New Strategies for Diabetes Management: Making it Work for the Highest-Risk Groups

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Objectives from Pharmacists
Upon completion of this activity pharmacists will be able to:

a.) Understand the shift from a glucose-centric to a cardiometabolic focus for diabetes outcomes in T2D

b.) Design effective treatment approaches for high-risk patients with diabetes and comorbidities

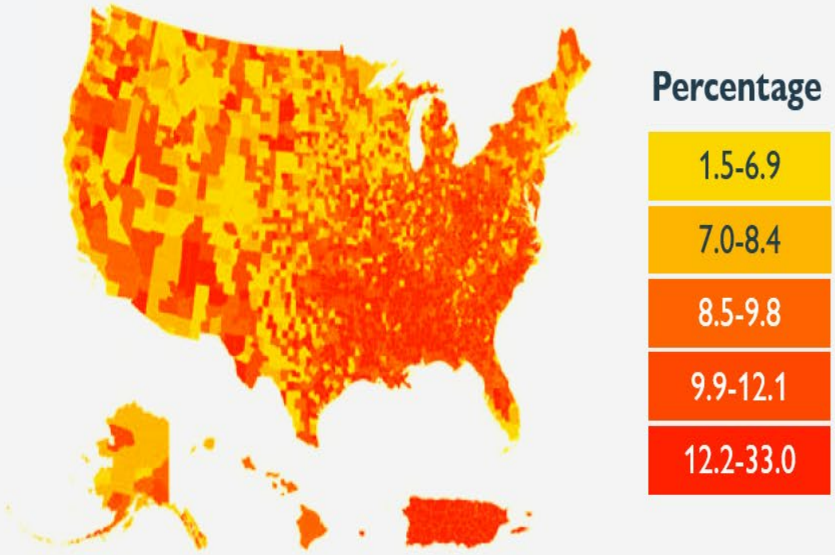
c.) List the limitations of current clinical practice guidelines for Diabetes as they apply to high-risk minorities

d.) Design an integrated approach to diabetes education/ management optimizing new diabetes-related technologies, and community-based resources

Objectives from Technicians
Upon completion of this activity, technicians will be able to:

- Discuss the effective treatment approach for high-risk patients with diabetes and kidney disease.
- List the reasons why clinicians need to focus on the management of Hypertension and Lifestyle Changes in African Americans.
- Explain the importance of medication adherence in patients that have type 2 diabetes.

THE PREVALENCE OF T2DM IS RAPIDLY INCREASING IN THE UNITED STATES



2016

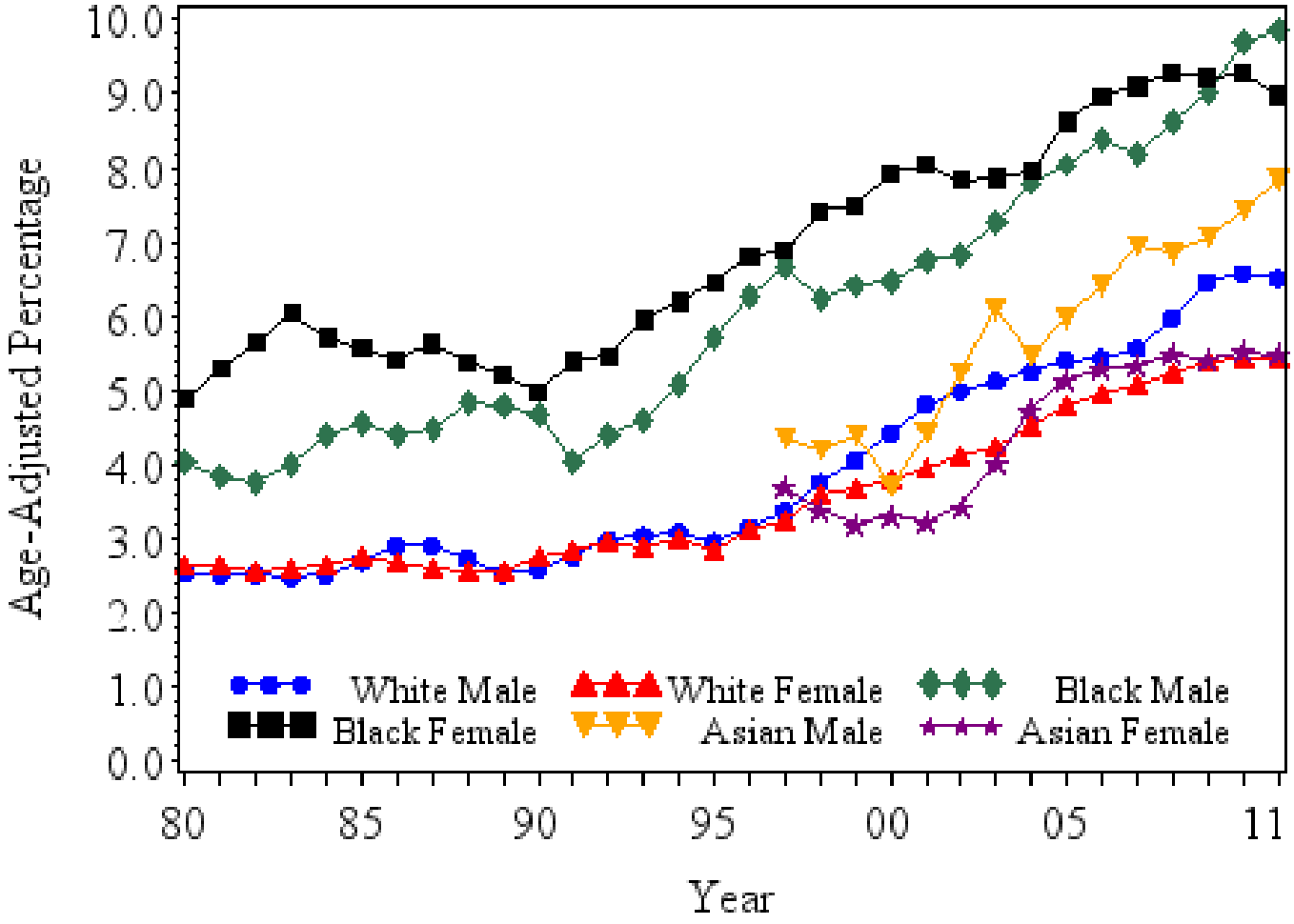
Age-adjusted, county-level prevalence of diagnosed diabetes among adults aged 20 years or older[1]

