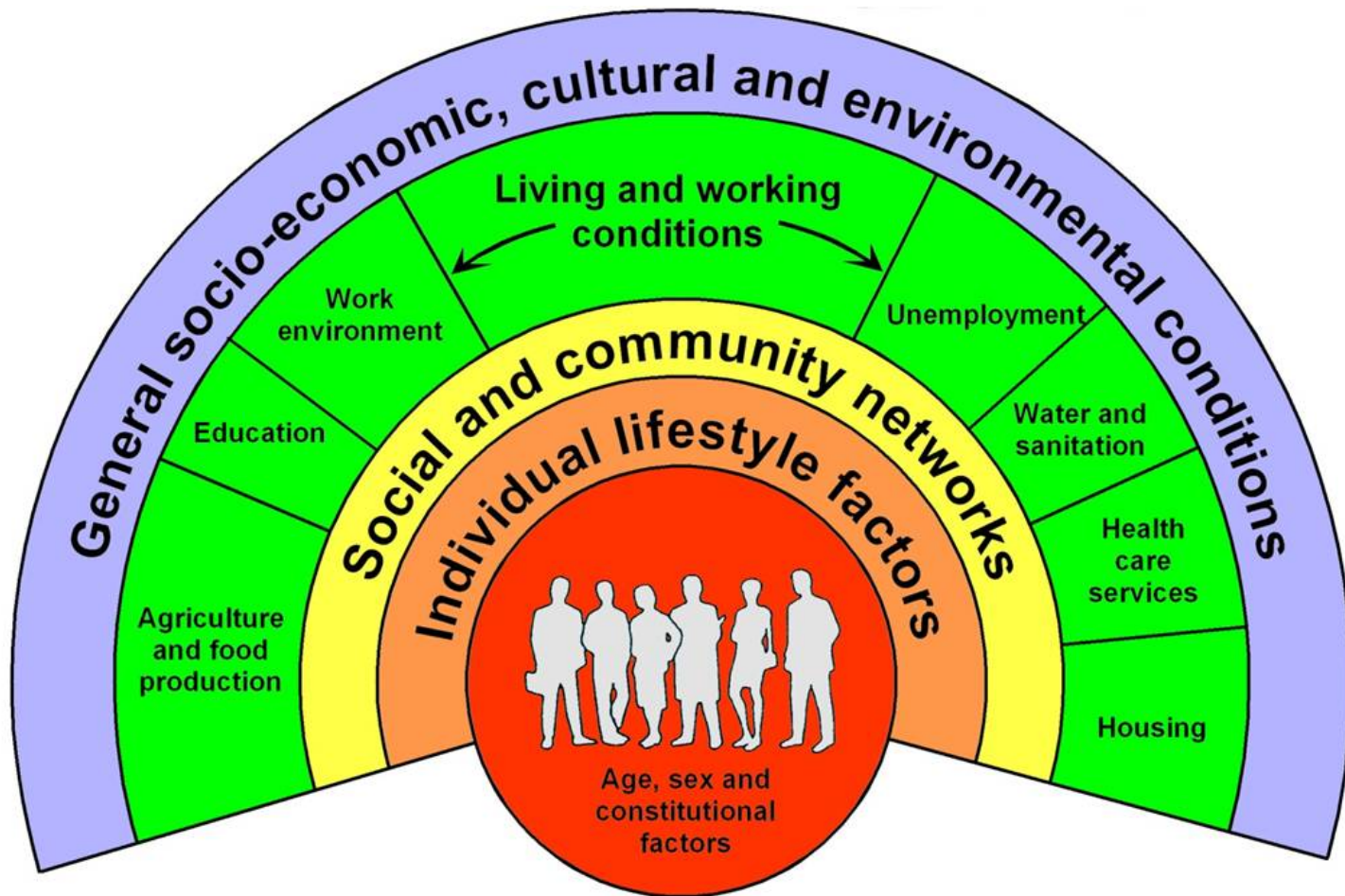
WE'RE LOOKING FOR:

