ACOI Annual Conference

Diversifying Clinical Trials: Strategies to Engage Women and Minority Participants

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Disparities in Health Care Research Disclosures

- I have no disclosures to report
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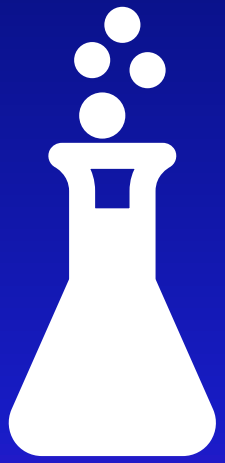
Disparities in Health Care
Learning Objectives

- Discuss & review the elements of the research enterprise and how it promotes disparities and may promote poor health

- Investigate what can be done to improve minorities participation in research and thus improve generalizability of the science

Why is recruitment of minorities and woman an important role for society?

The lack of diversity in clinical trails is a ____ problem?



Scientific

Medical

Moral

Why is recruitment of minorities and woman an important role for society?

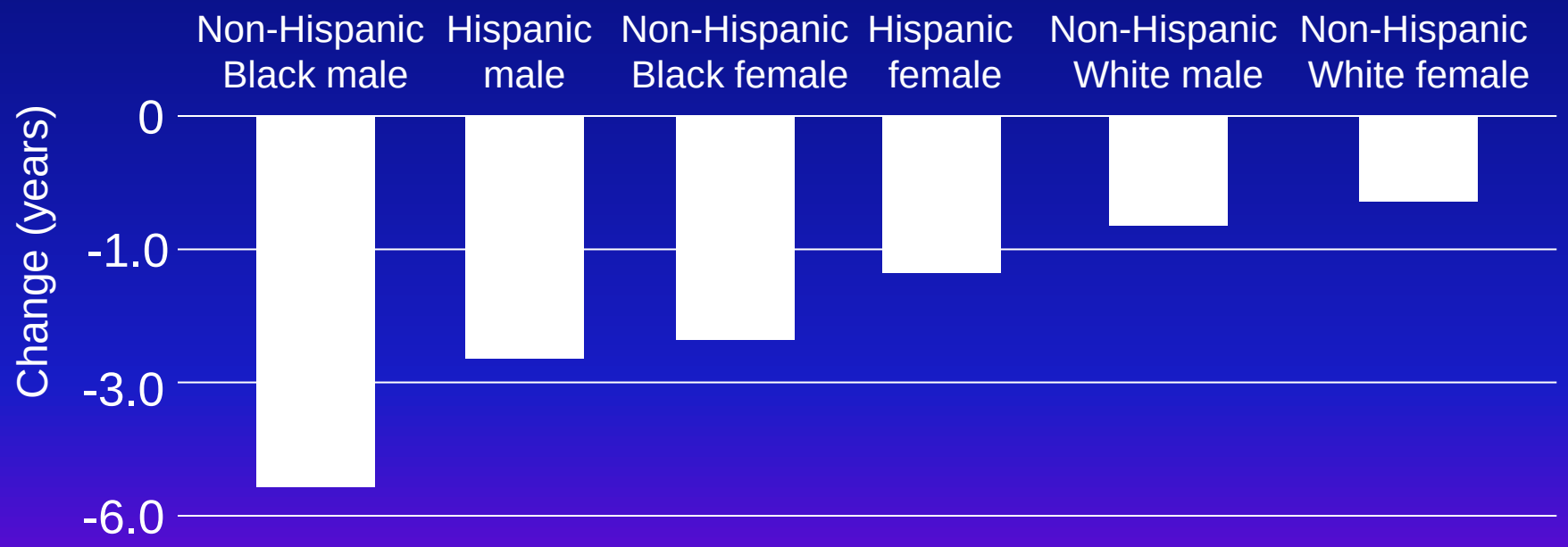
The average African-American male lives 5 years less than the average white American male

The average Hispanic male lives 2.1 years less than the average white American male

Lariscy JT, Nau C, Firebaugh G, Hummer RA. Hispanic-White Differences in Lifespan Variability in the United States. *Demography*. 2016;53(1):215-239. doi:10.1007/s13524-015-0450-x

In 2020, Black males lost 5 years of life in six months

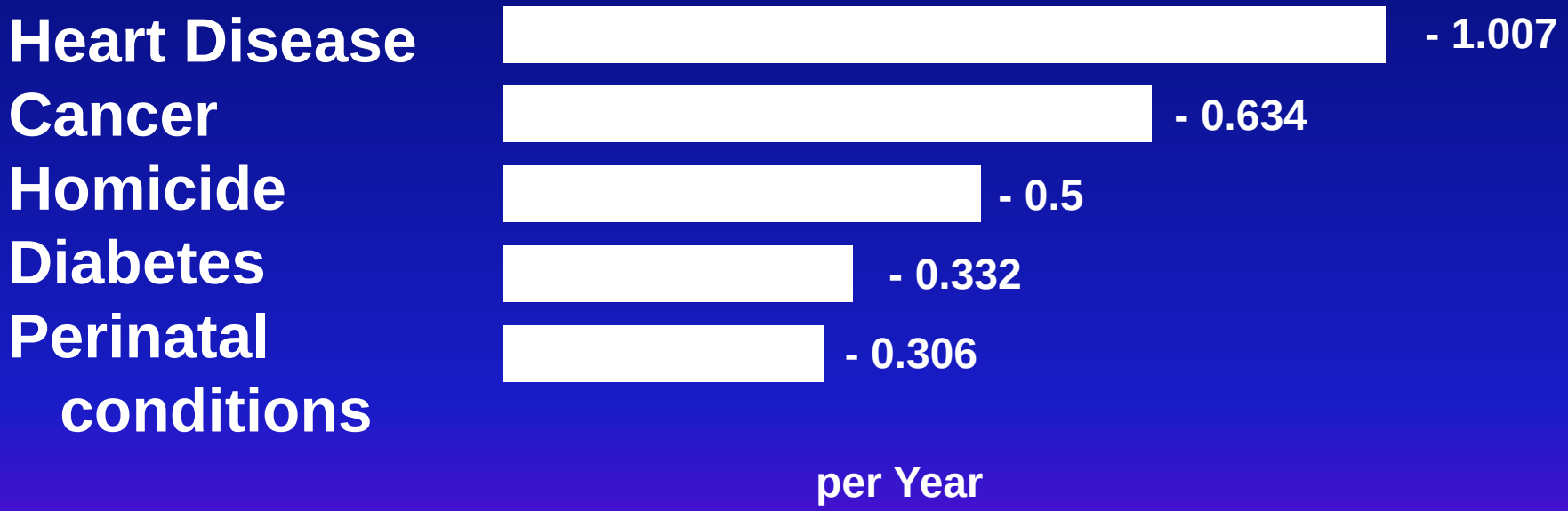
Change in life expectancy by gender, race and ethnicity from 2019 - 2020



Lariscy JT, Nau C, Firebaugh G, Hummer RA. Hispanic-White Differences in Lifespan Variability in the United States. *Demography*. 2016;53(1):215-239. doi:10.1007/s13524-015-0450-x

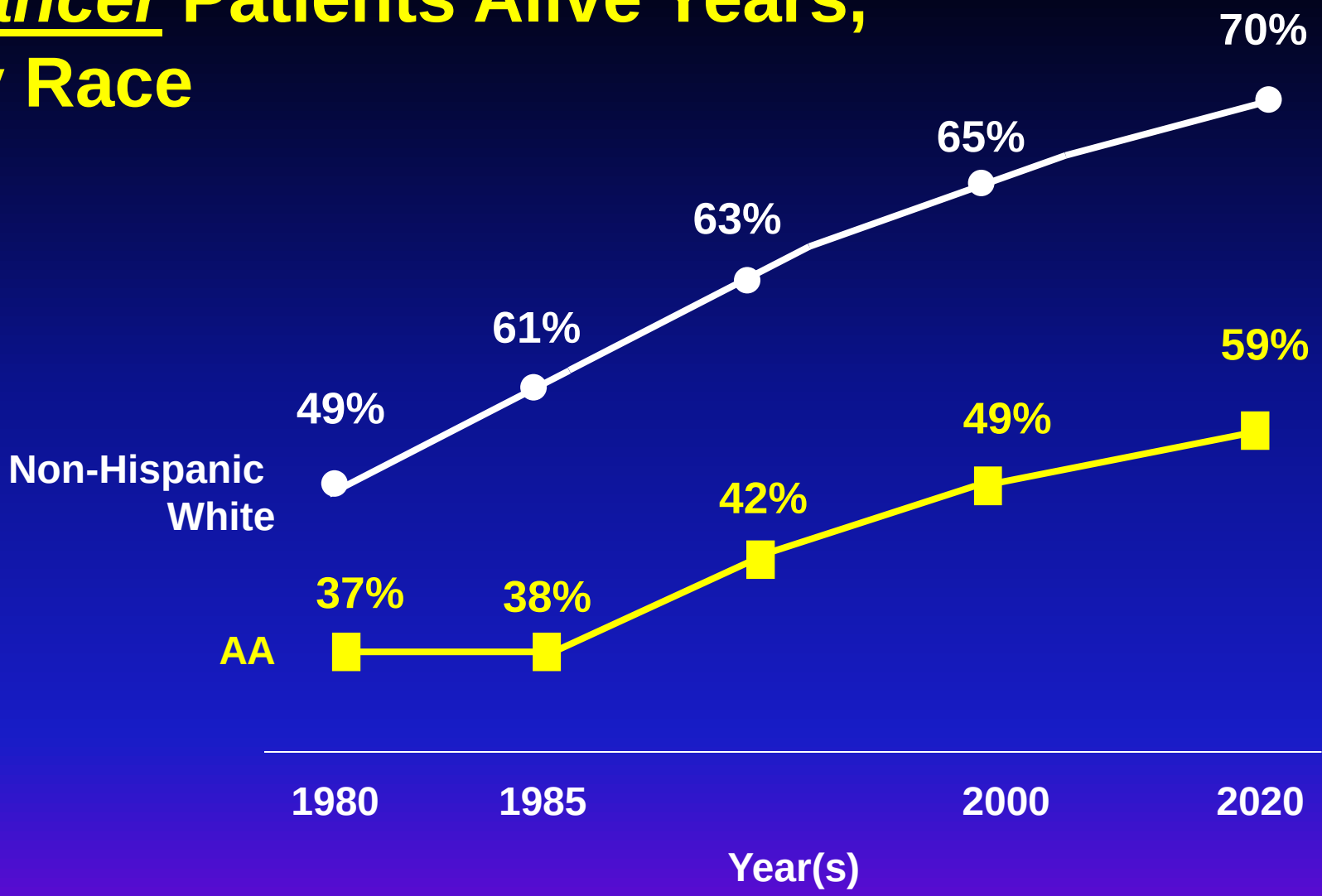
Why is recruitment an important role for society?

What was the cause of loss of life expectancy for African Americans



Murphy SL, Xu JQ, Kochanek KD. Deaths: Final data for 2010. National vital statistics reports; vol 61 no 4. Hyattsville, MD: National Center for Health Statistics. 2013..
HHS. Phase I Report: Recommendations for the framework and format of Healthy People 2020, Appendix 11. Measuring health disparities and health equity. 2008. Available from: http://www.healthypeople.gov/2010/hp2020/advisory/PhaseI/appendix11.htm?visit=1.

Cancer Patients Alive Years, by Race



Arriaga E. Changing trends in mortality decline during the last decades. In: Ruzicka LT, Wunsch GJ, Kane P, (eds.). Differential mortality: Methodological issues and biosocial factors. New York: Oxford University.

