



Promoting Clinical Trial Diversity for Racial and Ethnic Minority Populations Living with Diabetes

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Agenda

- Introduction to the American Diabetes Association
- Diabetes Disparities
- The Role of Clinical Trials in Health Equity
- ADA Initiatives
- Questions & Answers

Introduction to the ADA

- The American Diabetes Association (ADA) is the nation's leading voluntary health organization fighting to bend the curve on the diabetes epidemic and help people living with diabetes thrive.
- For over 80 years, the ADA has been driving discovery and research to treat, manage and prevent diabetes, while working relentlessly for a cure.

Our mission

- To prevent and cure diabetes and to improve the lives of all people affected by diabetes.

Our focus



**Increase
risk
awareness**



**Fund
innovative
research**



**Improve
medical
care**



**Engage
the
community**

Diabetes: a public health crisis

PREDIABETES



What is prediabetes?

Prediabetes is when your blood glucose (also called blood sugar) levels are higher than normal but aren't high enough to be diagnosed diabetes.



96 MILLION

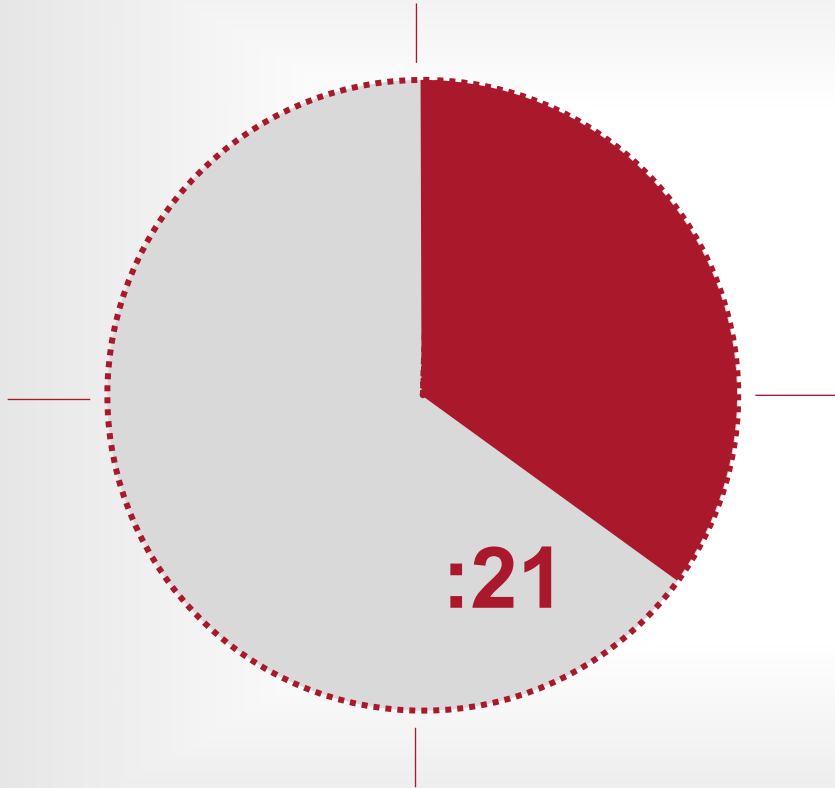
American adults have
prediabetes

Source: CDC National Diabetes
Statistics Report



8 in 10

Americans with
prediabetes don't know
they have it



EVERY 21 SECONDS

Someone in the U.S. is diagnosed with diabetes.

Source: CDC. National Diabetes Statistics Report, 2017



Why is diabetes serious?

The abnormal blood sugar levels found with diabetes—as well as the abnormal blood pressure and cholesterol that often accompany it—damages organs and nerves in the body and can lead to serious health consequences and risk of early death.



Why is insulin important?

Insulin, made by beta cells in the pancreas, is a hormone that's essential in controlling blood sugar. Insufficient insulin is common to all types of diabetes.

Primary types of diabetes

TYPE 1

Body destroys its insulin-producing cells

TYPE 2

Body unable to make enough insulin to meet its needs

GESTATIONAL

Body cannot make and use the extra insulin it needs for pregnancy

What are the symptoms of diabetes?

Symptoms include:

Urinating often

Feeling very thirsty

Feeling very hungry—even though you are eating

Extreme fatigue

Blurry vision

Cuts/bruises that are slow to heal

Weight loss—even though you are eating more (type 1)

Tingling, pain, or numbness in the hands/feet (type 2)

**Diabetes
increases risk
for many serious
health problems**



Heart disease



Stroke



Kidney failure



Blindness



Amputation

The staggering costs of diabetes

- People with diabetes account for \$1 of every \$4 spent on health care in the U.S.
- Diagnosed diabetes costs Americans an estimated \$327 billion annually.
- Health care costs for Americans with diabetes are 2.5 times higher than for those without diabetes.

Sources:

- <https://hpi.georgetown.edu/rxdrugs/>
- <https://www.diabetes.org/resources/statistics/cost-diabetes>
- <https://connect.asbms.org/07-2018/american-diabetes-association-report-diabetes-is-the-most-expensive-chronic-disease-in-america>
- <https://diabetesjournals.org/care/article/35/11/2243/30910/Health-Insurance-Coverage-Among-People-With-and>
- Casagrande, S. et al. Health Insurance Coverage Among People With and Without Diabetes in the U.S. Adult Population. *Diabetes Care* 1 November 2012; 35 (11): 2243–2249. <https://doi.org/10.2337/dc12-0257>

Diabetes Disparities

Compared to non-Hispanic whites, American Indians and Alaska Natives are twice as likely to be diagnosed with diabetes.

