



National Hispanic Medical Association

High Cholesterol in Our Communities: Strategies for a Healthier Future

Co-Hosts:



Alliance for
Patient Access



National Minority
Cardiovascular Alliance

Translating Discovery Science Into Public Health Impact: The Health Equity Challenge

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Director

National Heart, Lung, and Blood Institute

National Hispanic Medical Association

Congressional Briefing

July 25, 2019



NHLBI Mission - *Discovery Science That Enhances Human Health:* Accountable Stewardship and the Privilege of Public Service

NHLBI Enduring Principles

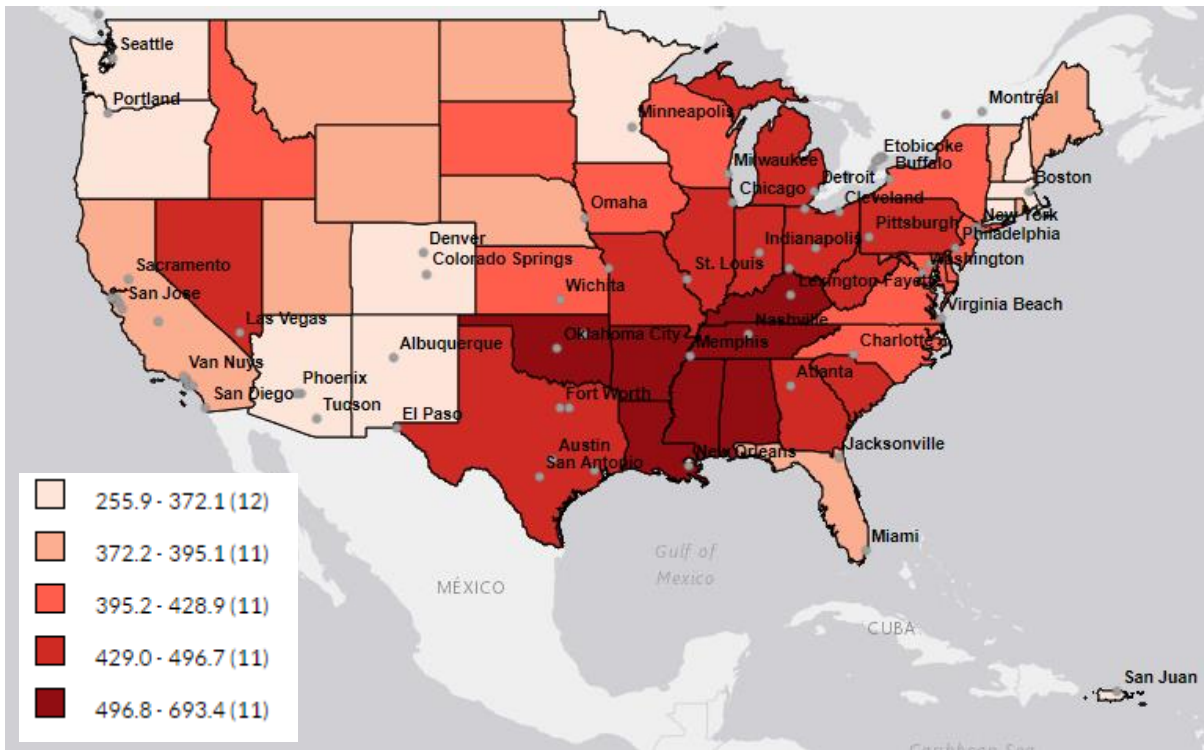
- Value investigator-initiated fundamental discovery science.
- Maintain a balanced, cross-disciplinary portfolio (basic, translational, clinical, population science).
- Train a diverse new generation of leaders in science.
- **Support implementation science that empowers patients and enables partners to improve the health of the nation.**
- **Innovate an evidence-based elimination of health inequities in the U.S. and around the world.**



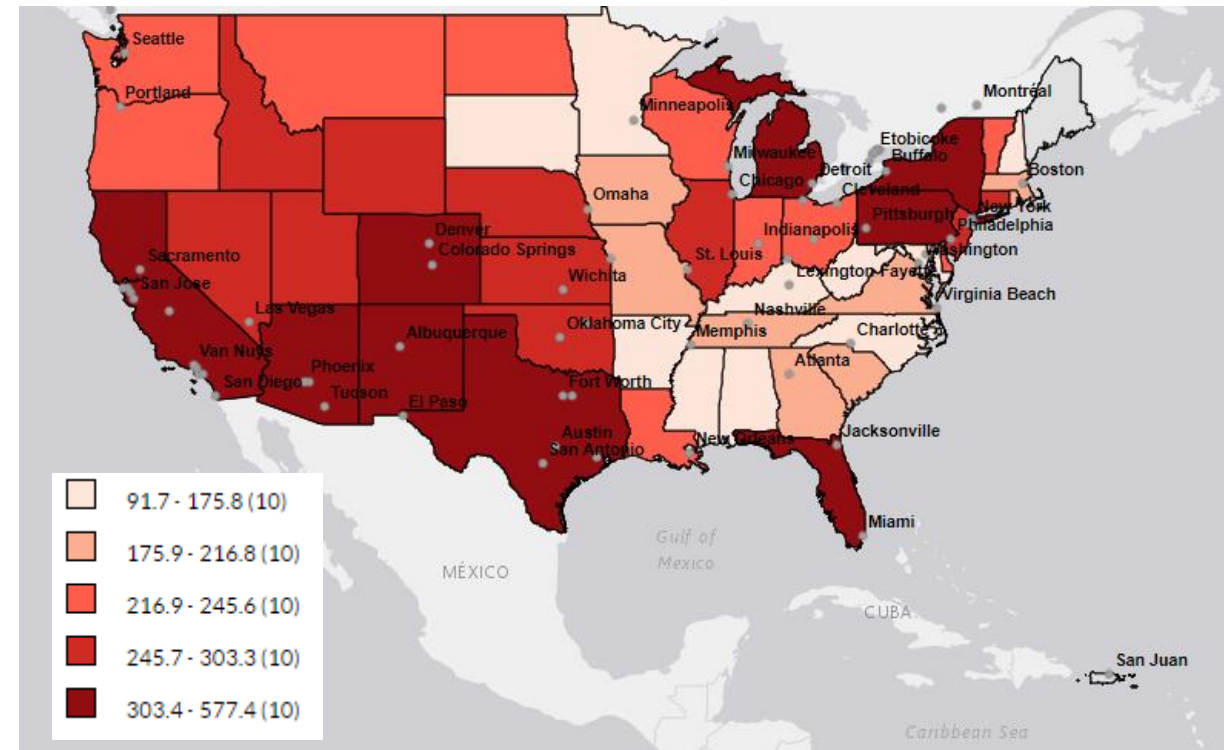
Heart Disease Mortality: The Unfinished Business of Health Disparities in High-Risk Populations

The burden of heart disease mortality persists among different ethnic groups.

**Heart Disease Death Rate Per 100,000, 35+,
All Races/Ethnicities, Both Genders, 2014-2016**



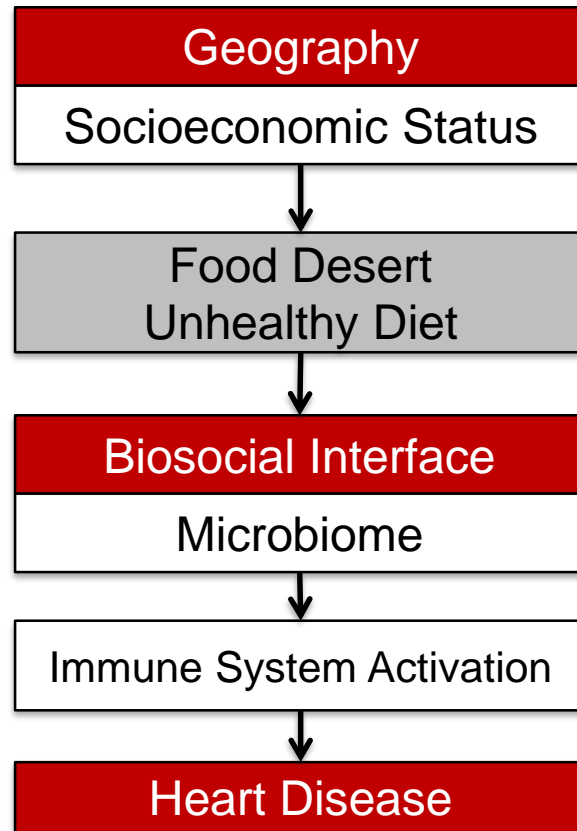
**Heart Disease Death Rate Per 100,000, 35+,
Hispanic, Both Genders, 2014-2016**



Social Determinants of Heart Disease: Addressing Disparities in at-Risk Populations

Understanding the Interplay of Social and Biological Systems ...

Risk Factors
High blood pressure
Smoking
High blood cholesterol
Overweight/Obesity
Physical inactivity
Diabetes
Family history
Age



... Describing and Understanding Prevalence and CVD Risk in Diverse Populations Through NHLBI-Supported Cohort Studies



- Longitudinal, multiethnic, community-based cohort study
- Original cohort: 6,814
- Ages: 45-84
- 1,437 Hispanic men and women enrolled



- Largest U.S. Hispanic/Latino health study
- Original cohort: 16,415
- Ages: 18-74
- 4,000 participants self-identified as Mexican/Mexican American; Puerto Rican; Cuban; Dominican; Central American; South American; Other

Understanding Risk in Diverse Cultures: Multifactorial, Multi-Level Influences of Cardiovascular Health

Risk Factors Measured

Blood pressure

Smoking status

Blood cholesterol level

Body Mass Index (BMI)