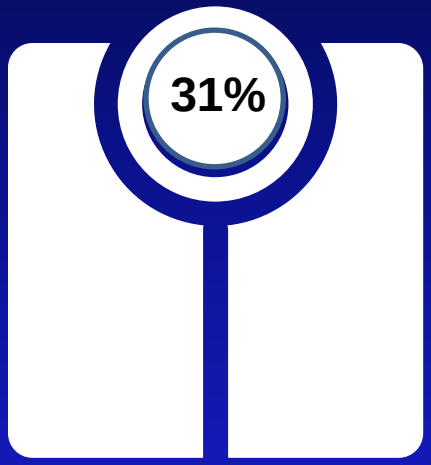
Difference in the leading causes of death for racial minorities

Non-Hispanic Whites		Hispanics
Heart disease	→	Cancer
Cancer	→	Heart Disease
Lower Resp Disease		Unintentional injuries
Unintentional injuries		Stroke
Stroke		Diabetes
Alzheimer's Disease		Lower Resp Diseases
Suicide	→	Kidney disease

Vital Statistics Cooperative Program Mortality Data Files, 2019.

Difference in selected chronic disease burden for Hispanics

Obese



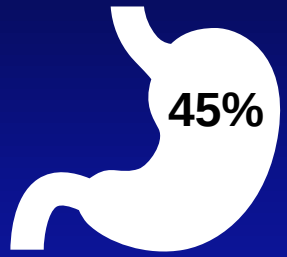
Adult Hispanics in the US

Diabetes

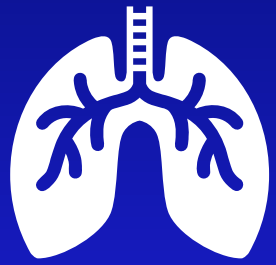
9.5%

Mexican Americans are 2x more likely

Cancer

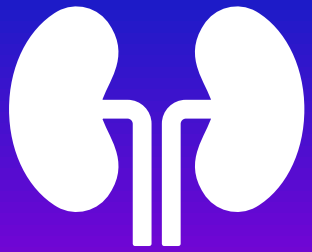


Colorectal



Lung / Bronchus

43%



Prostate

80%

How did we get here?

DO/MD
trust

One size
fits all

Individual
& cultural

Institutions

Scientific
enterprise

Organizations: How widespread are disparities in care delivery at your organization?

550 institutions surveyed of both executives (54%) and clinicians (43%) responded to the question:

Extremely widespread	5%
Very widespread	48%
Widespread	29%
Not very widespread	38%
None	15%

82% (Extremely widespread + Very widespread + Widespread)

Horvat L, Horey D, Romios P, Kis-Rigo J. Cultural competence education for health professionals. *Cochrane Database Syst Rev*. 2014;(5):CD009405. Published 2014 May 5. doi:10.1002/14651858.CD009405.pub2

How widespread are disparities in care delivery at your organization

1/3rd had NO programs to support social needs

Over ½ reported that their patients were "impacted" to "extremely impacted" by the organization

Behavioral health, chronic disease management, and preventable hospitalization = areas of highest prevalence

½ reported being impacted by interpersonal racism at their organization

Lin OM, Reid HW, Fabbro RL, et al. Association of Provider Perspectives on Race and Racial Health Care Disparities with Patient Perceptions of Care and Health Outcomes. *Health Equity*. 2021;5(1):466-475. Published 2021 Jul 5. doi:10.1089/heq.2021.0018

To what degree are patients impacted by the delivery of care

Extremely impacted	8%
Very impacted	14%
Impacted	37%
Not very impacted	29%
Not at all	11%

59%

Higher incidence of executive 65%, clinical leaders (64%) and clinicians (54%) surveyed think patients have been impacted by delivery of care

Lin OM, Reid HW, Fabbro RL, et al. Association of Provider Perspectives on Race and Racial Health Care Disparities with Patient Perceptions of Care and Health Outcomes. *Health Equity*. 2021;5(1):466-475. Published 2021 Jul 5. doi:10.1089/heq.2021.0018

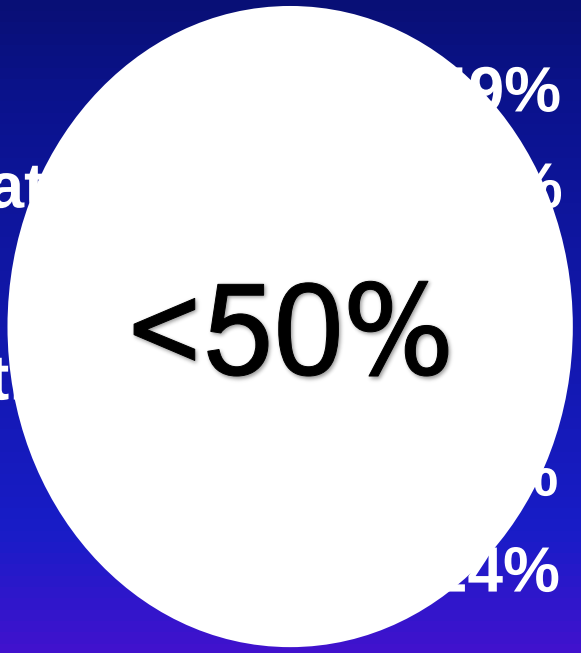
What are the top areas where disparities in care delivery are most prevalent

Behavioral health	50%
Chronic disease management (e.g. diabetes, CAD, HF, HTN)	50%
Preventable hospitalizations	37%
Specialty Care	24%
Ambulatory	23%
Readmissions	17%
Emergency departments	13%
Surgical procedures (e.g. minor)	10%
Inpatient care	<5%

Lin OM, Reid HW, Fabbro RL, et al. Association of Provider Perspectives on Race and Racial Health Care Disparities with Patient Perceptions of Care and Health Outcomes. *Health Equity*. 2021;5(1):466-475. Published 2021 Jul 5. doi:10.1089/heq.2021.0018

Does your organization provide a training program to clinical staff that addresses interpersonal racism & promotes health equity?

- Implicit racial bias training
- Training about social determinat
- Antiracism training
- Training in cultural and linguist
- Immigrant or refugee care
- No specific training



Williams DR, Rucker TD. Understanding and addressing racial disparities in health care. *Health Care Financ Rev*. 2000;21(4):75-90.
https://www.cdc.gov/healthequity/racism-disparities/index.html

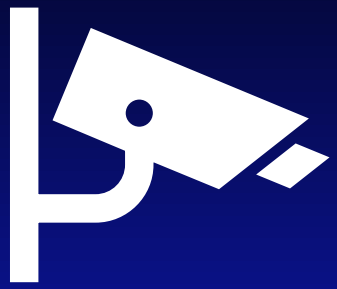
NEJM Catalyst Innovations in Care Delivery 2021; 03
DOI:https://doi.org/10.1056/CAT.21.0033

How effective are *current training* programs to address interpersonal racism and promote health equity?

Extremely effective	3%
Very effective	12%
Effective	27%
Moderately effective	28%
Slightly effective	10%
No training programs	21%

Challenges that occur in the Research Enterprise

The time and financial demand of clinical practice



The increasing complexity of regulations & contracts

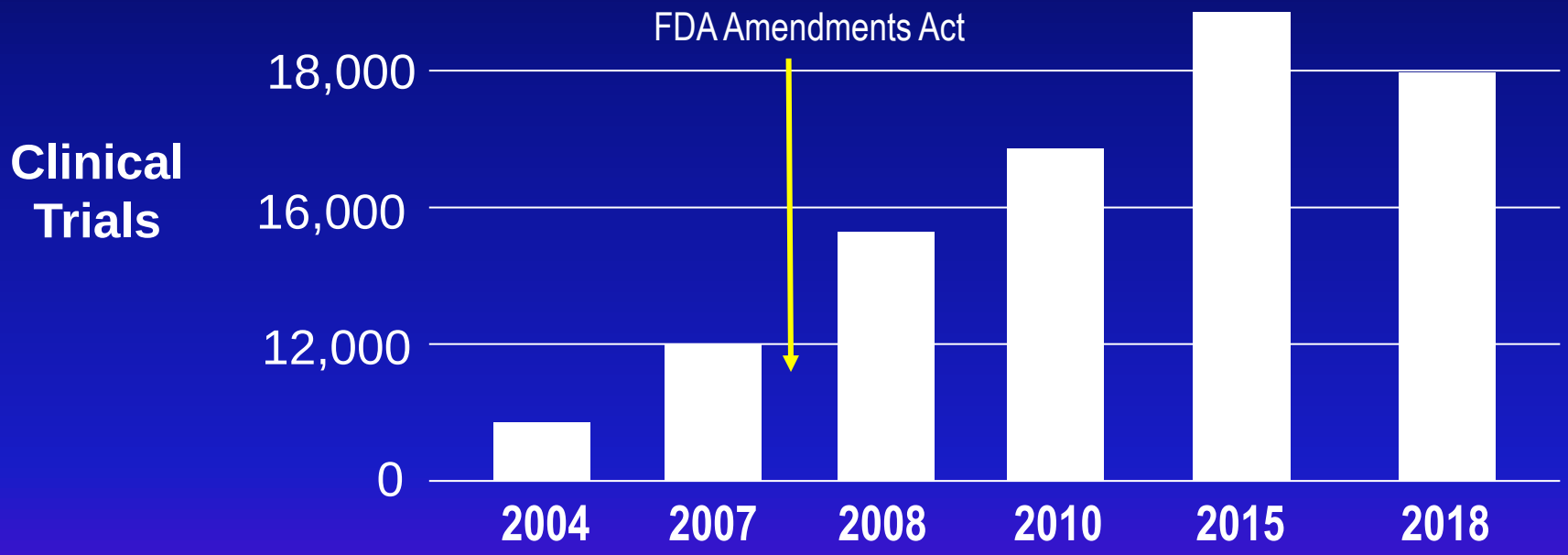
The lack of local supportive infrastructure
Inadequate research training

Less enjoyment from participation (e.g., increasing business aspects, contract organization pressures

Data collection challenges (medical records, reimbursement, quality control, pay for performance)

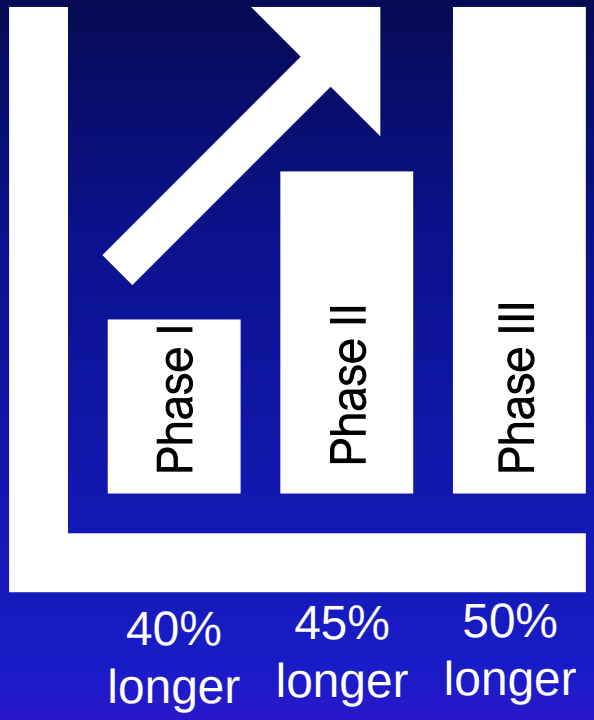
Transforming Clinical Research in the United States: Challenges and Opportunities