Compared to non-Hispanic whites, Blacks and Hispanics are more than 50% more likely to be diagnosed with diabetes.

Compared to non-Hispanic whites, Asian Americans are 10% more likely to be diagnosed with diabetes.

Source:

CDC 2021. Summary Health Statistics.

David C. Radley et al., *Achieving Racial and Ethnic Equity in U.S. Health Care: A Scorecard of State Performance* (Commonwealth Fund, Nov. 2021). <https://doi.org/10.26099/ggmq-mm33>

Diabetes disparities for African Americans

- Diabetes and other related chronic conditions are nearly twice as common among African Americans than white Americans.
- African Americans are 2.3 times more likely to die from diabetes than whites.
- Every four minutes in America, a limb is amputated due to diabetes. African Americans experience amputation at a rate twice as high as non-minorities.

Source: Centers for Disease Control and Prevention. National Diabetes Statistics Report website. <https://www.cdc.gov/diabetes/data/statistics-report/index.html>. Accessed February 4, 2022

PRIMARY FACTORS FUELING THE CRISIS

SOCIAL DETERMINANTS



Poverty; lack of access to adequate health care, health insurance, nutritious foods, outdoor space and medications

BIOLOGICAL FACTORS



Age, genetics, and ethnicity

LIFESTYLE FACTORS



Unhealthy food and physical inactivity leading to obesity

Impact of COVID-19

- One in four insulin-dependent Americans report rationing their insulin supply due to financial difficulty.
- Based on a December 2020 national ADA survey of people with diabetes:
 - 12% of people with diabetes who had health insurance experienced a disruption in insurance coverage since the start of the pandemic.
 - For those who lost coverage during COVID-19, 50% reported they were not able to regain coverage.

Sources:

Herkert D, Vijayakumar P, Luo J, et al. Cost-Related Insulin Underuse Among Patients With Diabetes. *JAMA Intern Med.* 2019;179(1):112–114.

doi:10.1001/jamainternmed.2018.5008

Thrivable and the American Diabetes Association. (2020). *Effects of the COVID-19 Pandemic on People with Diabetes.*

<https://www.diabetes.org/sites/default/files/2020-12/ADA%20Thrivable%20Data%20Deck.pdf>

Our Initiatives

ADA and Health Equity Now

- The COVID-19 pandemic and instances of racial injustice highlight a core problem: health inequity. This inequity worsens outcomes and increases risk for diabetes patients, and it undermines underserved communities.
- In 2020, the ADA created Health Equity Now to ensure that the 122 million Americans living with diabetes and prediabetes get equal access to healthcare, regardless of factors like race, income, and gender.

Health Equity Now



Cure



Cuisine



Care



Connect



Cost

The Role of Clinical Trials in Health Equity

- While Americans of color are nearly twice as likely to have diabetes as whites, minority participation in diabetes clinical trials is low.
- Low diversity extends to both clinical trial staff and trial participants.
- Because diabetes products often serve large minority populations, there can be insufficient understanding of how the products affect the populations that use them.

FDA Drug Trial Snapshot

African Americans are 50% more likely to be diagnosed with diabetes than non-Hispanic whites, yet they are consistently underrepresented in diabetes clinical trials.

Drug	White	Black	Asian	Hispanic or Latino
Adlyxin	70%	3%	21%	25%
Ozempic	70%	6%	11%	16%
Steglatro	77%	5%	13%	24%
Ryzodeg (only T2DM)	47%	4%	48%	7%
Tresiba (only T2DM)	70%	7%	21%	12%

SOURCE: 2015-2017 FDA drug trials snapshots: <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots>

Diversity in Clinical Trials: The Current Challenge

- The lack of diversity in clinical trials is a multifaceted issue:
 - Medical mistrust
 - Participation barriers
 - Homogenous populations of physicians and others conducting clinical trials

Medical Mistrust

- Historical mistrust
- Current mistrust
- Investigator bias

Participation Barriers

- Lack of access to transportation
- Limited Health and Research Literacy
- Lack of knowledge about ongoing clinical trials
- Lost wages

Homogeneous Healthcare Providers

- Lack of diversity among research leaders and trainees
- Disparities in research funding

Scientific Sessions

- The ADA's annual Scientific Sessions attracts attendees from all 50 states and more than 100 countries, all with one goal: sharing research advances to improve the lives of people with and affected by diabetes.
- The **2021 ADA Virtual Scientific Sessions** offered researchers and health care professionals the unique opportunity to share ideas and learn about the significant advances and breakthroughs in diabetes.
- Previous sessions have highlighted diabetes disparities and the importance of clinical trial diversity.
- Our 82nd Scientific Session will be in June.

Research Awards

- ADA has a sustained commitment towards minority investigators and research prioritizing underrepresented populations.
- Since 2005, ADA has awarded 190 research grants, a total investment of over 11 million dollars.

minority-focused awards

Undergraduate

Postdoctoral

Junior Faculty

Roundtable on Promoting Diversity in Diabetes Clinical Trials

- Best practices, current clinical diversity recommendations, and policies will be reviewed.
- Consensus recommendations that advance best practices and policy changes that will lead to increased diversity in diabetes-focused clinical trials will be developed.

Diversity in Clinical Trials: our current interests

Our current clinical trial interests

- Better collection of subgroup data
- Social determinants of health (SDOH) barriers that prevent minorities from participating in clinical trials
- Medical system distrust



Questions & Answers

Thank you!

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Connected for Life