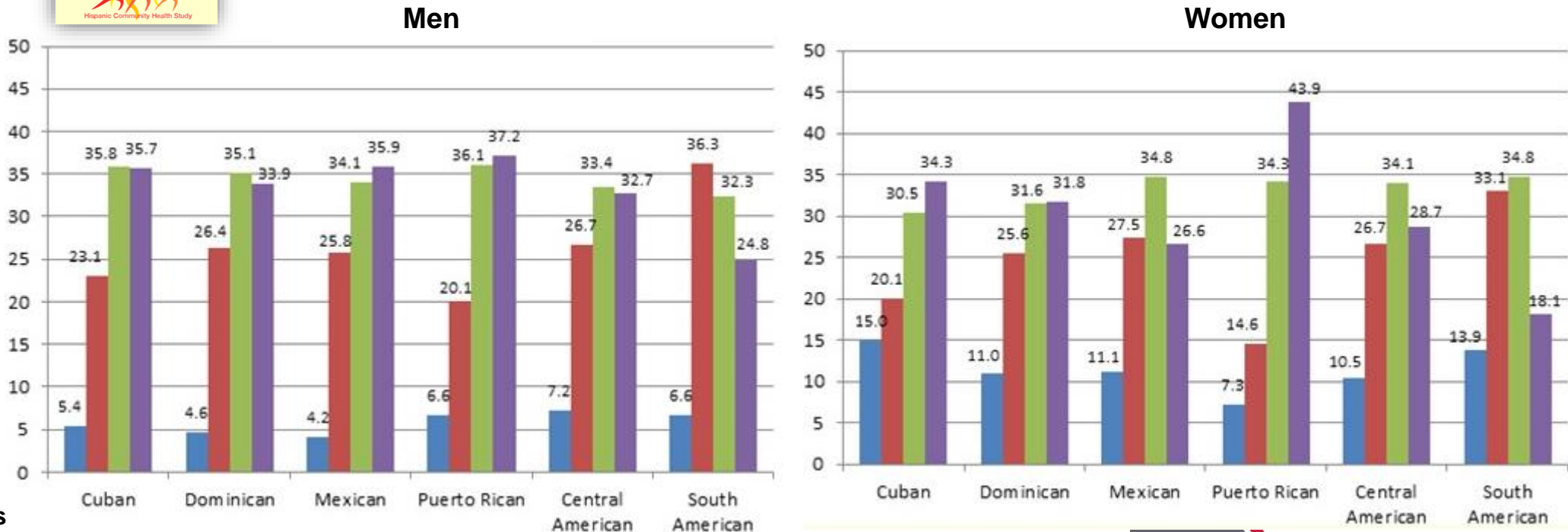
Diabetes (and history of diabetes)

- Low risk
- 0 Risk Factors
- 1 Risk Factor
- 2+ Risk Factors

The majority of US Hispanic/Latino adults had one or more risk factors for CVD, with significant variation by country of origin. In all groups, men had more risk factors for CVD than women.



Age-Adjusted Prevalence of CVD Risk Profiles by Hispanic/Latino Background



Multifactorial, Multi-Level Influences of Cardiovascular Health Among Hispanics/Latinos

Demographics:
Race, Subgroups,
Gender, Geography



Socioeconomic Status:
Income, Education,
Employment



Different Adverse
Risk Profiles by
Hispanic Subgroup

Health Systems:
Access, Health
Literacy, Language,
Provider relationships



Psychosocial Factors:
Acculturation,
Culture



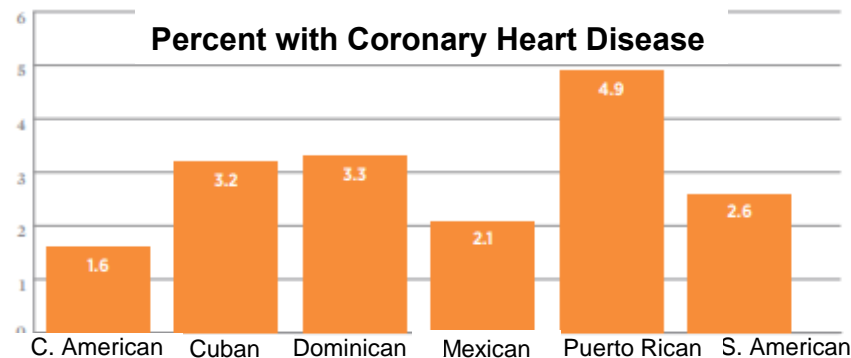
Multifactorial, Multi-Level Influences of Cardiovascular Health Among Hispanics/Latinos

Demographics

- Racially diverse population
- Lower SES among Puerto Ricans assoc. with ↑BP

Socioeconomic Status (SES)

- SES comparable to NHB (income, poverty, education, occupation, wealth)
- Education strongest SES predictor of CVD (53% HS or greater vs. 90% in gen. pop)



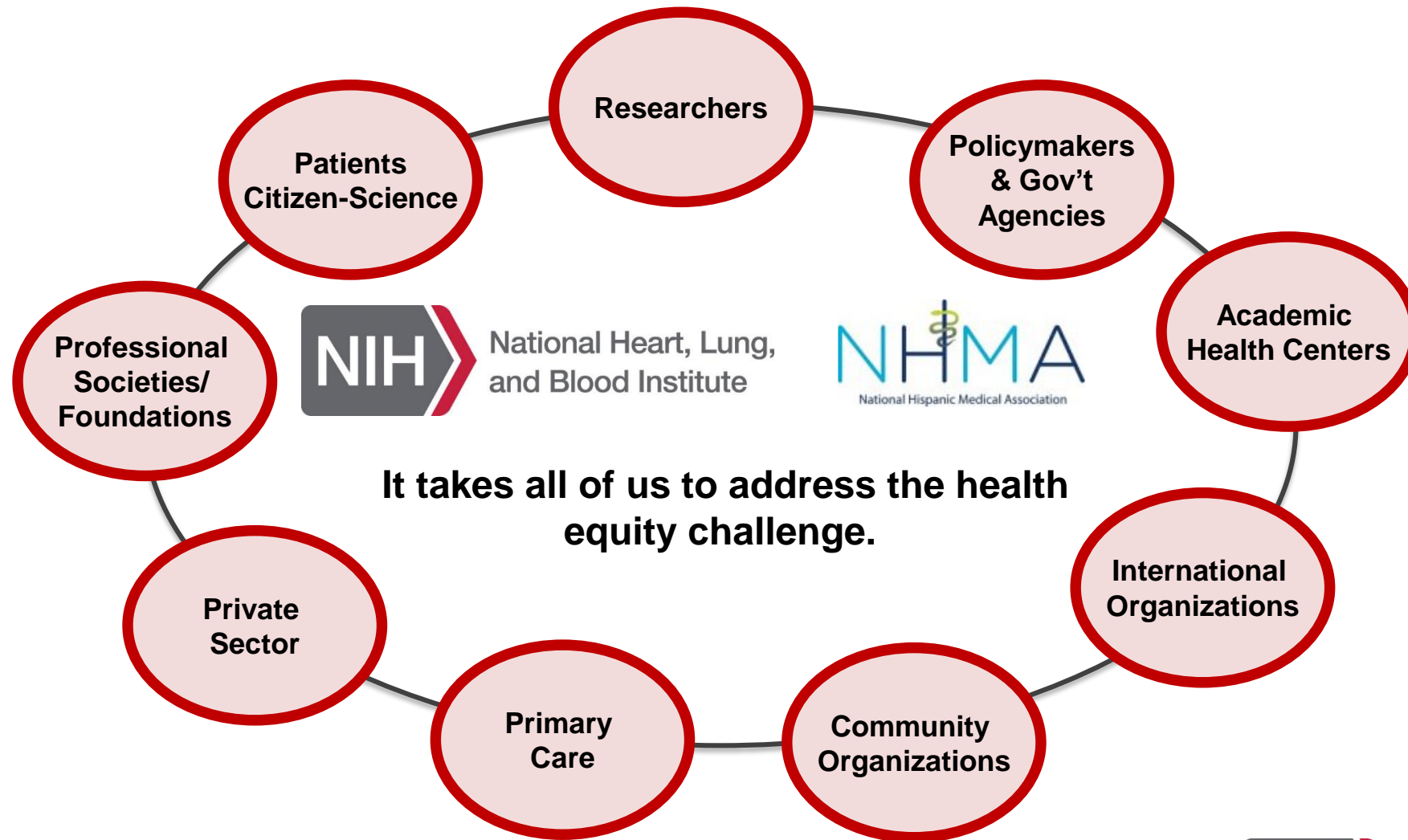
Health System

- Large proportion lack insurance
 - 30% of uninsured vs. 11% NHB, 20% NHB
- Health literacy influences navigation & care
 - ↓health literacy predicts ↑mortality in HF

Psychosocial Factors

- Relationship b/w acculturation & CV risk
- Strong negative effects of ↑acculturation on CV risk factors but positive effects on prevention services
- Among Mexican women, highly acculturated ↑ BMI and BP

A Dialogue with the NHLBI Circle of Partners: A Diverse Community Addressing the Health Equity Challenge





National Heart, Lung,
and Blood Institute



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Understanding Cholesterol in Hispanics/Latinos

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Albert Einstein College of Medicine, Bronx, NY

Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION



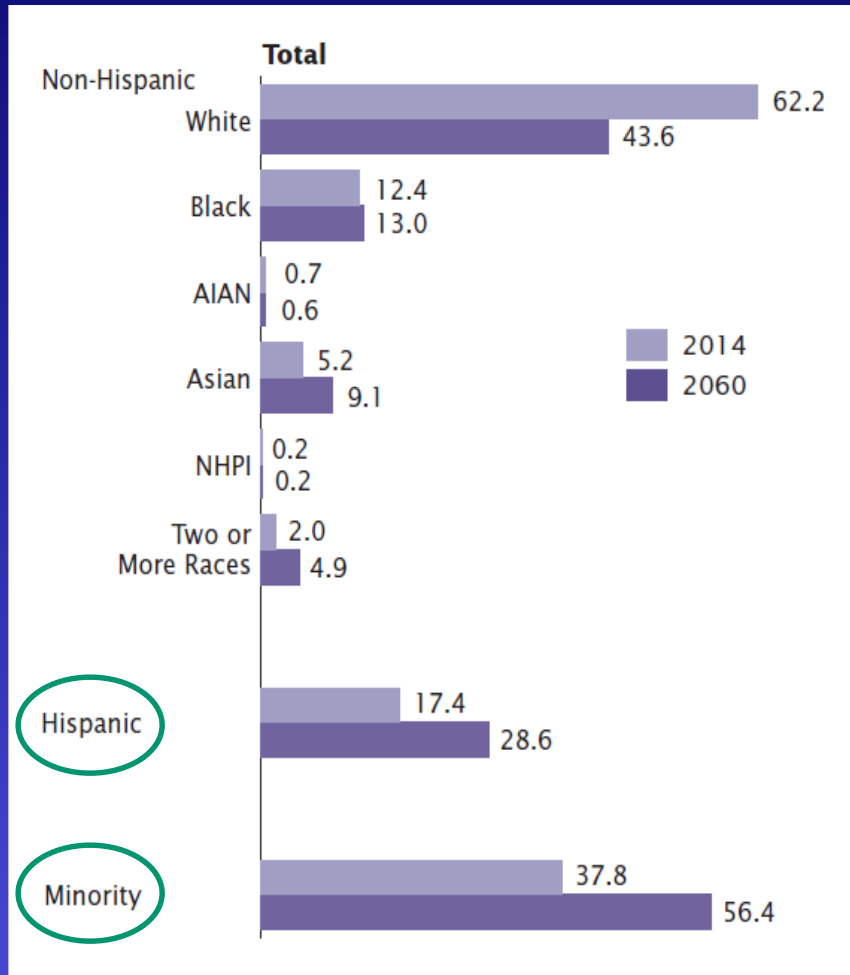
Status of Cardiovascular Disease and Stroke in Hispanics/Latinos in the United States: A Science Advisory From the American Heart Association