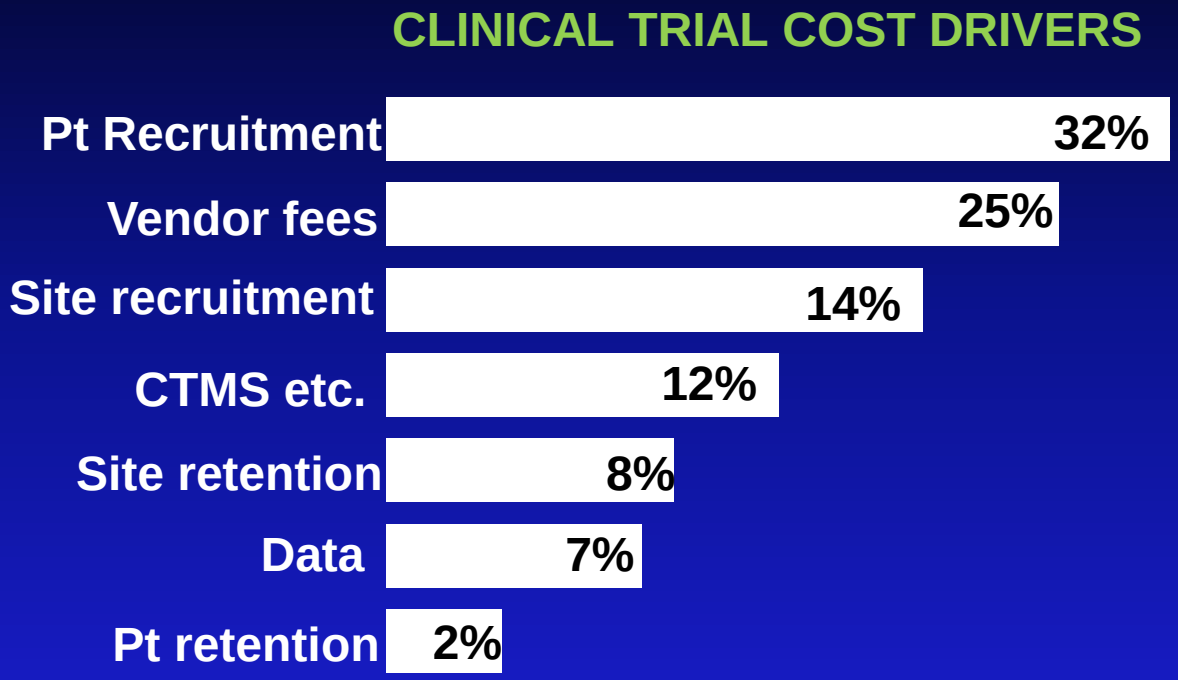
Timeline reflecting the number of clinical trials registered on clinicaltrials.gov and regulatory changes



Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation. *Transforming Clinical Research in the United States: Challenges and Opportunities: Workshop Summary*. Washington (DC): National Academies Press (US)

Average Delay and Trial Cost Drivers





Krischer, J. (2017, February 28). "Experience with Direct-to-Patient Recruitment for Enrollment into a Clinical Trial in a Rare Disease: A Web-Based Study". Retrieved November 13, 2017, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5350442/?report=classic.

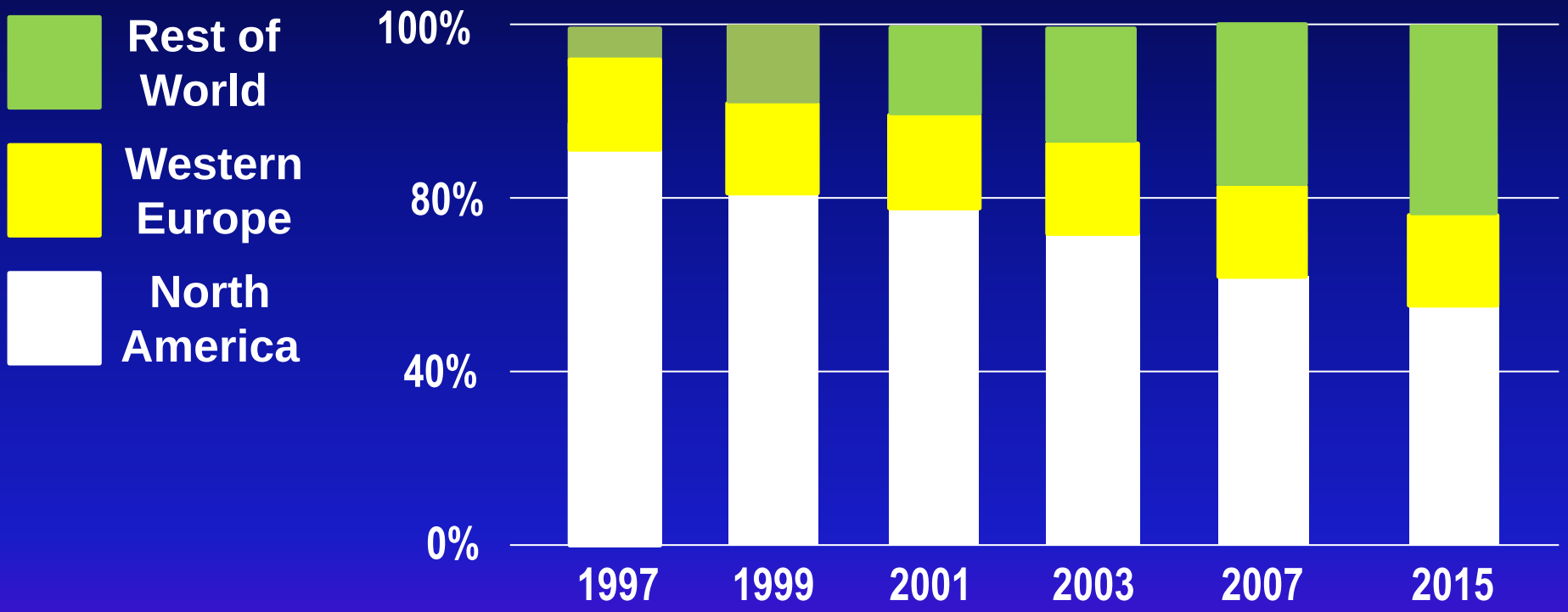
Roberts, D. (2016, March 28). "Contract research organizations in oncology clinical research: Challenges and opportunities". from http://onlinelibrary.wiley.com/doi/10.1002/cncr.29994/full.

Roberts, L. (2011, April 11). "How Watson for Clinical Trial Matching is Accelerating the Screening Process", from https://www.ibm.com/blogs/think/2017/04/watson-health-screening/.

Baum, S. (2017, September 8). "Three approaches to enhancing clinical trial recruitment". from https://medcitynews.com/2017/09/three-approaches-enhancing-clinical-trial-recruitment/?rf=1.

Geana, M. (2016, June 21). "Searching for cures: Inner-city and rural patients' awareness and perceptions of cancer clinical trials", from http://www.sciencedirect.com/science/article/pii/S2451865416300503.

The Proportion of Clinical Investigators from North America to the World



The proportion of clinic investigators has decrease since 1997, while the proportion of investigators from Europe and the rest of the work has increased. e.g. Regulatory Issues

NCRR (National Center for Research Resources). NIH Roadmap Re-Engineering the Clinical Research Enterprise: Inventory and Evaluation of Clinical Research Networks (IECRN): Complete Project Report. Washington, DC: NIH; 2006.

Krall RL. US Clinical Research. Presentation at the Institute of Medicine Workshop on Transforming Clinical Research in the United States; October 7–8, 2009; Washington, DC. 2009.

Increasing Diversity in Clinical Trials: Overcoming Critical Barriers

- **Identification of 5 critical barriers to participation in clinical trials**

Mistrust : Lack of understanding the value, fear, stigma of participating and communication style of investigators/staff

Lack of comfort with the trial process: lack of information, process, fear, family members opinion, and health literacy

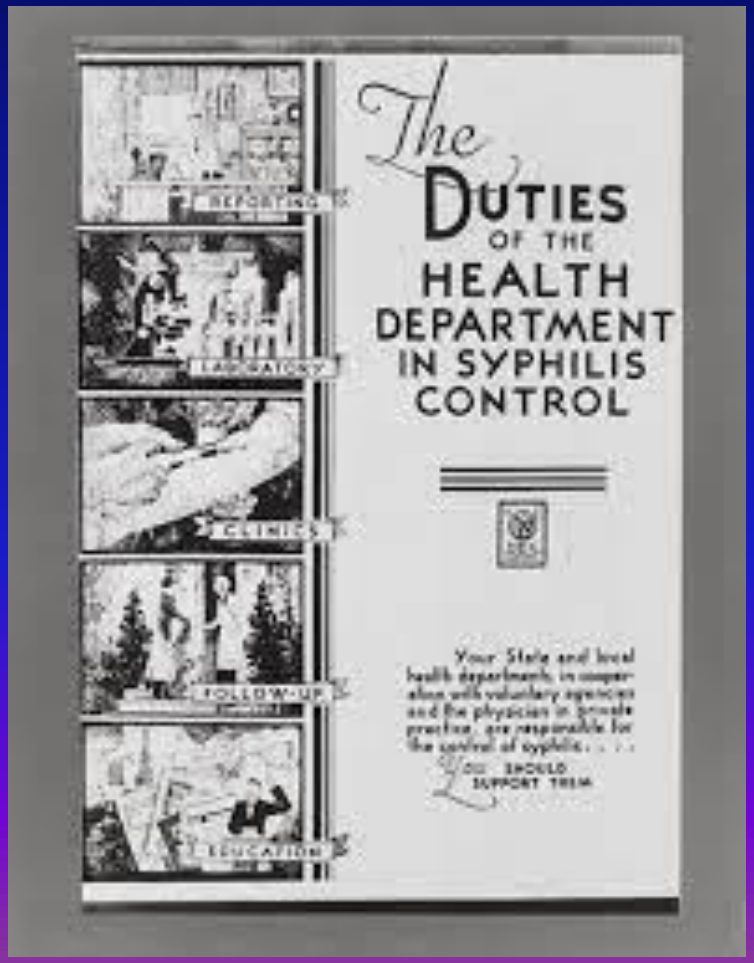
Lack of information about clinical trials: fears of not getting treatment or of participating

Time and resource constraints: financial burden, time commitment, transportation, compensation and logistics

Lack of trial awareness: understanding the value and importance to advance care and health

Increasing Diversity in Clinical Trials: Overcoming Critical Barriers: Mistrust

- **Mistrust** : Lack of understanding the value, fear, stigma of participating and communication style of investigators/staff



The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER
The Associated Press

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

Officials of the health service who initiated the experiment have long since retired. Current officials, who say they have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