- Men, including transgender men
- Transgender women
- 18-50 years old

Volunteers are paid
an average of \$2,500
over the length of the study

50 cards for 12 weeks \$1,875

Recruitment Strategy: Social Determinants of Health



Source: Dahlgren and Whitehead, 1991



Recruitment Strategy: Promote Health

- Promote Health, asks about the presence of basic needs (shelter, food, health insurance, etc.) as well as trauma (adverse childhood experiences/intimate partner violence)
- Screen, assess, refer and link high-risk individuals to needed services
- Personalized list of free, local resources to help them address their needs

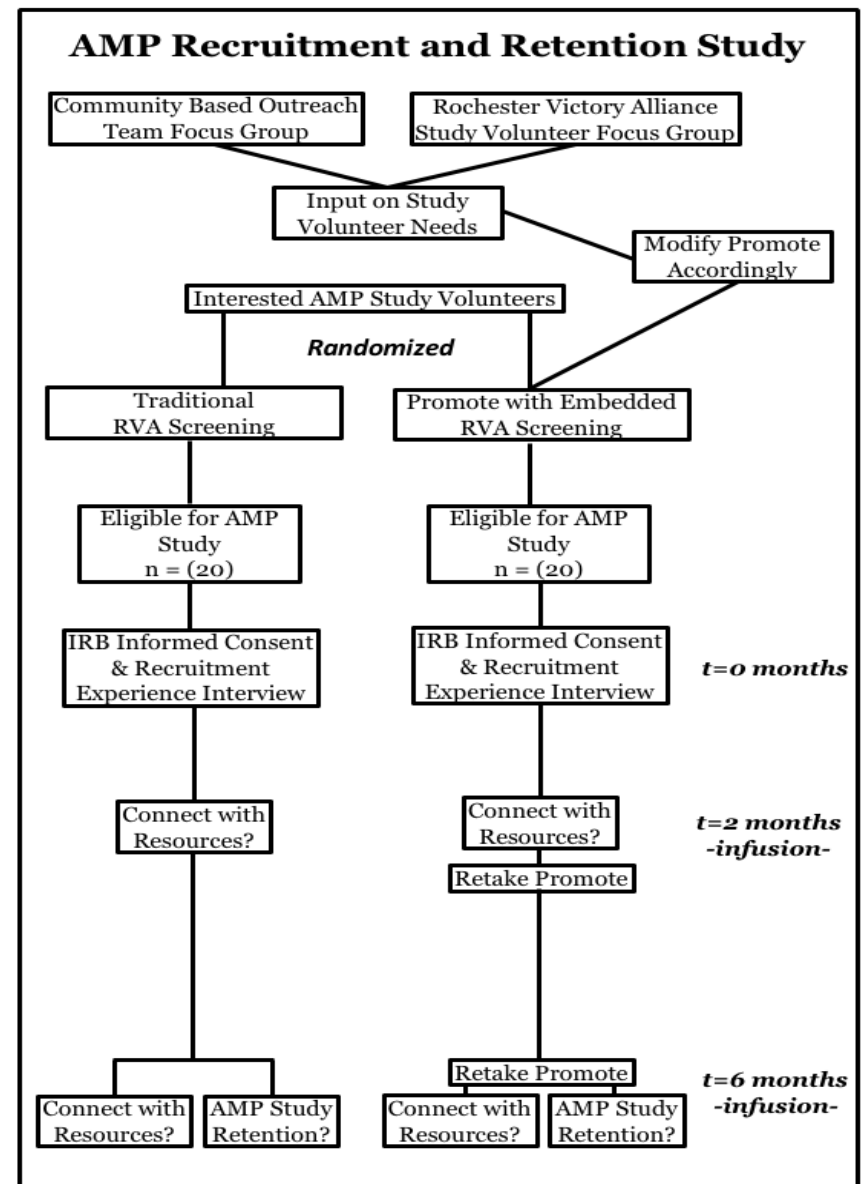
HVTN Award

“Exploring the Use of an eScreen Tool to Meet the Needs of Potential HVTN Study Participants”

Why eScreen?

- Low resource option
- Real time data
- Similar or greater rates of disclosure vs. interviews
- Client preferred due to anonymity
- Provides health information and referrals

This RCT will study Promote's efficacy to improve the recruitment process for high-risk individuals, allowing a potential participant to engage in client-centered care and prioritize their service needs, over traditional screening.



Outcome

This study has the potential to identify innovative community engagement approaches and outcomes, and potentially improving participation and retention rates in HIV prevention studies.



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