Carlos J. Rodriguez, Matthew Allison, Martha L. Daviglus, Carmen R. Isasi, Colleen Keller, Enrique C. Leira, Latha Palaniappan, Ileana L. Piña, Sarah M. Ramirez, Beatriz Rodriguez and Mario Sims

on behalf of the American Heart Association Council on Epidemiology and Prevention, Council on Clinical Cardiology, and Council on Cardiovascular and Stroke Nursing

Circulation. 2014;130:593-625

US population composition

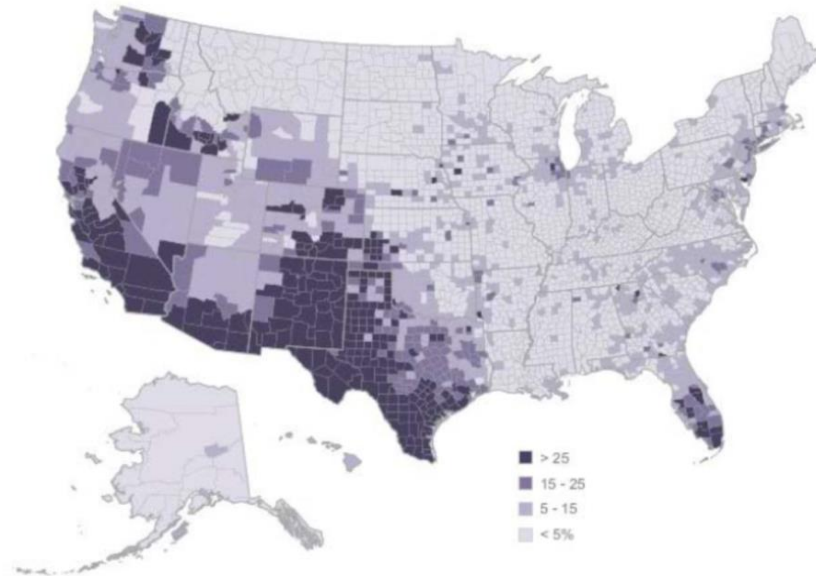


- 17.4% of the US population is Hispanic
- >55 million Hispanics resided in the 50 states and DC
- US is projected to become more racially and ethnically diverse
- The public health impact of the Hispanic population is significant

US Hispanic population

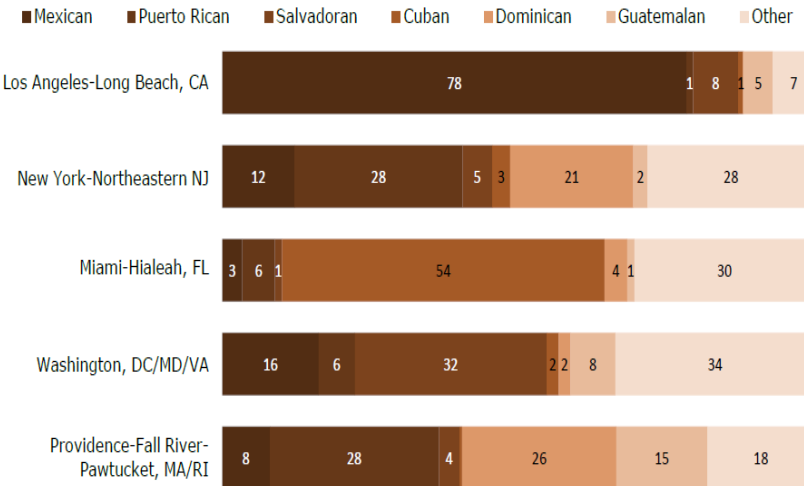
The Distribution of the Nation's Hispanic Population, 2011

Hispanic population share by county



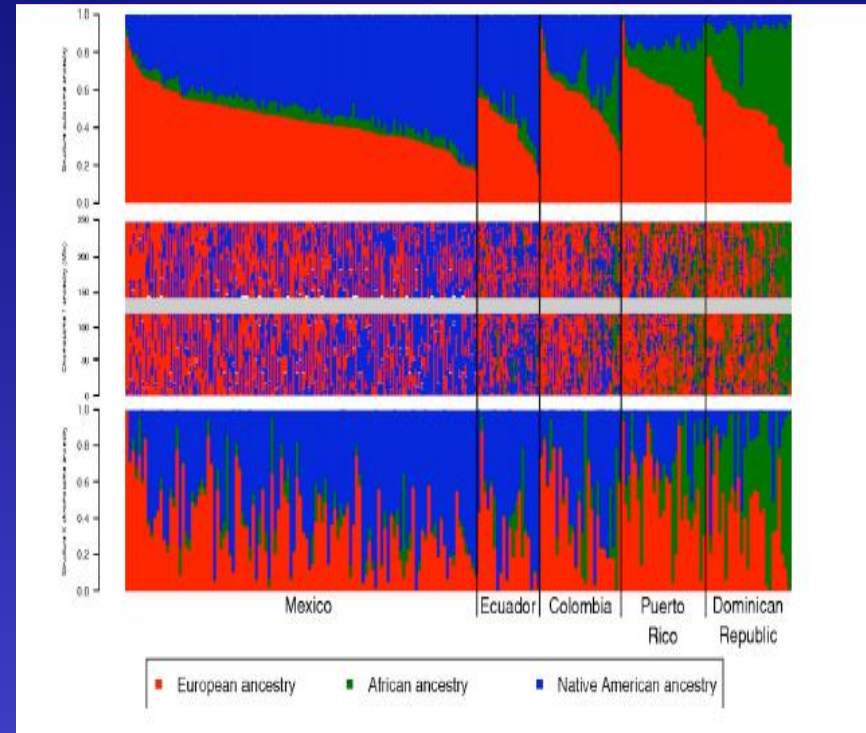
Largest Hispanic Origin Group Shares in Select Metropolitan Areas, 2011

% of the Hispanic population in the metro area that is ...

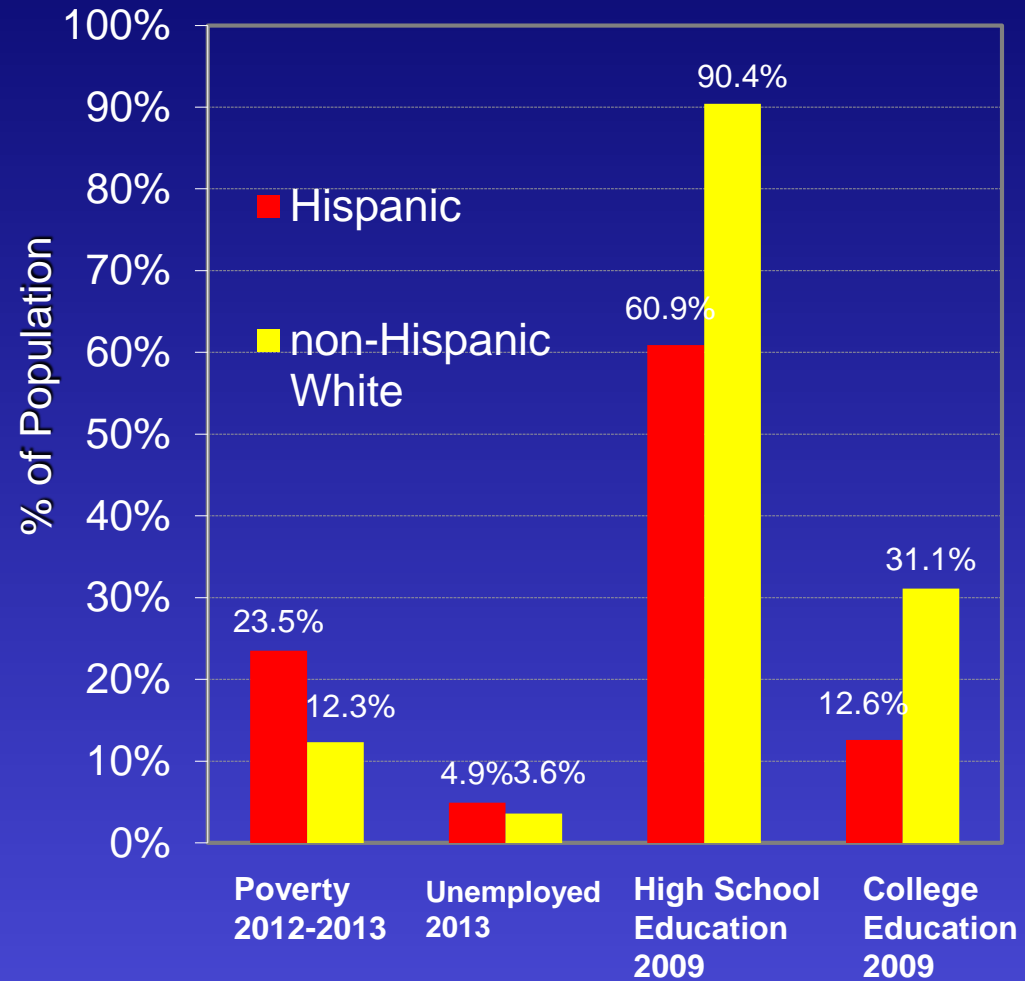


Genetic / Racial Diversity among Hispanics

- Being Hispanic is not a Race, it is an Ethnicity
- US concept of Race of only white or black is confusing to Hispanics
- Hispanics are an admixed population of varying racial admixture of
 - West African
 - European Caucasian
 - Native American ancestry