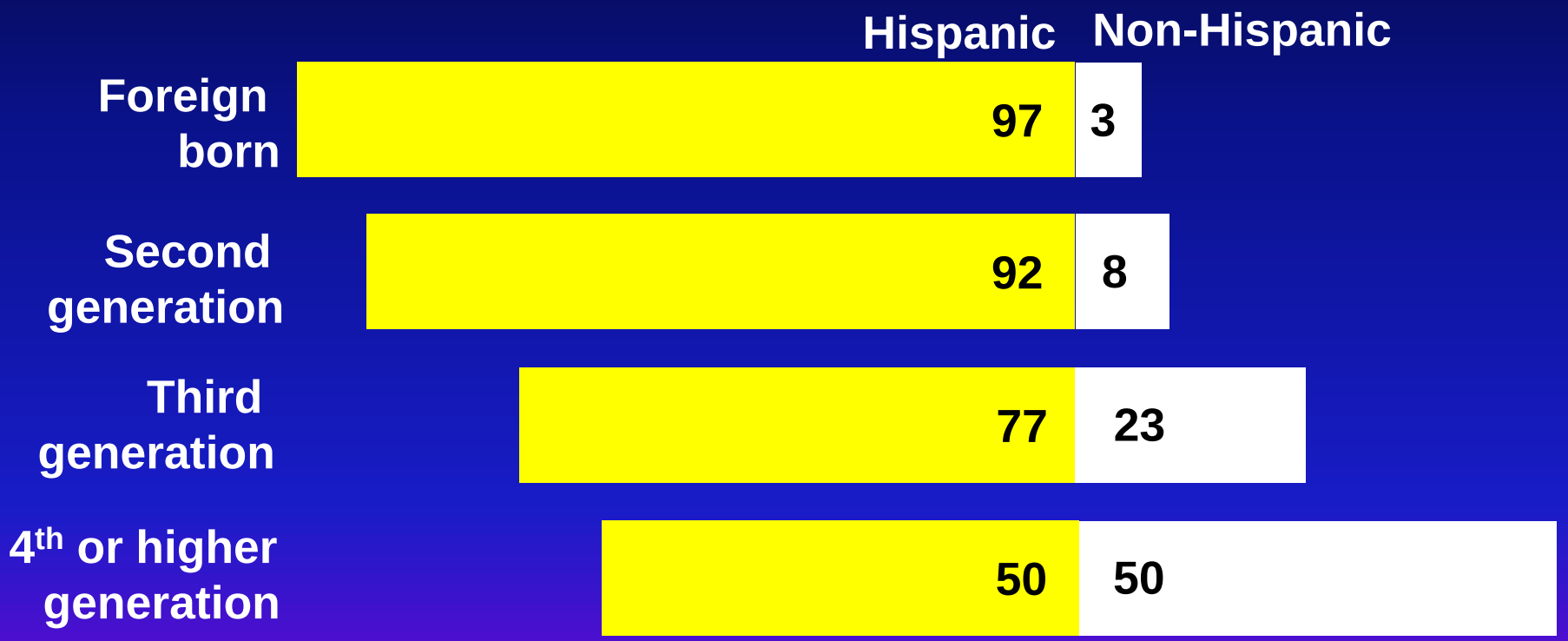
Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men,

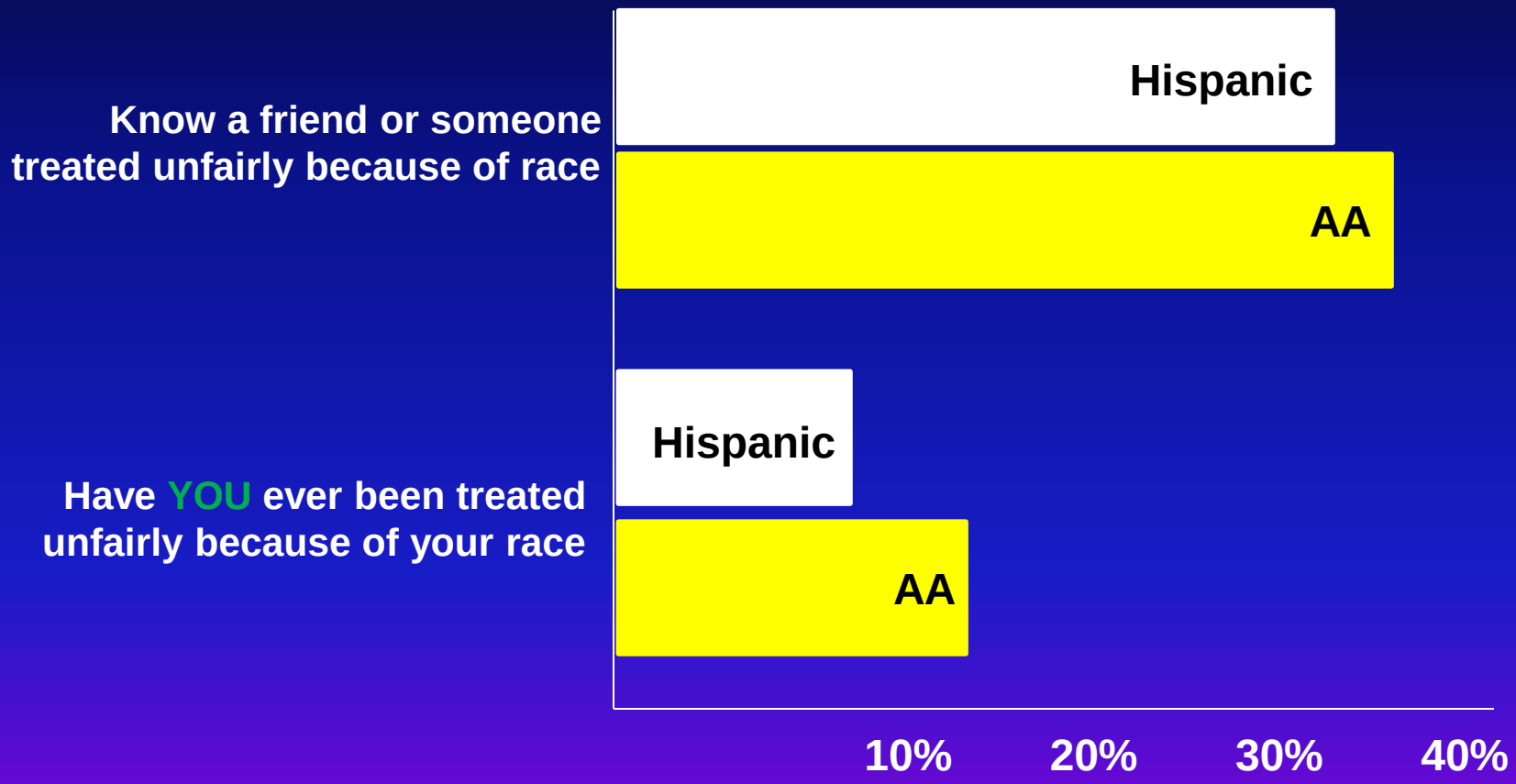
Among Americans with Hispanic ancestry, share that identifies as Hispanic or Latino falls across immigrant generations

% of US adults with Hispanic ancestry who self-identify as _____?



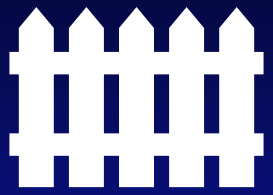
https://www.pewresearch.org/hispanic/2017/12/20/hispanic-identity-fades-across-generations-as-immigrant-connections-fall-away/

Experience With Being Treated Unfairly When Seeking Medical Care Because of Race/Ethnicity



Source: Kaiser Family Foundation Survey of Race, Ethnicity and Medical Care: Public Perceptions and Experiences, 10/99

Increasing Diversity in Clinical Trials: Overcoming Critical Barriers



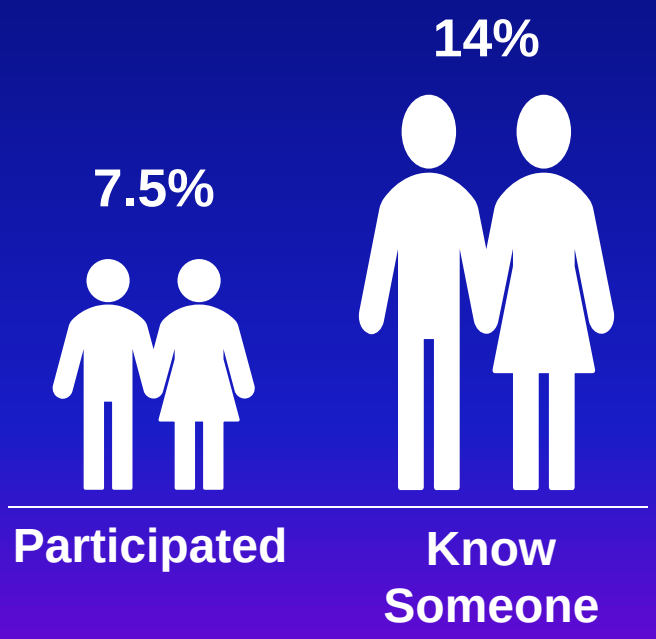
Lack of comfort with the trial process

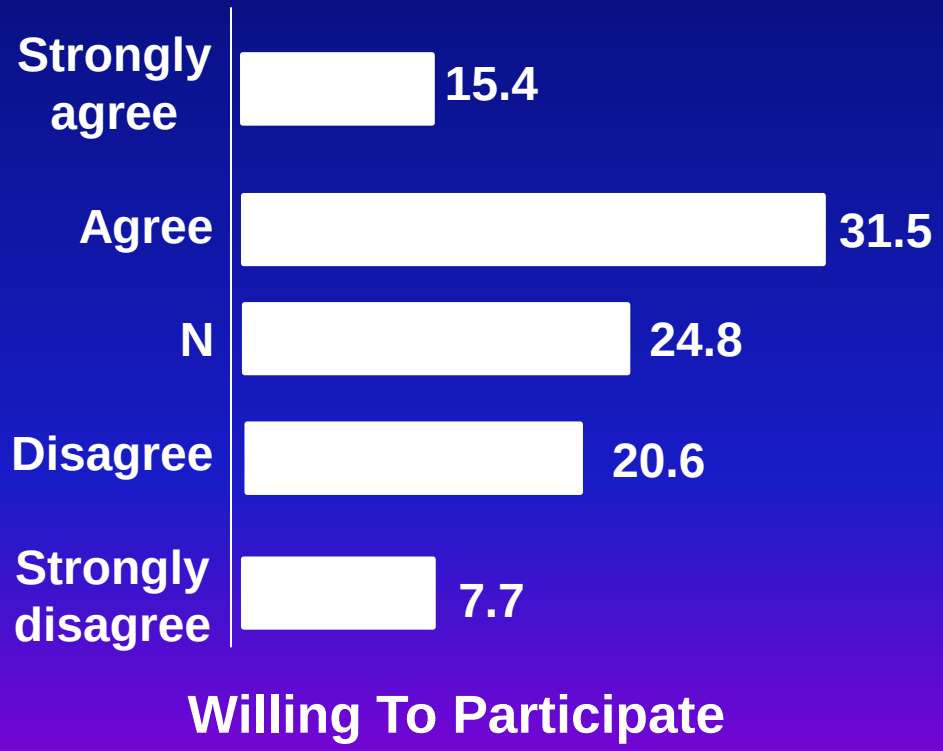
Lack of information about clinical trials

- **Study: “Are Minorities Willing To Participate”**
- **N=288, Mean age 43±16**
- **FHC and IM Clinics**
- **$2 incentive for survey completion**
- **Variables included: General attitudes, Interest and willingness, Knowledge of clinical trials, Medical history, Demographics**

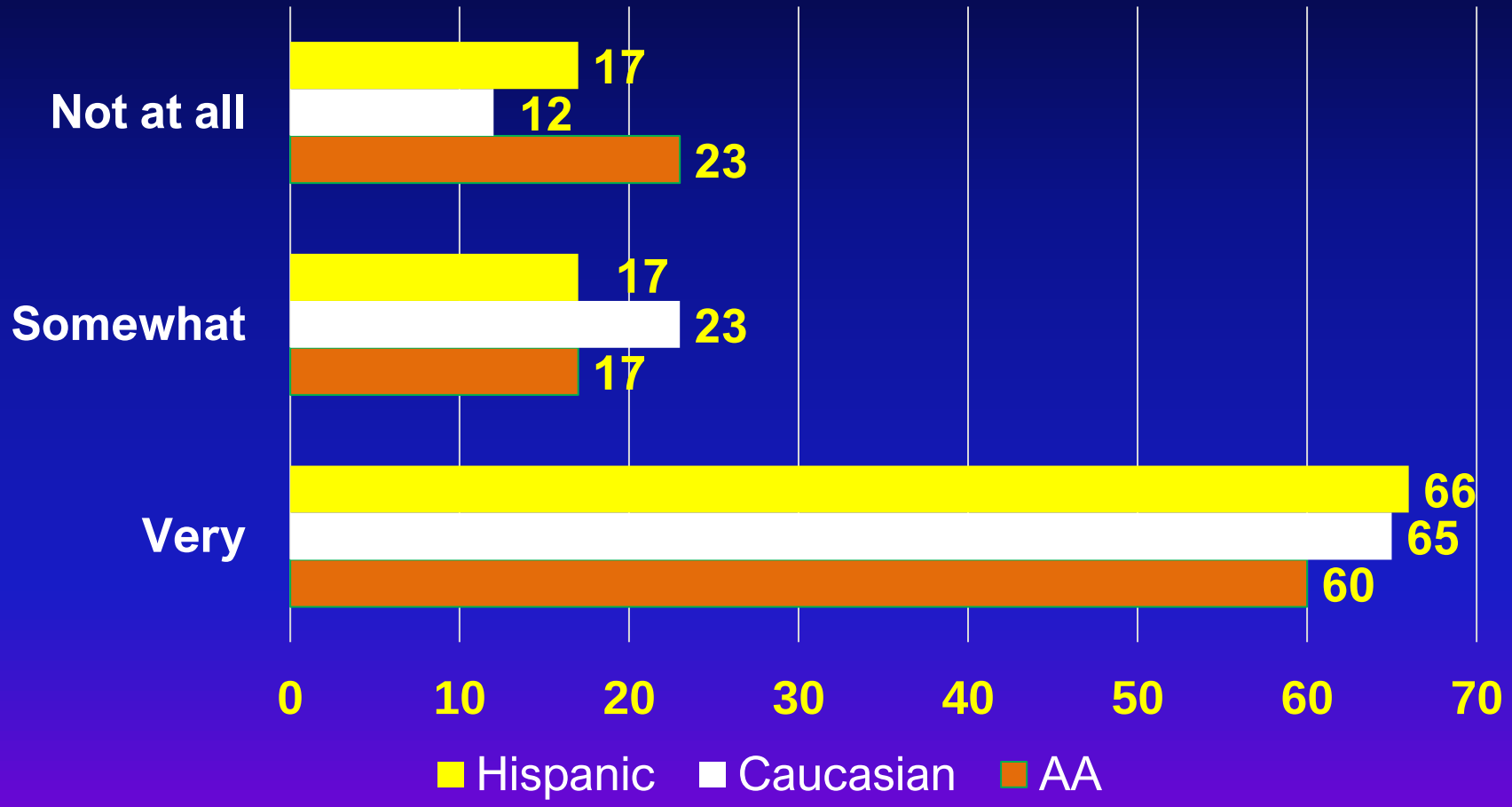
Increasing Diversity in Clinical Trials:

- Study: “Are Minorities Willing To Participate” n=288
- Only 7 percent of patients reported previous clinical trial participation (n=21/287 with 95% CI of 4.8-10.9%)
- 2/3rd expressed willingness to participate in research (171/288)





Willingness to Participate in Clinical Trials by Ethnicity



Chi Square X^2 = 4.75, p = 0.132

Increasing Diversity in Clinical Trials Summary

- Factors which predicted willingness to participate in clinical trials included:
  - Family or friends in clinical trials ($p < 0.001$)
  - Higher household incomes ($p=0.02$)
  - Older mean age ($p=0.05$)
  - Positive attitudes toward clinical trials ($p < 0.001$)
  - Patient motivation to find new treatments ($p < 0.001$)

Increasing Diversity in Clinical Trials: The Numbers Don't Lie: Adults > 16 years old

Lack of comfort with the trial process

Lack of information about clinical trials

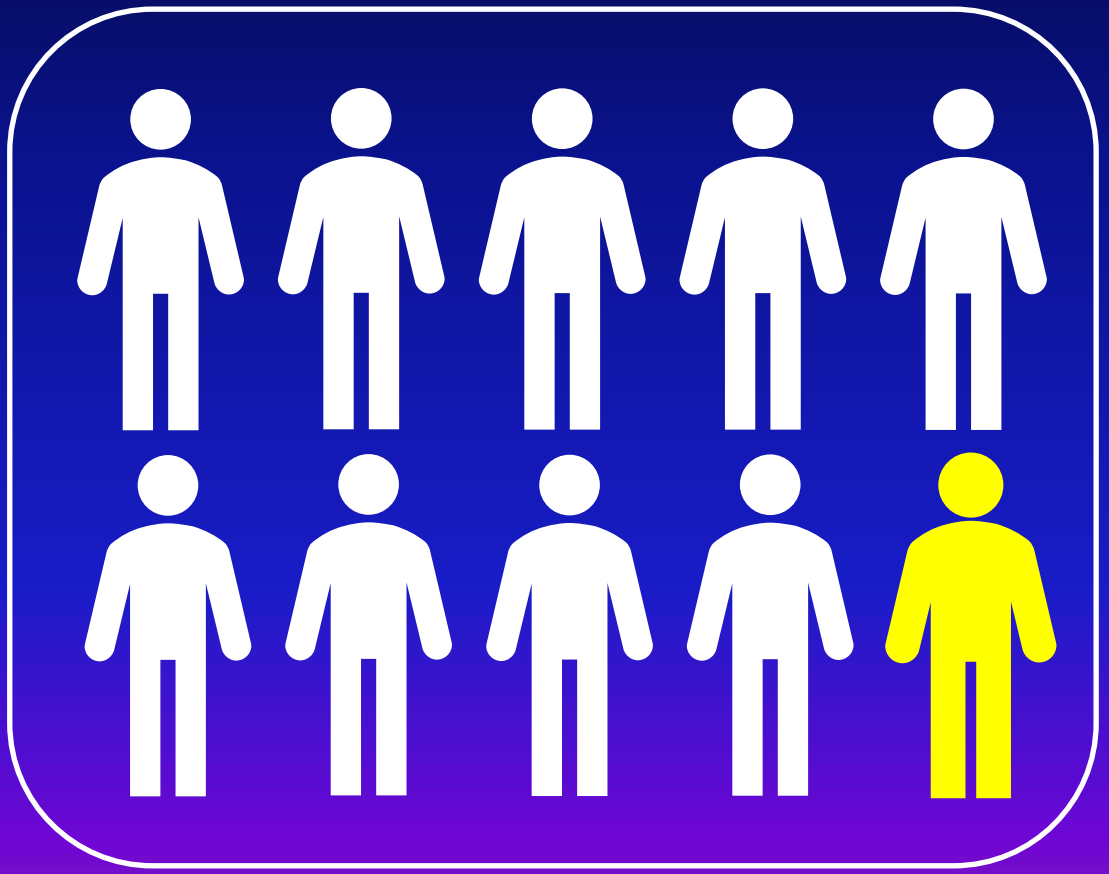
14% of US population reads <5th grade level

29% of US population at the 8th grade level

Increasing Diversity in Clinical Trials: Health literacy

The degree to which individuals have the capacity to *obtain, process,* and *understand* basic health information & services needed to make appropriate health decisions

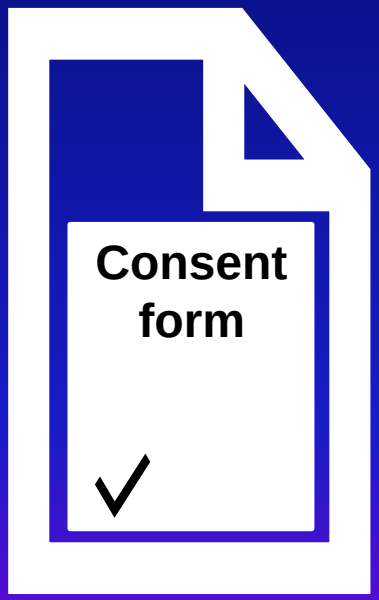
9/10
people

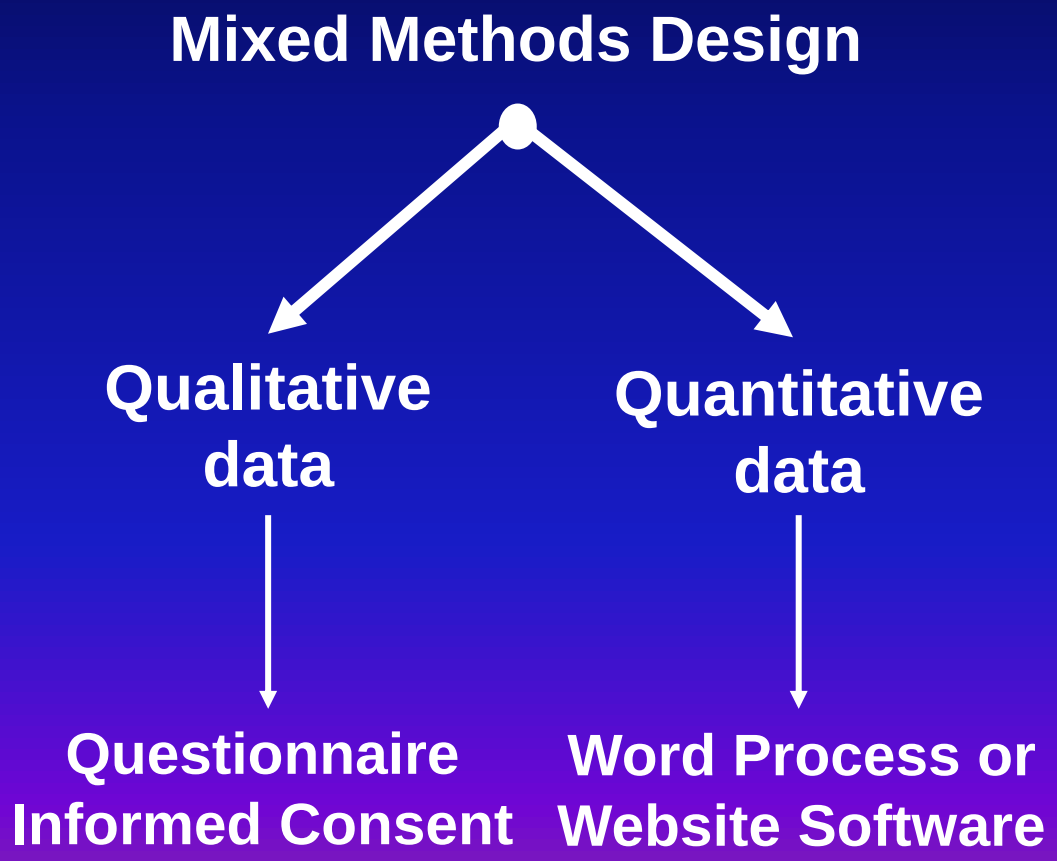


Source: Williams MV, Parker RM, Baker DW, et al. Inadequate Functional Health Literacy Among Patients at Two Public Hospitals. *JAMA* 1995 Dec 6; 274(21):1,677–82