Hispanic Socioeconomic Status



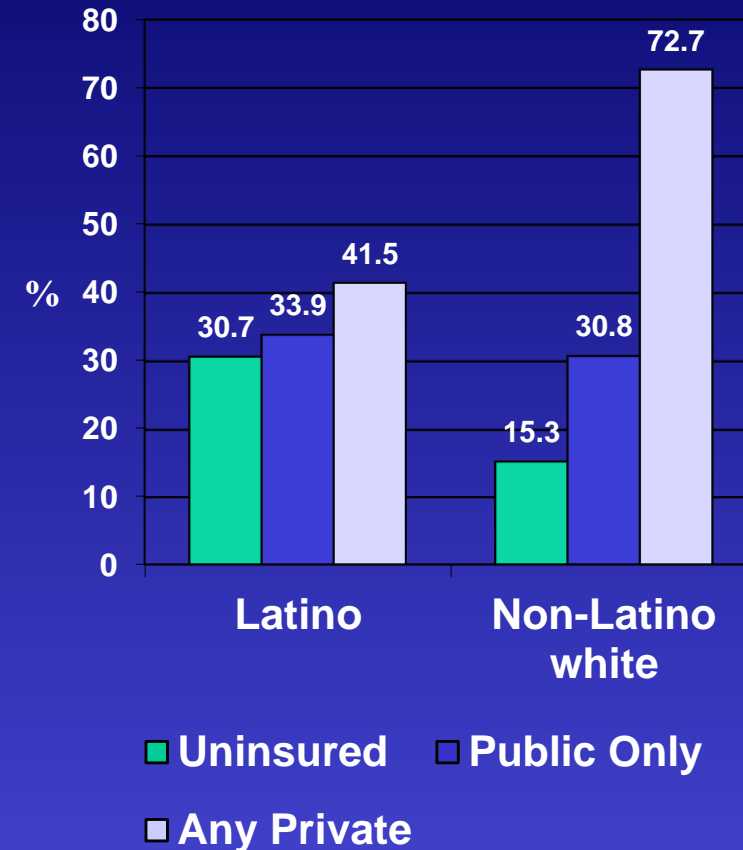
1. U.S. Census Bureau. Income in the United States; 2013.

2. U.S. Census Bureau. Educational Attainment in the United States; 2009.

3. U.S. Census Bureau. Employment Status; 2013.

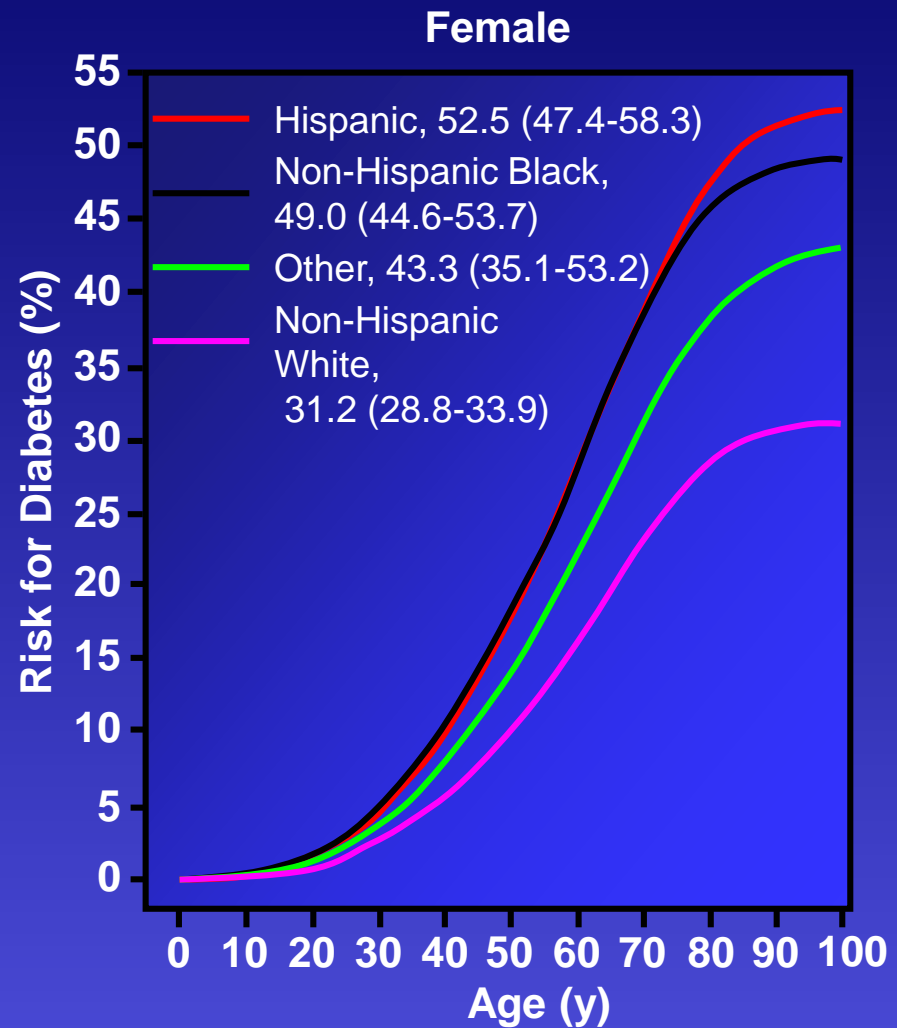
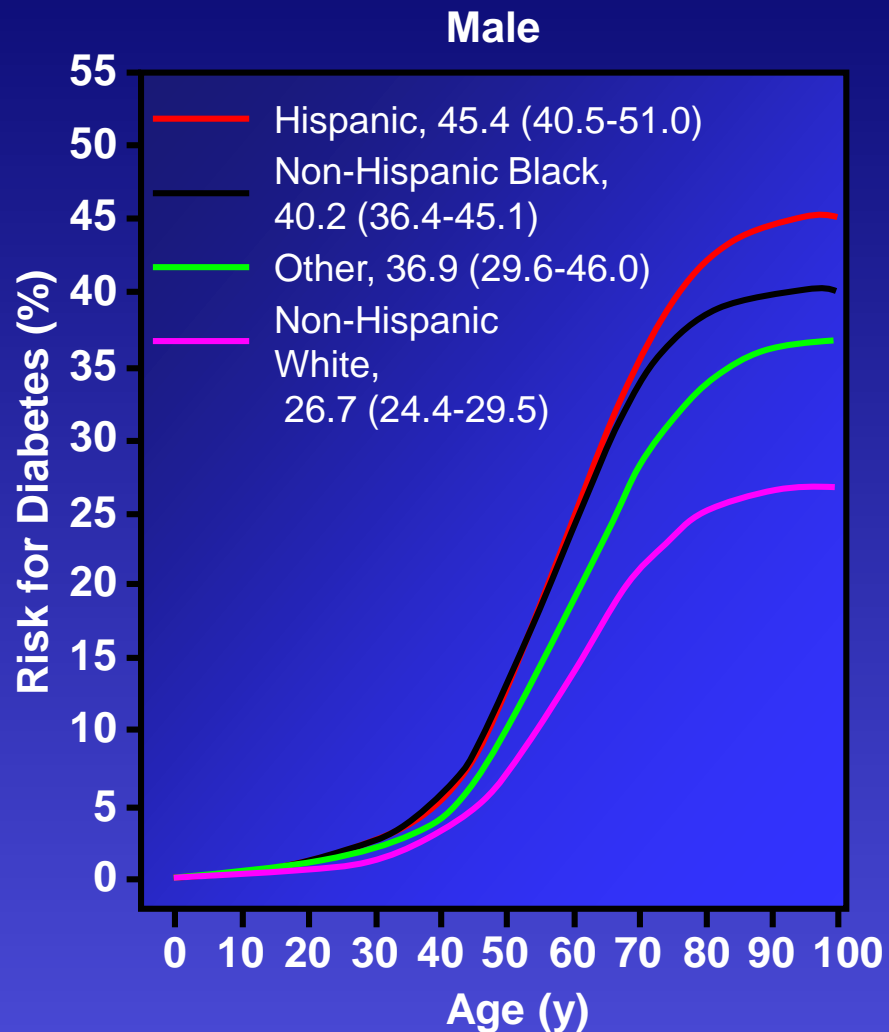
Access to Health Care: Health Insurance

- Hispanics are twice more likely than non-Hispanic whites to lack health insurance
- Despite employment at similar rates; Hispanics are disproportionately uninsured
- Hispanics are three times LESS likely to have a regular health care provider

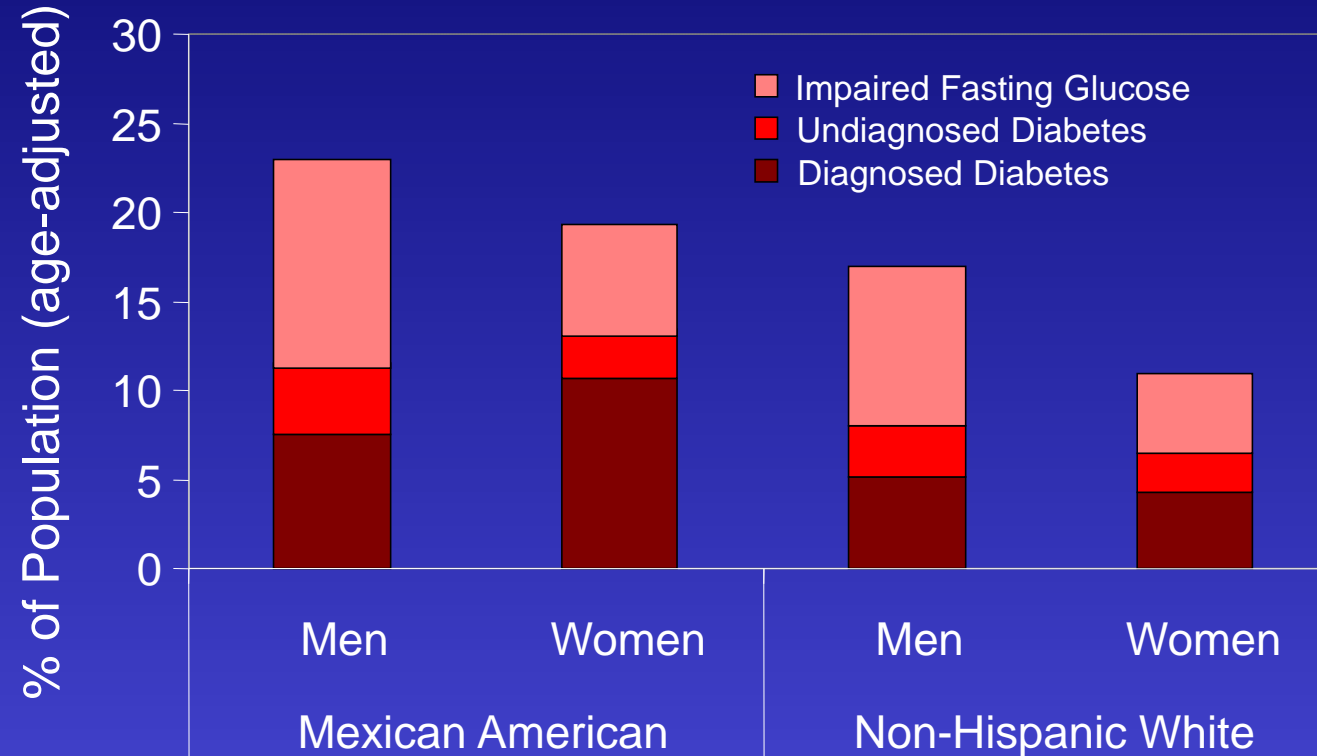


1. DeNavas-Walt C, Proctor BD, Smith JC. Income, Poverty, and Health Insurance Coverage in the United States: 2011.
2. Livingston G, Minushkin S, Cohn D. Hispanics and Health Care in the United States. Washington, DC; 2008.