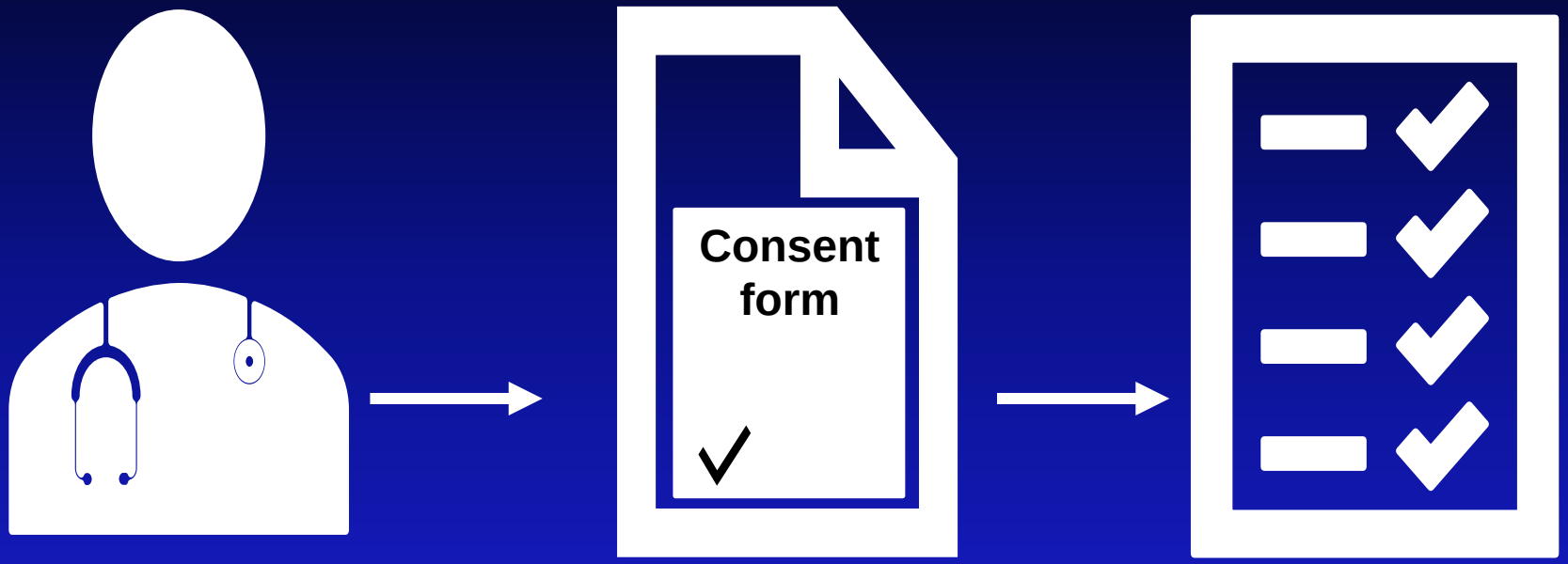
Readability of Research Informed Consent Documents:

- Do Patients Know What They Are Signing?





Methods: Data collection



Healthcare professionals

Read, 11 pages

ICD Questionnaire

Assess Chelation Therapy (TACT)

Readability of Research Informed Consent Documents

- Analyzed 42 cancer related informed consent documents
- Average number of paragraphs = 246 ± 125
- ICD averaged 18.8 ± 1.59 words per sentence
- Average of 4,703 words ± 1717 in each ICDs

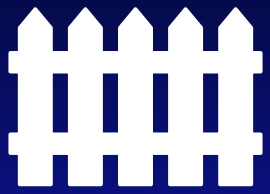
Formula Used	mean text grade level predicted
SMOG	9.6 ± 0.84
FOG	12.7 ± 1.1
Flesch-Kincaid	10.7 ± 1.2
Coleman Liau score	12.0 ± 0.7
Flesch Reading Ease	50.8 ± 6.0

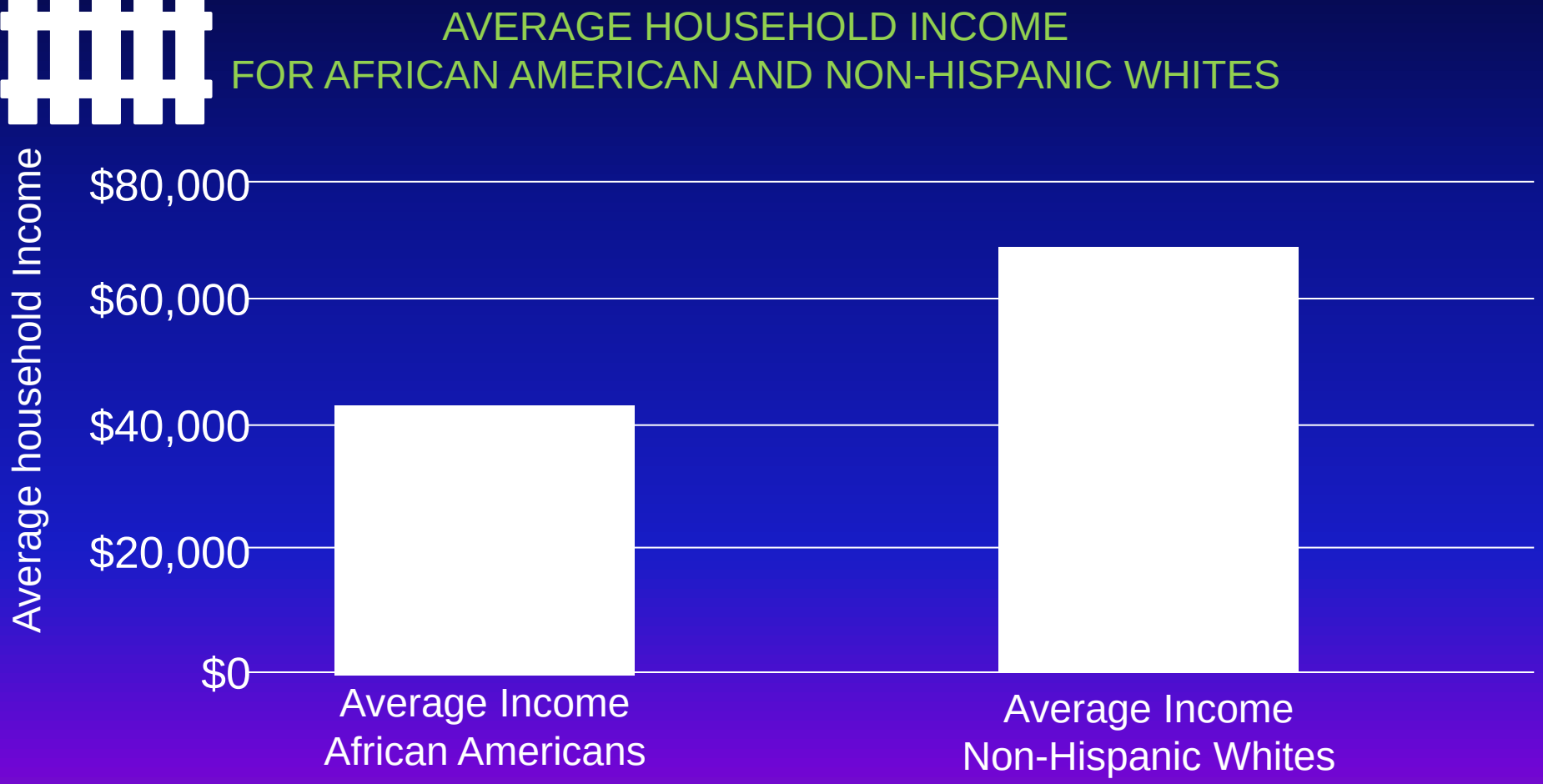
Table: The mean text grade levels predicted by the 5 readability formula

Increasing Diversity in Clinical Trials: Complexity in research studies is real

- 99% indicated that they believed research helped doctors better understand and treat disease
- 83% expressed the desire that the patient should be told about the results
  - Avg. grade level was 19 ± 2 years
  - Average age = 30.2 year
  - 83% had worries about the study but all would consent anyway

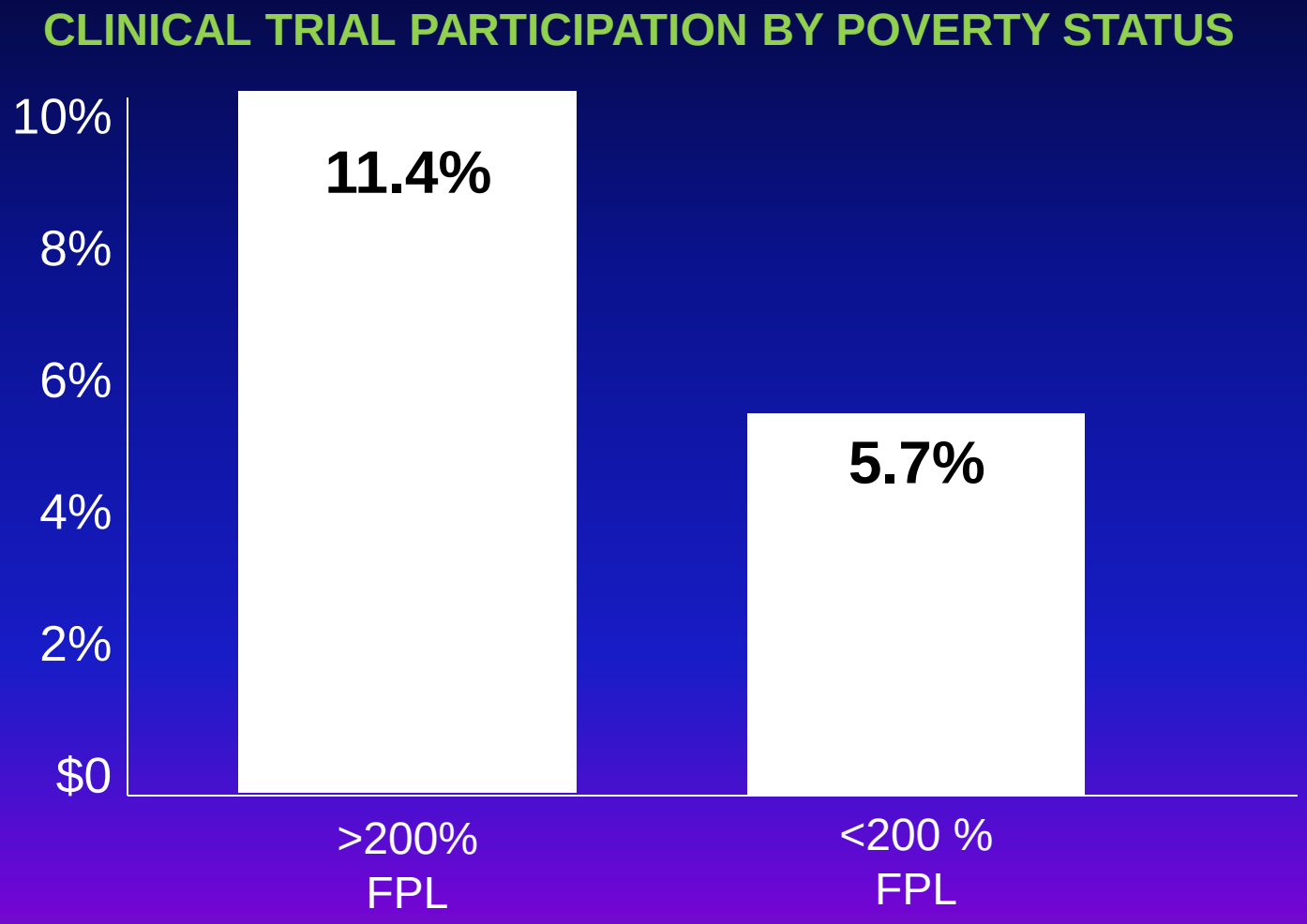
Increasing Diversity in Clinical Trials: - Time and Resource Constraints





Sources: Income and Poverty in the Unities States: 2018. US Census Bureau.

Increasing Diversity in Clinical Trials: Overcoming Barriers Resource Constraints



Increasing Diversity in Clinical Trials: Race & Concentrated Poverty

- **3 of 4 persons living in concentrated poverty are Black or Latino even though there are more poor Whites in absolute numbers**
  - ***Concentrated Poverty: neighborhoods where over 40% of residents live below the Federal Poverty Line***
- **Only 1/5 of the schools with less than 10% black or Latino populations are high poverty schools**

Duda C, Mahon I, Chen MH, et al. Impact and costs of targeted recruitment of minorities to the National Lung Screening Trial. *Clin Trials*. 2011;8(2):214-223. doi:10.1177/1740774510396742

What are some simple things to improve the recruitment of minorities in clinical research?

- Mentoring
- Focus on recruitment of minorities
- Recruit and train more minorities in the concepts, ideal and process of clinical and scientific research

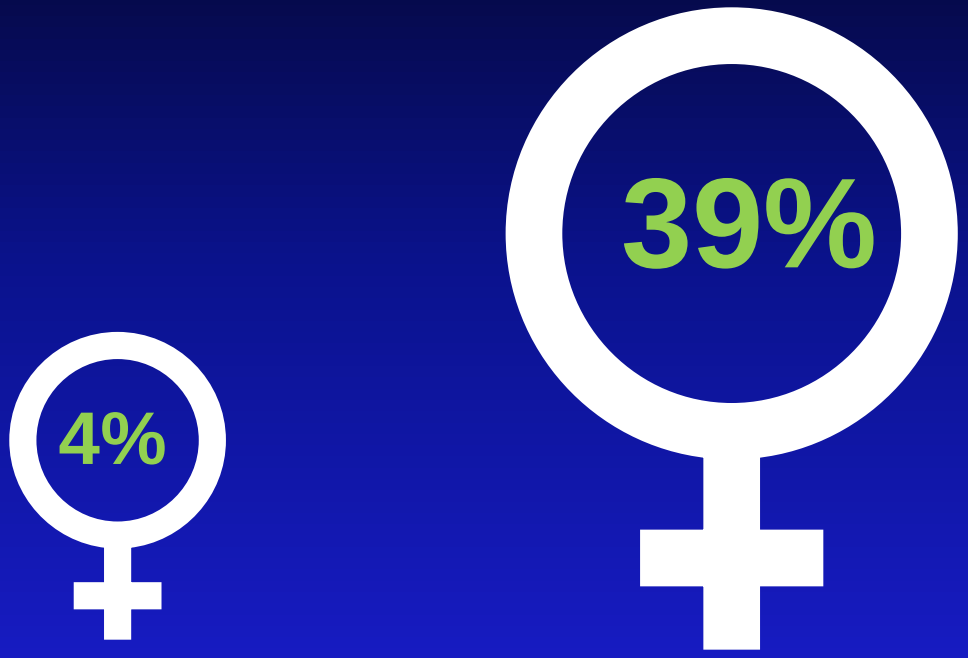
Increasing Diversity in Clinical Trials: Overcoming Critical Barriers

at the Solvay conference on physics in 1927

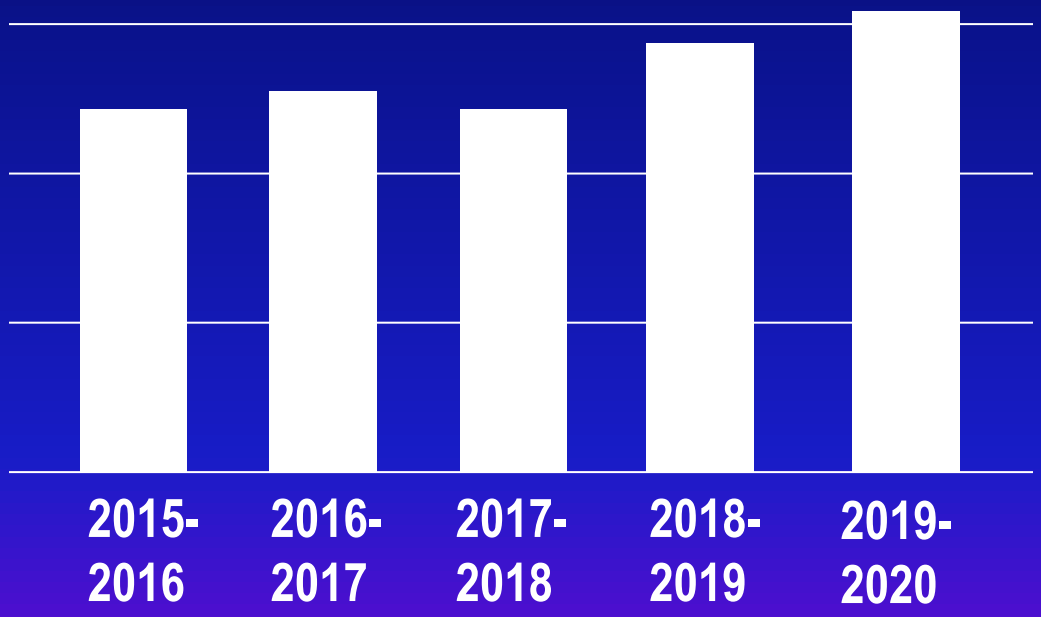
Increasing Diversity in Clinical Trials: Higher Education

- Racial breakdown of college students who received college degrees in 2003:
  - Whites 70%
  - Blacks 8.7%
  - Hispanics 6.3%
  - Asians 6.2%
- 74% of students at the 146 most selective four-year colleges and universities in the U.S. came from the top socioeconomic status quarter of American families; 3% from the bottom quarter

Only 4% of full-time faculty are Black, African American, Hispanic or Latino, and Pacific Islander Females



In 2019, for the first time ever, the majority of medical students are women



6.3% ↑ In Hispanic, Latino, or of Spanish Origin

3.2% ↑ In black or African American

5.5% ↑ In American Indian or Alaska Native

https://www.aamc.org/news-insights/press-releases/majority-us-medical-students-are-women-new-data-show

Increasing Diversity in Clinical Trials: 2015 Medical School Graduates

6%

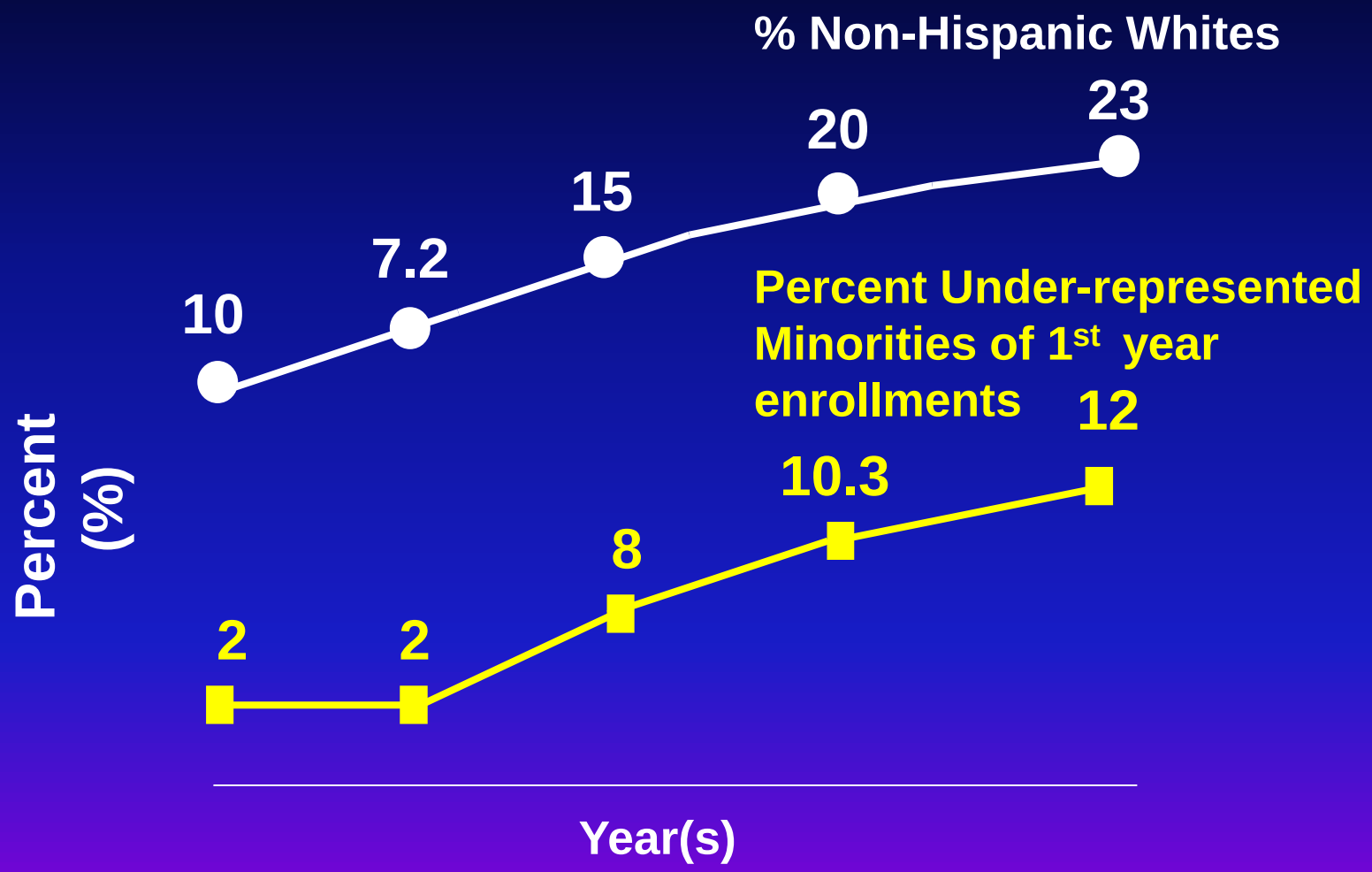
Black or African American

5%

Hispanic or Latino

The Minority Tax: An Unseen Plight of Diversity in Medical Education – IMDiversity

Increasing Diversity in Clinical Trials: Medical School Enrollment Trends



Source: Association of American Medical Colleges Datebook: Statistical information Related to Medical Education 2000

Confronting Disparities in Research: Issues such as workforce demographics & cultural competence

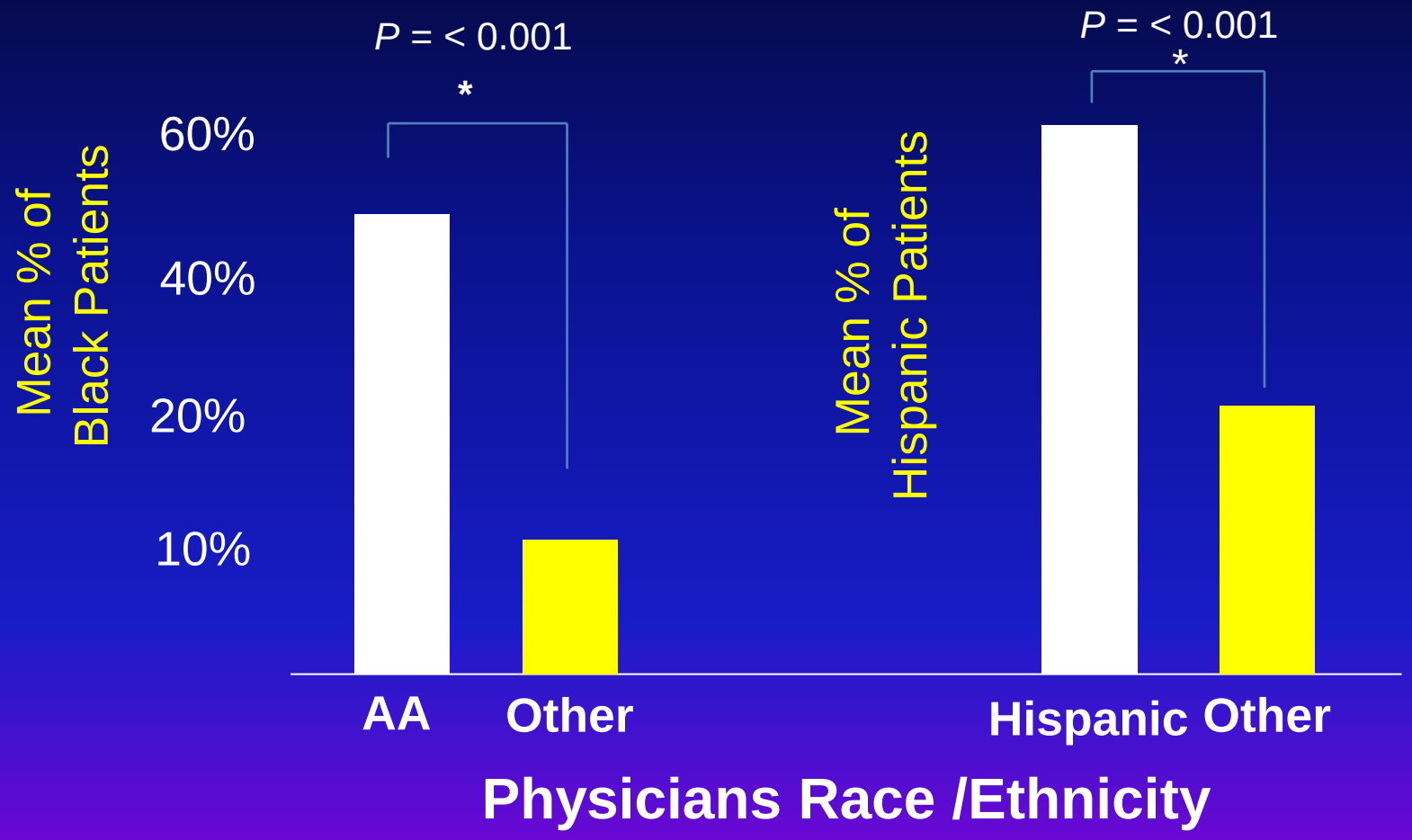


Figure: Komaromy et al. 334 (20): 1305, May 1996
Commonwealth Fund., 2002; Saha., 1999