Cumulative Lifetime Risk of Diabetes



Diabetes or Impaired Fasting Glucose: Latinos/Hispanics vs. Non-Hispanic Whites

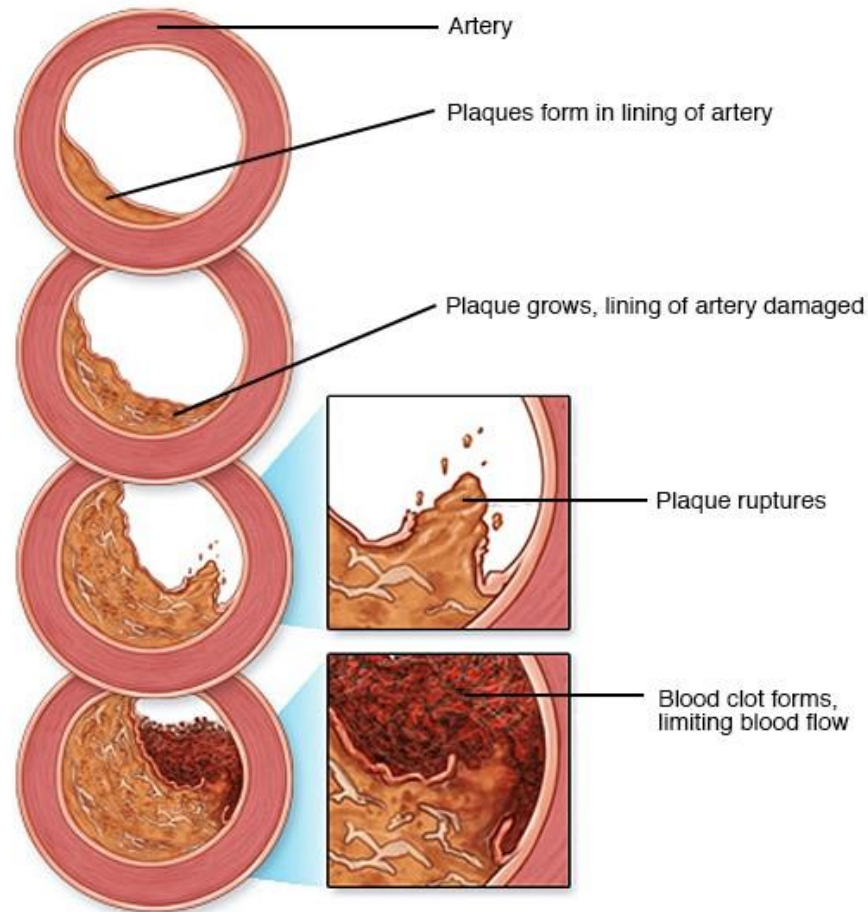
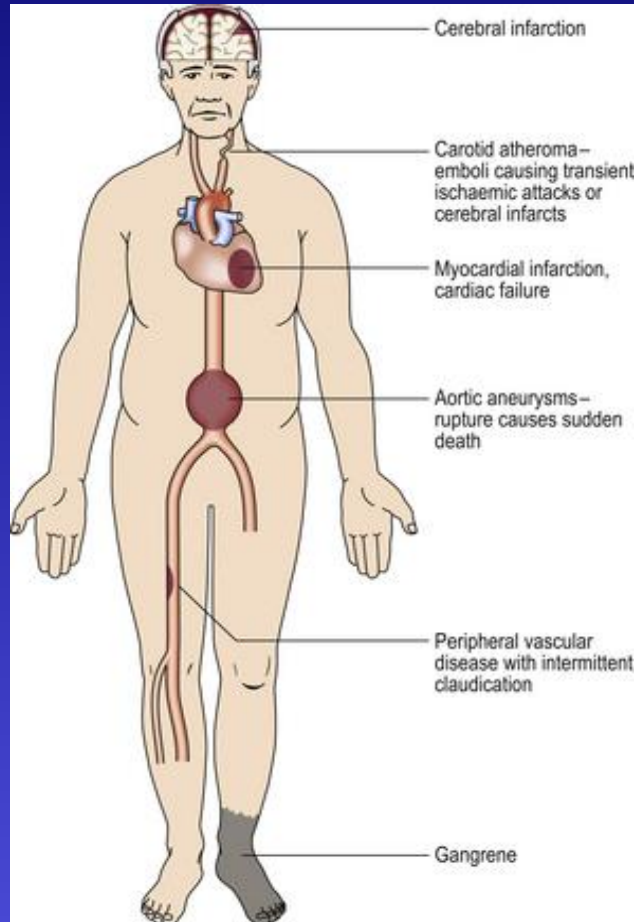


Prevalence Overweight and Obesity Among U.S. Adults* by Race / Ethnicity

	Overweight (BMI \geq 25) Prevalence (%)	Obesity (BMI \geq 30) Prevalence (%)
Racial / Ethnic Group	2011 to 2012	2011 to 2012
Black (non-Hispanic)	67.2	47.8
Mexican American	77.9	42.5
White (non-Hispanic)	67.2	32.6

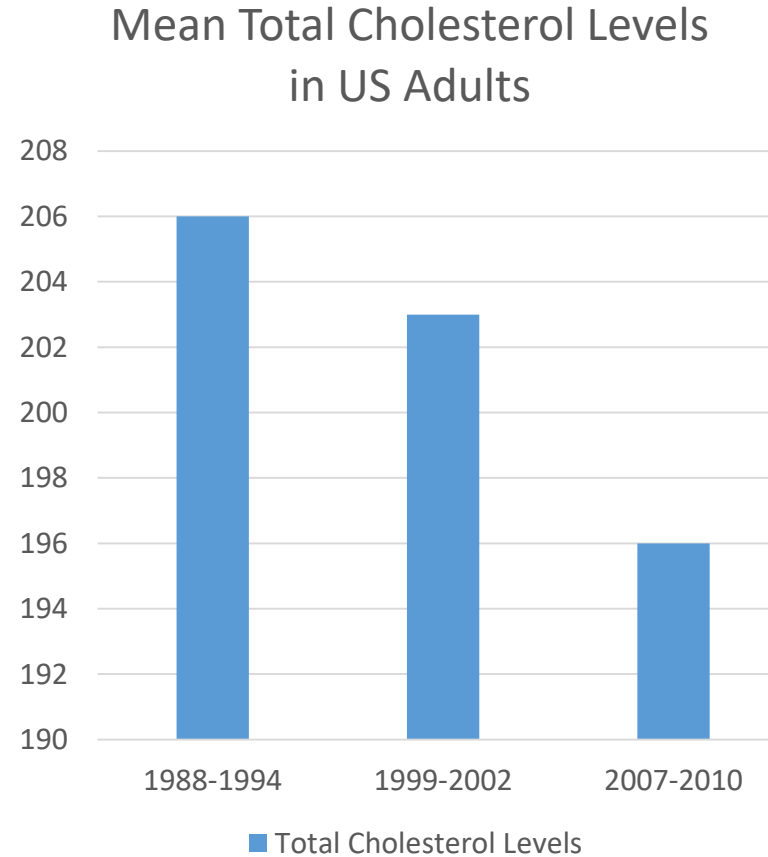
Ogden, et al. JAMA.2014;311:806-14
*Ages 20 and older

LDL "Bad"  **Cholesterol** + **HDL** "Good"  **Cholesterol** + **TRIGLYCERIDES/5** = **TOTAL CHOLESTEROL**



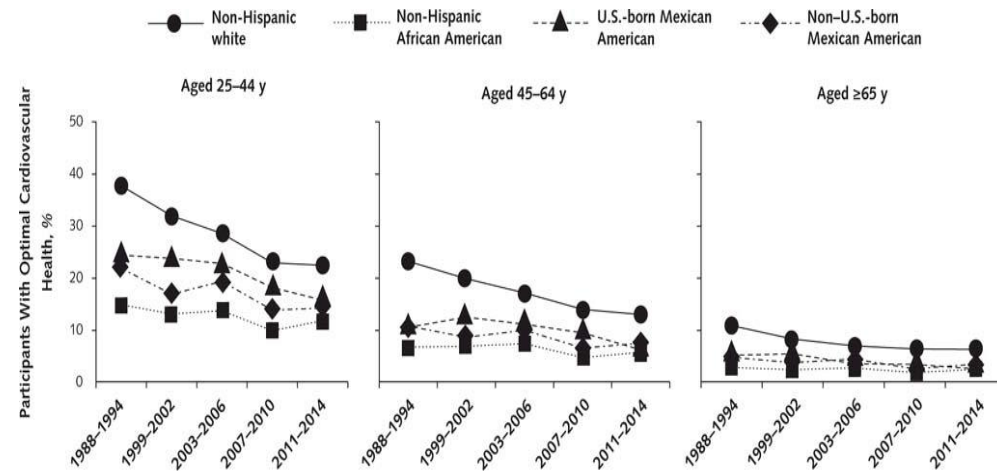
High Blood Cholesterol

- An estimated 28.5 million adults ≥ 20 years of age have serum TC levels ≥ 240 mg/dL (11.9% prevalence)
 - $\approx 5.8\%$ of adults have undiagnosed hypercholesterolemia
- Women had higher prevalence of high TC (13.0%) than males (10.6%)
- Crude mean total cholesterol level in adults is < 200 mg/dl
- From 1988 to 2014, mean serum TC for adults ≥ 20 years of age
 - Likely reflects greater uptake of cholesterol-lowering medications rather than changes in dietary patterns



Cardiovascular Health Disparities

- Lower CV health among minorities
 - 40% among whites,
 - 25% among Mexican Americans
 - 15% among African Americans
- Worsening CVH among whites has reduced persistent disparities in the heart health of minorities



Ann Intern Med. 2018;168(8):541-549.