Increasing Diversity in Clinical Trials: Maldistribution Limits Access

- **Poor urban racial and ethnic communities are more likely to have a physician shortage.**
  - **Poor urban communities with high proportions of Hispanic(H) and African Americans(AA) have:**
    - **Only 24 physicians /100,000 people,**
    - **Compared to 69 physicians /100,000 in similar communities with a low proportion of Hispanic and AA**

Duda C, Mahon I, Chen MH, et al. Impact and costs of targeted recruitment of minorities to the National Lung Screening Trial. *Clin Trials*. 2011;8(2):214-223. doi:10.1177/1740774510396742

Strategies to Increase Minority Clinical Trial Participation are Effective

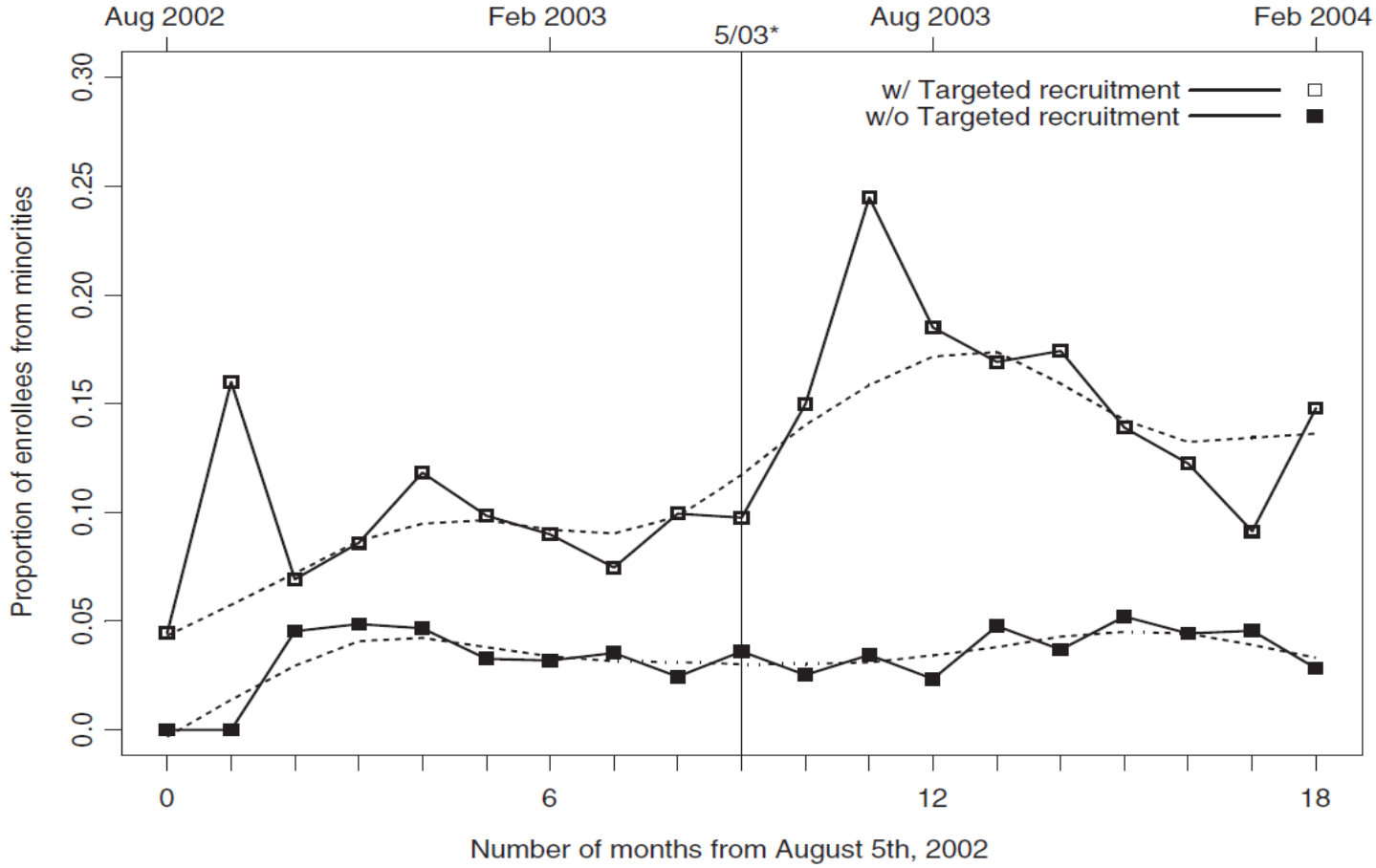


Figure 1 Proportion of enrollees from minorities each month for institutions with targeted recruitment strategies (top curves) and all others (lower curves) Notes: Dashed lines without points are derived from Lowess smoothers with 6-month windows. *5/03 – Date corresponding to when institutions with targeted recruitment initiated some or all strategies

Duda et al. Clinical Trials 2011; 8: 214–223.

Evolving Role of Physicians in Medical Research

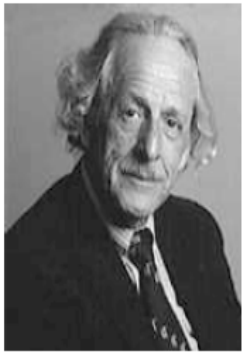
- Science needs to AGAIN becomes integral to medical education
- Inspire studies by clinical observations
- Institutional leadership to cultivate a climate of mutual respect and trust
- All trainees need to experience research
- Have PhD trainees experience clinical medicine

From The American Scholar, Volume 53, No. 3, Summer 1984.

The End of the Physician-Scientist?

GORDON N. GILL

Essays of an Information Scientist: Science Reviews, Journalism Inventiveness and Other Essays, Vol:14, p.261, 1991



Not the End of the Physician-Scientist

Reprinted from *THE SCIENTIST* ® 1(21):9, 21 September 1987.

During the past 20 years, colleges of osteopathic medicine (COMs)

NUMBER of RESEARCH AWARDS BY SOURCE

Funding Source	Grants, No. (%) 1999	2004	Net Change
AOA	17 (5.4)	3 (0.7)	-14
CDC	1 (0.3)	3 (0.7)	2
DOD	1 (0.3)	6 (1.3)	5
Foundations	35 (11.1)	50 (11.1)	15
HRSA	3 (0.9)	0 (0)	-3
NIH	80 (25.5)	115 (25.6)	35
Pharmaceutical Companies	95 (30.2)	126 (28.1)	31
State and Local	7 (2.2)	10 (2.2)	3
Other Federal	20 (6.4)	19 (4.2)	-1
Other*	55 (17.5)	117 (26.0)	62
Total	**314 (99.8)**	**449 (99.9)**	**135**

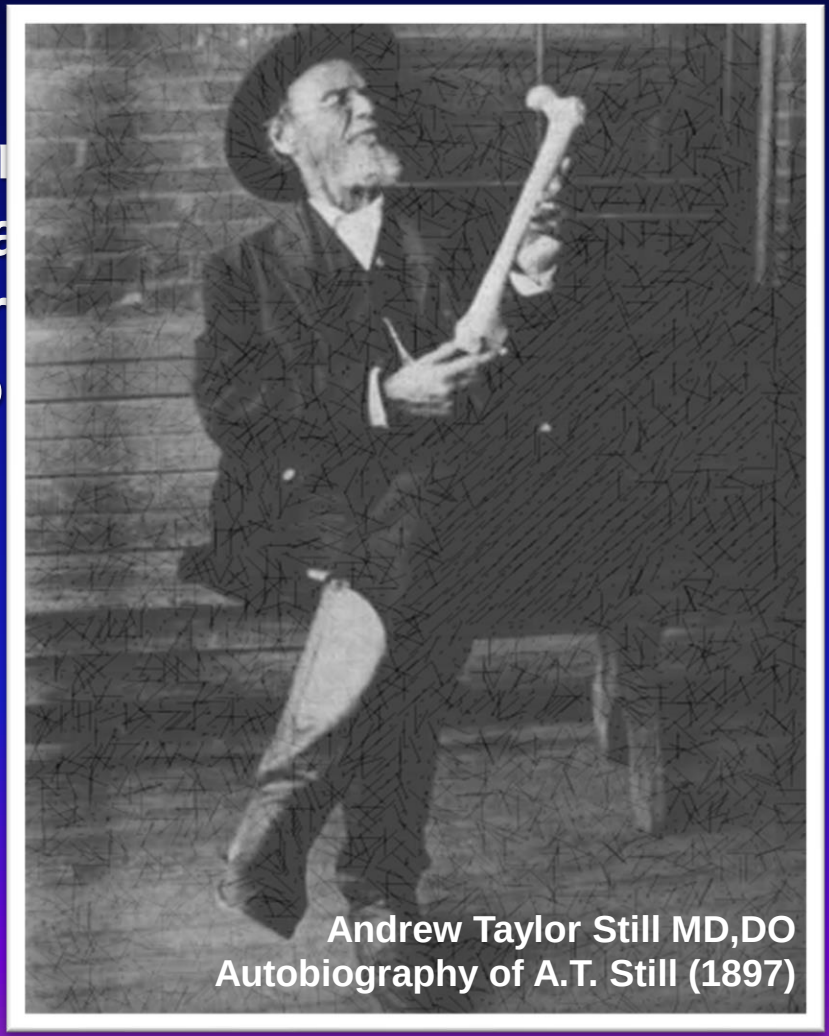
* Includes American Hospital Association, biotechnology companies, school support, and sources listed as "other" by the reporting institutions.

Abbreviations: AOA, American Osteopathic Association; CDC, Centers for Disease Control and Prevention; DOD, US Department of Defense; HRSA, Health Resources and Services Administration; NIH, National Institutes of Health.

J Am Osteopath Assoc. 2012;112(11):716-724

Racial & Ethnic Disparities in Health
Who made this statement

- It is a philosophy which e
  obstetrics and general pra
  a person of reason and pr
  They also should have no
  they are demonstrated.”



Andrew Taylor Still MD,DO
Autobiography of A.T. Still (1897)

Confronting Racial & Ethnic Disparities Join In You Have A Voice

Conclusions

- There is always going to be disparities, however the ones in health care can be improved.
- We need to make changes to how we mentor, teach, learn and discuss cross cultural care.
- We need to improve the science behind what we do in medicine – so that all can be helped.