Dyslipidemia and High Cholesterol among Hispanics/Latinos

Dyslipidemia Patterns among Hispanics/Latinos of Diverse Background in the United States



Carlos J. Rodríguez, MD, MPH,^a Martha L. Daviglus, MD, PhD,^b Katrina Swett, MS,^a Hector M. González, PhD,^c Linda C. Gallo, PhD,^d Sylvia Wassertheil-Smoller, PhD,^e Aida L. Giachello, PhD,^f Yanping Teng, PhD,^g Neil Schneiderman, PhD,^h Gregory A. Talavera, MD, MPH,ⁱ Robert C. Kaplan, PhD^e

- 2/3 (65%) of Hispanics had some form of Dyslipidemia
- 41% had low HDL-C
- 15% had high TGs
- 35% have high non-HDL-C

Rodriguez C., *American Journal of Medicine*. 2014 December; 127(12):1186–1194

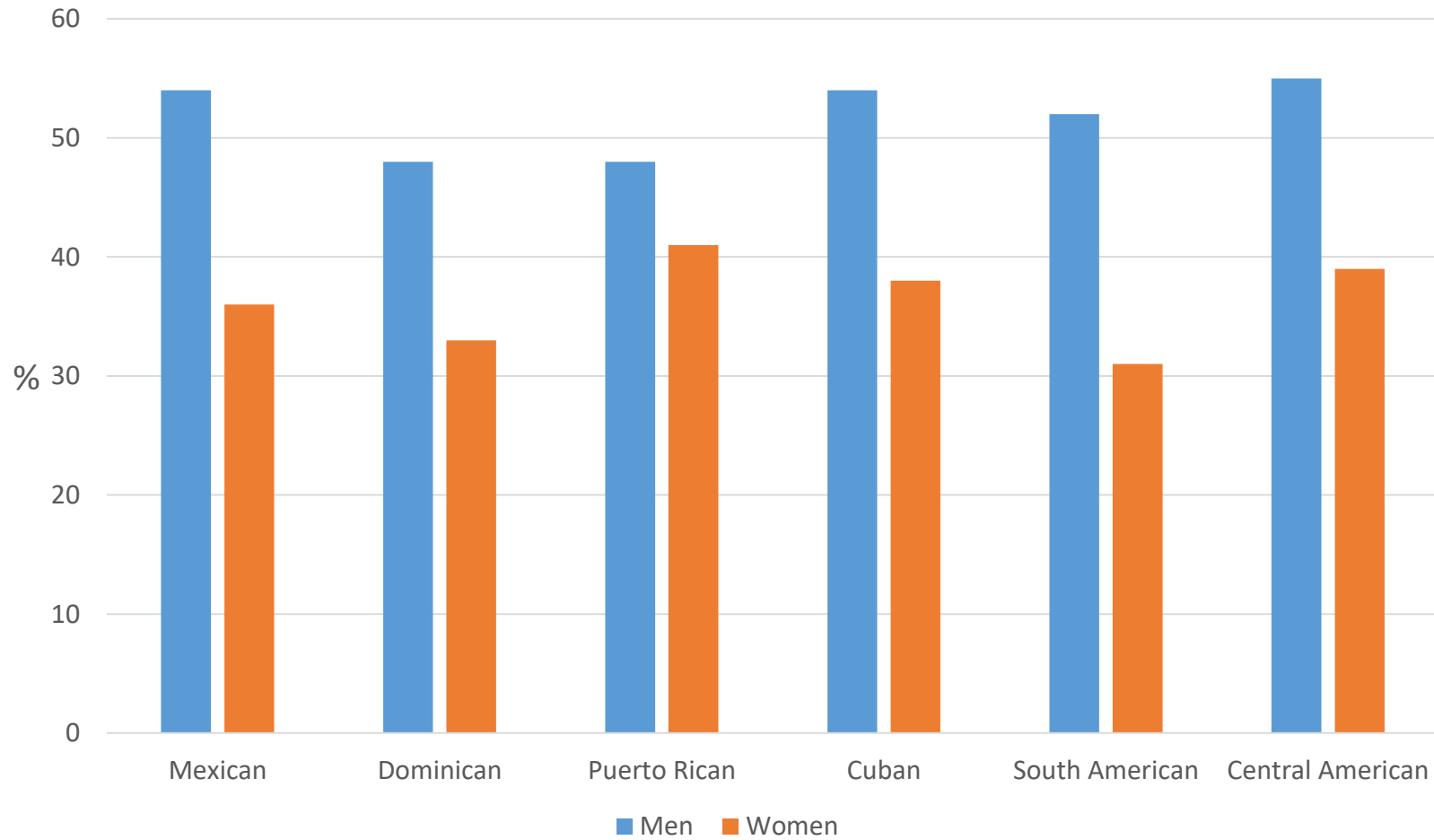
High Cholesterol Awareness, Treatment, and Control Among Hispanic/Latinos: Results From the Hispanic Community Health Study/Study of Latinos

Carlos J. Rodríguez, MD, MPH; Jianwen Cai, PhD; Katrina Swett, MS; Hector M. González, PhD; Gregory A. Talavera, MD; Lisa M. Wruck, PhD; Sylvia Wassertheil-Smoller, PhD; Donald Lloyd-Jones, MD, ScM; Robert Kaplan, PhD; Martha L. Daviglus, MD, PhD

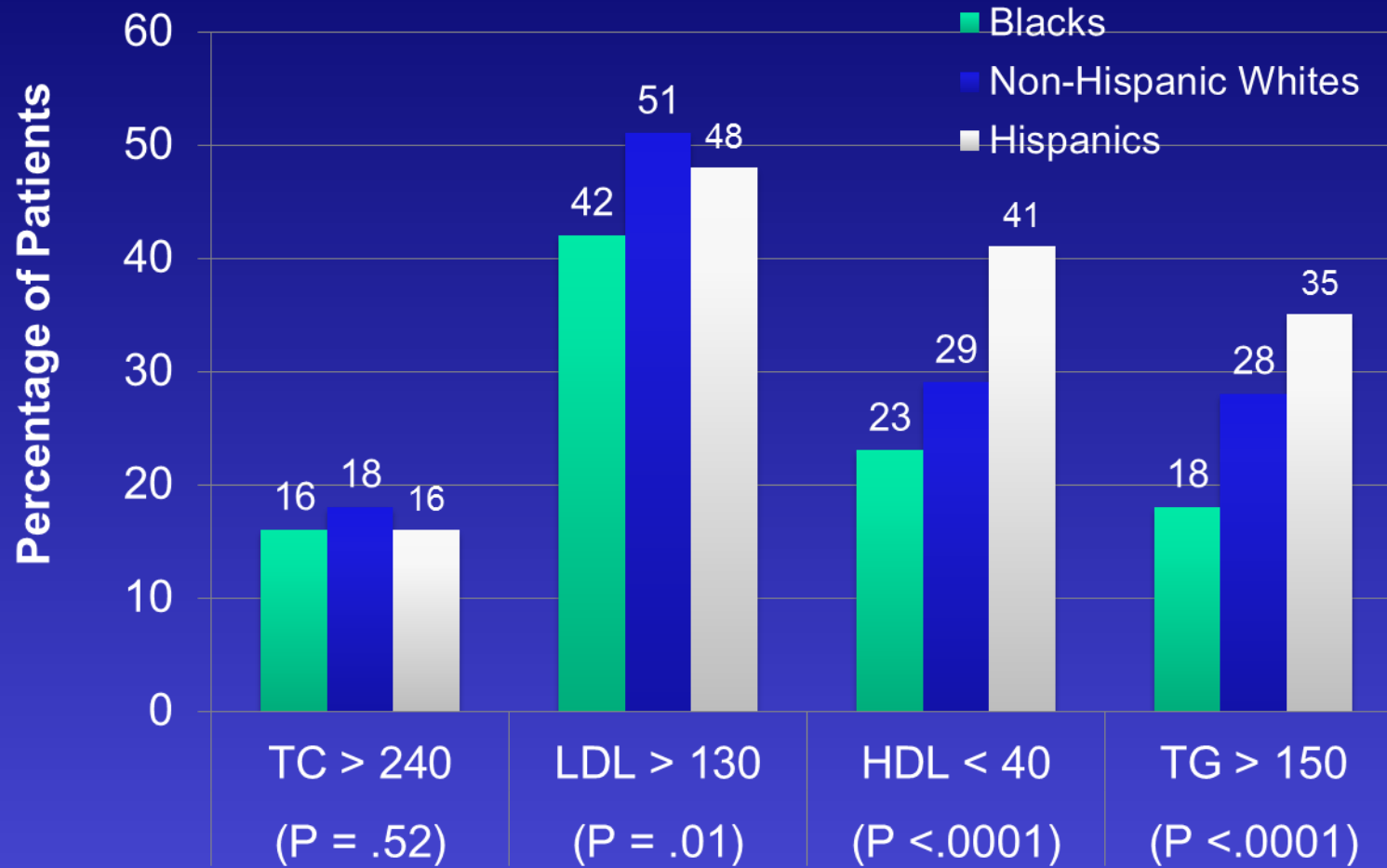
- Among Hispanics with Hypercholesterolemia
- 49% are not aware
- 30% are receiving treatment
- Of those receiving treatment, 64% are uncontrolled

Rodriguez C., *J Am Heart Assoc*. 2015 June; 4:e001867 doi: 10.1161/JAHA.115.001867

Hypercholesterolemia Prevalence by Hispanic Background (HCHS/SOL)



Dyslipidemia by Race-Ethnicity: NOMAS



Rodriguez C., *Circulation* 2006; 113: e379

Rodriguez C., *Am J Cardiol* 2002; 89:178

Ethnic Variations in Lipid Parameters in IRAS

	African Americans	Hispanics	Non-Hispanic Whites	P Value
# of patients (%)	462 (27)	546 (34)	612 (38)	
TC (mg/dL)	212.5	211.1	213.2	.782
LDL-C (mg/dL)	143.8	139.4	140.7	.410
HDL-C (mg/dL)	47.0	42.3	44.0	<.001
TG (mg/dL)	102.1	147.7	134.0	<.001
LDL size (Å)	262.1	257.6	259.2	<.001

TC= total cholesterol; LDL-C= low-density lipoprotein cholesterol; HDL-C= high-density lipoprotein cholesterol; TG= triglycerides.

Evolution of Cholesterol Guidelines: ATP III to 2013 ACC/AHA to 2018 ACC/AHA

- Outcome being prevented:
 - Then: Coronary heart disease
 - Now: Atherosclerotic cardiovascular disease (MI, angina, stroke, TIA, PAD)PROBLEM: Less data on Hispanics
- 10 year Risk Calculator
 - Then: Modified FRS
 - Now: Pooled Cohort Equation- ASCVD risk estimatorPROBLEM: Hispanics are not included in risk estimator
- Recommended Therapy:
 - Then: Any lipid drug; then later other lipid meds were added
 - Now: Statins alone; PCSK9PROBLEM: Poor screening, poor drug initiation among Hispanics
- Monitoring lipid levels
 - Then: no monitoring
 - Now: monitoring of LDLc after initiation of therapyPROBLEM: Less intensification of treatment and monitoring among Hispanics

**Primary Prevention:
Assess ASCVD Risk in Each Age Group
Emphasize Adherence to Healthy Lifestyle**

Age 0-19 y
Lifestyle to prevent or reduce ASCVD risk
Diagnosis of Familial Hypercholesterolemia → statin

Age 20-39 y
Estimate lifetime risk to encourage lifestyle to reduce ASCVD risk
Consider statin if family history premature ASCVD and LDL-C ≥160 mg/dL (≥4.1 mmol/L)

Age 40-75 y and LDL-C ≥70- <190 mg/dL (≥1.8- <4.9 mmol/L) without diabetes mellitus
10-year ASCVD risk percent begins risk discussion

LDL-C ≥190 mg/dL (≥4.9 mmol/L)
No risk assessment; High-intensity statin (Class I)

Diabetes mellitus and age 40-75 y
Moderate-intensity statin (Class I)

Diabetes mellitus and age 40-75 y
Risk assessment to consider high-intensity statin (Class IIa)

Age >75 y
Clinical assessment, Risk discussion

ASCVD Risk Enhancers:

- Family history of premature ASCVD
- Persistently elevated LDL-C ≥160 mg/dL (≥4.1 mmol/L)
- Chronic kidney disease
- Metabolic syndrome
- Conditions specific to women (e.g., preeclampsia, premature menopause)
- Inflammatory diseases (especially rheumatoid arthritis, psoriasis, HIV)
- Ethnicity (e.g., South Asian ancestry)

Lipid/Biomarkers:

- Persistently elevated triglycerides (≥175 mg/dL, (≥2.0 mmol/L))

In selected individuals if measured:

- hs-CRP ≥2.0 mg/L
- Lp(a) levels >50 mg/dL or >125 nmol/L
- apoB ≥130 mg/dL
- Ankle-brachial index (ABI) <0.9

<5%
"Low Risk"

Risk discussion:
Emphasize lifestyle to reduce risk factors (Class I)

5% - <7.5%
"Borderline Risk"

Risk discussion:
If risk enhancers present then risk discussion regarding moderate-intensity statin therapy (Class IIb)

≥7.5% - <20%
"Intermediate Risk"

Risk discussion:
If risk estimate + risk enhancers favor statin, initiate moderate-intensity statin to reduce LDL-C by 30% - 49% (Class I)

≥20%
"High Risk"

Risk discussion:
Initiate statin to reduce LDL-C ≥50% (Class I)

If risk decision is uncertain:
Consider measuring CAC in selected adults:
CAC = zero (lowers risk; consider no statin, unless diabetes, family history of premature CHD, or cigarette smoking are present)
CAC = 1-99 favors statin (especially after age 55)
CAC = 100+ and/or ≥75th percentile, initiate statin therapy

Summary Recommendations

1. **Increase Health Care Access:** affect morbidity and mortality across different populations
2. **Diversifying the Health Care Workforce:** facilitated by expanding the numbers of non-physician providers
3. **Extend Cultural Competency Training Programs**
4. **Diversity in Randomized Clinical Trials:** most are industry-sponsored and do not include Hispanics
5. **Costs of Medications Are Prohibitive:** Insurance companies and Pharma can form a coalition to address this
6. **EMR data** can be de-identified and aggregated
7. **Increase NIH Research That Is More Inclusive Of Minorities:** translational, clinical, population science



CAPT Richardae Araojo, PharmD, MS
Associate Commissioner for Minority Health
Director, FDA Office of Minority Health and Health Equity
NHMA Congressional Briefing, July 2019

Disclaimer

- This presentation represents the personal opinions of the speaker and does not necessarily represent the views or policies of FDA
- No conflicts of interest to declare

Overview



- Overview of the U.S. Food and Drug Administration's Office of Minority Health and Health Equity
- FDA Policy Strategies to Support Diverse Participation in Clinical Trials
- Communication & Outreach Strategies to Improve Diverse Participation in Clinical Trials and Cardiovascular Health

FDA Office of Minority Health and Health Equity (OMHHE)

Mission

To promote and protect the health of diverse populations through research and communication that addresses health disparities.

Vision

To create a world where health equity is a reality for all.



The Need for Diverse Participation

- Racial and ethnic minorities have been historically and remain under-represented in clinical trials
- Need representation to study the effects of medical products in the people who will ultimately use them
- Racial/ethnic minority populations may respond differently to medical products (ex: heart failure medications)
- To understand health disparities - diseases that occur more frequently or appear differently in diverse populations



Barriers to Diverse Participation

- Mistrust and distrust of the medical system due to historical abuses
- Lack of awareness on the patient's part
- Inadequate recruitment and retention efforts
- Lack of minority physicians, researchers, and clinical investigators
- Misunderstanding of racial/ethnic minorities' beliefs and values that contribute to their decision making process
- Lack of culturally/linguistically appropriate communication
- Perception that minorities do not want to participate
- Physicians/providers may not talk to their patients about clinical trials
- Enrollment criteria
- Return of Results
- Privacy concerns
- Lack of access

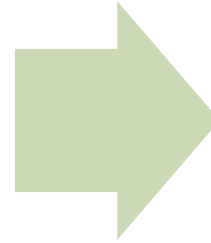
FDA Safety and Innovation Act (FDASIA) Section 907

Action Plan Priorities & Strategies



Priority One

Improve the completeness and quality of demographic subgroup data collection, reporting and analysis
(Quality)

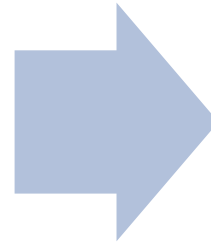


FDA Guidance Documents

Collection of Race and Ethnicity Data in Clinical Trials
Evaluation and Reporting of Age, Race, and Ethnicity Specific Data in Medical Device Clinical Studies

Priority Two

Identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation
(Participation)

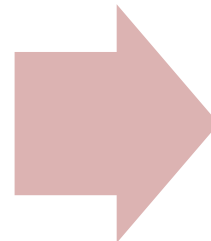


Public Meetings

Tools to support diverse clinical trial participation

Priority Three

Make demographic subgroup data more available and transparent
(Transparency)



Drug Trials Snapshots

(Center for Drug Evaluation and Research)

Drug Trials Snapshots: Summaries (2016-2018)



	WOMEN	BLACK or AFRICAN AMERICAN	ASIAN	WHITE	OTHER*	AGE 65 AND OLDER
2016	48%	7%	11%	76%	7%	21%

	WOMEN	BLACK or AFRICAN AMERICAN	ASIAN	WHITE	HISPANIC	AGE 65 AND OLDER
2017	55%	7%	11%	77%	14%	32%

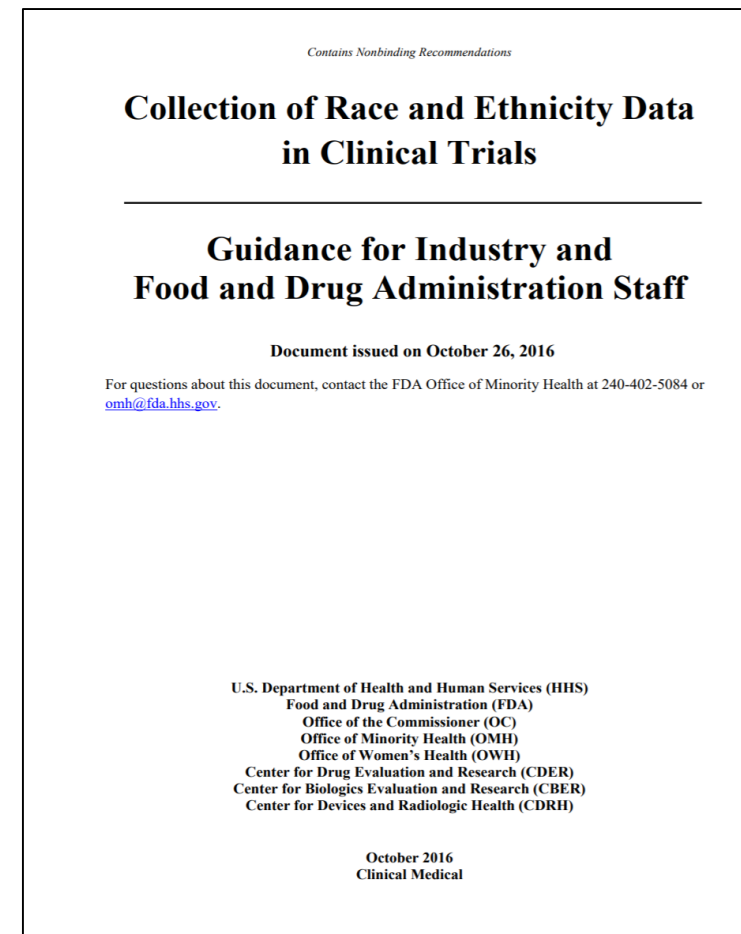
	WOMEN	BLACK or AFRICAN AMERICAN	ASIAN	WHITE	HISPANIC	AGE 65 AND OLDER
2018	56%	11%	10%	69%	14%	15%

* The percentages of the categories “American Indian or Alaska Native (AI/AN),” “Native Hawaiian or Other Pacific Islander (NH/OPI),” and “Unknown/Unreported” were small enough that we combined them into the “Other” category for the purposes of this review.

**These particular subgroups were calculated as part of a Geriatrics Report and are not a regular feature of the Drug Trial Snapshots

Clinically Relevant Enrollment

- FDA expectations are that sponsors enroll participants who **reflect the demographics for clinically relevant populations** with regard to age, gender, race, and ethnicity
- **A plan to address inclusion of clinically relevant subpopulations** should be submitted for discussion to the Agency at the earliest phase of development and, for drugs and biologics, no later than the end of the phase 2 meeting



Ongoing FDA Efforts



- FDA Reauthorization Act of 2017
 - CDER/CBER Draft Guidance for Industry on Enhancing the Diversity of Clinical Trial Populations - Eligibility Criteria, Enrollment Practices, and Trial Designs (June 2019)
- 21st Century Cures Act
 - Patient Engagement Efforts

Diversity in Clinical Trials Campaign



Videos

Newsletters & E-alerts

Webpage

Stakeholder Collaboration

Podcasts

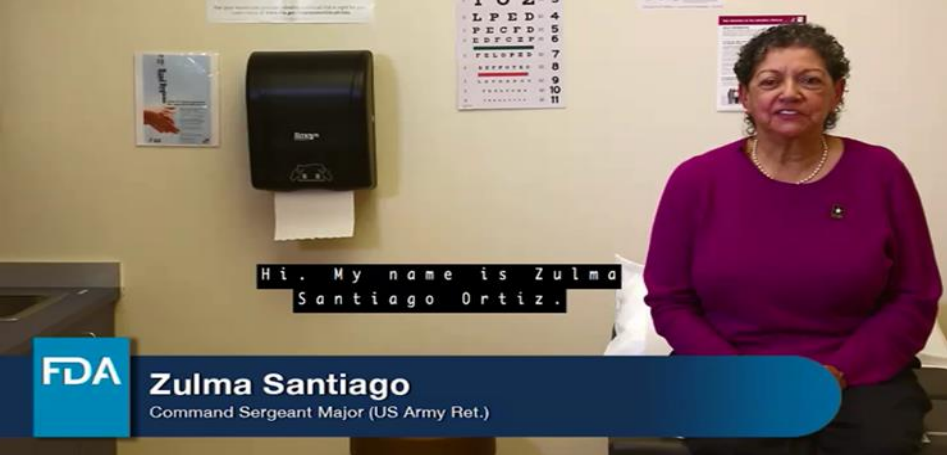
Social Media

Communications Toolkit

Graphics



Latinos Can Make a Difference in Clinical Trials



Hi. My name is Zulma Santiago Ortiz.



Zulma Santiago
Command Sergeant Major (US Army Ret.)



Hi. My name is Quinyardo.



Quinyardo McClain
Staff Sergeant (US Army Ret.)



Diverse Participation in Clinical Trials Videos and Podcast

Highlights the importance of racial and ethnic minority participation in clinical trials.

Each video features a different theme and key message.

Diversity in Clinical Trials Resources



Minorities In Clinical Trials

FACT SHEET

Clinical trials are research studies that determine whether medical products like medicines, vaccines, or devices are safe and effective. These studies may show which medical approaches work best for certain illnesses or groups of people.

Office of Minority Health

4 things you should know about The importance of minority

Become a Research Volunteer

Research *needs* you
It's **YOUR** decision

Las minorías en los estudios clínicos

HOJA INFORMATIVA

Los estudios clínicos son estudios de investigación que determinan si los productos médicos como medicamentos, vacunas o dispositivos son seguros y eficaces. Estos estudios pueden demostrar qué enfoques médicos funcionan mejor para ciertas enfermedades o grupos de personas.

Oficina de Salud de las Minorías

4 Cosas que debe saber acerca de los estudios clínicos

- Los estudios clínicos son estudios de investigación realizados con personas— están diseñados para responder preguntas específicas de investigación acerca de productos o procedimientos médicos. Los investigadores deben seguir protocolos específicos y las pautas de seguridad de la FDA para realizar cada estudio de la manera más segura posible.
- La participación siempre es voluntaria— y usted puede dejar el estudio cuando quiera.
- Los estudios clínicos con frecuencia necesitan voluntarios saludables para ayudar a responder preguntas de investigación.
- La FDA no realiza estudios clínicos: la FDA trabaja con empresas que desarrollan productos médicos para proteger a los participantes y revisar los resultados para asegurar que el producto médico sea seguro y eficiente.

La importancia de la participación de las minorías en los estudios clínicos

Los participantes de estudios clínicos deben representar a los pacientes que utilizarán los productos médicos. Esto con frecuencia no es el caso— las minorías raciales y

étnicos están subrepresentados en los estudios clínicos. Esto es una preocupación porque las personas de diferentes edades, razas y etnias pueden reaccionar de manera diferente a los productos médicos. Estamos comprometidos en trabajar con las empresas para cambiar esta situación. Participar en un estudio clínico puede ser una buena decisión para usted si:

- Usted y su médico creen que los tratamientos actuales no son buenas opciones y un estudio clínico ofrece alternativas adicionales.
- Usted quiere ayudar a asegurar que los beneficios y riesgos de los productos médicos se estudien en los pacientes de grupos diversos que los necesitan.
- Usted quiere ayudar a los investigadores a encontrar mejores maneras de combatir enfermedades.

Si piensa que un estudio clínico puede ser adecuado para usted, hable con su médico. También puede buscar los estudios clínicos a través de nuestra base de datos en línea www.ClinicalTrials.gov.

Si quiere conocer más acerca de un medicamento aprobado recientemente que pueda estar tomando, visite las **Fichas de Ensayos Farmacológicos (Drug Trials Snapshot)** — una base de datos que le proporciona información sobre quiénes participan en un estudio para la aprobación de medicamentos. Puede encontrar más información en www.FDA.gov/DrugTrialsSnapshot.

Para obtener más información sobre la salud de las minorías, vaya a www.fda.gov/minorityhealth. Para ver videos y ver una lista de preguntas para hacer a los investigadores, vaya a www.hhs.gov/about-research-participation.

La FDA es una agencia dentro del Departamento de Salud y Servicios Humanos de EE. UU. que protege la salud pública al asegurar la seguridad y eficacia de los medicamentos humanos y veterinarios, vacunas y otros productos biológicos para uso humano y dispositivos médicos. La agencia también es responsable de la seguridad y profesión del suministro de alimentos, cosméticos, suplementos nutricionales y productos que emiten radiación electrónica y de la regulación de productos de tabaco de la nación.

Participe en una investigación como voluntario(a)

La investigación necesita de **USTED**.
Es **SU** decisión.

Services

FDA
Departamento de Salud y Servicios Humanos de los Estados Unidos
Administración de Alimentos y Medicamentos (FDA)
Oficina de Salud de las Minorías

Minorities in Clinical Trials

Clinical trials are research studies that determine whether medical products like medicines, vaccines, or devices are safe and effective for people. Participants in clinical trials should represent the patients that will be using the medical products, though this is often not the case. Racial and ethnic minorities are underrepresented in clinical trials. This is a concern because people of different ages, races, and ethnicities may react differently to medical products. If you think a clinical trial may be right for you, talk to your doctor.

You can also search for clinical trials on ClinicalTrials.gov—an online database of clinical trials sponsored by FDA and the National Institutes of Health (NIH).

Watch this webinar for help navigating ClinicalTrials.gov

Search ClinicalTrials.gov! Enter a word or phrase, such as the name of a medical condition or intervention. Example: Cancer AND Los Angeles

Clinical Trial Resources

- About Research Participation
- Fact Sheet: Minorities in Clinical Trials [Spanish]
- Brochure: Become a Research Volunteer! [Spanish]
- Webinar: Get to Know ClinicalTrials.gov! [Slides]
- Clinical Trial Diversity Toolkit
- Collection of Race and Ethnicity Data in Clinical Trials- Guidance for Industry and FDA Staff
- FDASIA Section 907: Inclusion of Demographic Subgroups in Clinical Trials
- Women in Clinical Trials
- Drug Trials Snapshots
- Inside Clinical Trials: Testing Medical Products in People
- NIH Infographic- Why do researchers do different types of clinical studies?
- Clinical Trials: What Patients Need to Know

Consumer Updates

- FDA Encourages More Participation, Diversity in Clinical Trials [Spanish]
- Who's in Clinical Trials? [Spanish]
- Would Your Child Benefit from a Clinical Trial? [Spanish]

Journal Publications

- Strategies for Increased Inclusion of Racial and Ethnic Minorities in Clinical Trials

FDA Voices, Interviews, and Outreach

- Mission Possible: Moving the Needle Forward to Advance Health Equity



Cardiovascular Health



- Research & Collaboration
 - Intramural
 - Extramural/Centers of Excellence in Regulatory Science and Innovation (CERSIs)



Follow the ABCS

Reduce your risk for heart disease and stroke

#LoveMyHeart

Siga el ABCS

Reduzca su riesgo de sufrir afecciones cardíacas y derrames cerebrales

#LoveMyHeart

Outreach & Communication

- Culturally and linguistically competent education and resources
- Partnerships and Collaborations

A B C S

Aspirin Therapy <small>Use as appropriate</small>	<small>Control your high</small> Blood Pressure
<small>Manage your high</small> Cholesterol	<small>Don't</small> Smoke

www.fda.gov/healthequity
 FDA Office of Minority Health and Health Equity

A B C S

<small>Use</small> Aspirina <small>como terapia según sea indicado</small>	<small>Mantenga una</small> Buena <small>presión arterial</small>
<small>Controle su</small> Colesterol	<small>No</small> Fume

www.fda.gov/healthequity
 Oficina de Salud de las Minorías y Equidad en la Salud de la FDA

Stakeholder Engagement & Collaboration



- The Alliance of Multicultural Physicians
- National Minority Cardiovascular Alliance
- Puerto Rico Clinical Research Summit (May 2018 & 2019)
 - Co-organized by FDA OMHHE, Puerto Rico Consortium for Clinical Investigation, Yale University, Universidad de Puerto Rico, Universidad Central del Caribe, Ponce Health Sciences University, and Puerto Rico Science, Technology & Research Trust
- Yale and FDA OMHHE Memorandum of Understanding
 - To advance the Yale Cultural Ambassadors Program and engagement of community partners to increase diverse participation in clinical research

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healthequity@fda.hhs.gov



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National Hispanic Medical Association

High Cholesterol in Our Communities: Strategies for a Healthier Future

Co-Hosts:



Alliance for
Patient Access



National Minority
Cardiovascular Alliance