90%-95% of people with diabetes have T2DM[1]

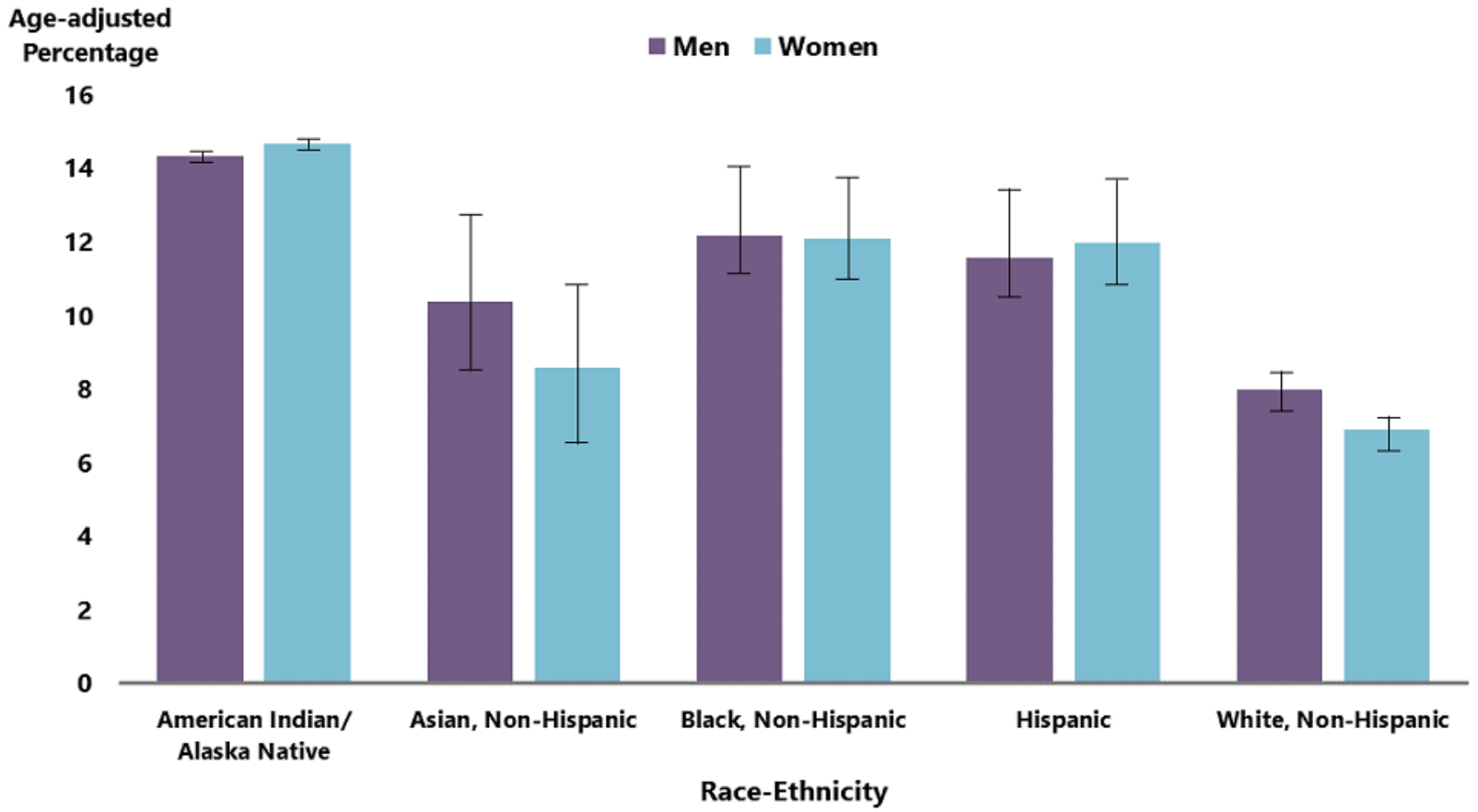
2022[1]	2030[2,3]
37.3 million people had diabetes	**~55 million** people will have diabetes
11.3% of US population	**15.5%** of US population

Source: Centers for Disease Control and Prevention. Reference to specific commercial products, manufacturers, companies, or trademarks does not constitute its endorsement or recommendation by the U.S. Government, Department of Health and Human Services, or Centers for Disease Control and Prevention. Material is available on the agency website for no charge. 1. Centers for Disease Control and Prevention. National Diabetes Statistics Report. https://www.cdc.gov/diabetes/data/statistics-report/index.html. Accessed October 21, 2022. 2. Rowley WR, et al. *Popul Health Manag*. 2017;20:6-12. 3. Vespa J, et al. *Curr Popul Rep Popul Estim Proj*. 2018;(P25-1144):1-15.

Diabetes in the United States, 1980-2011



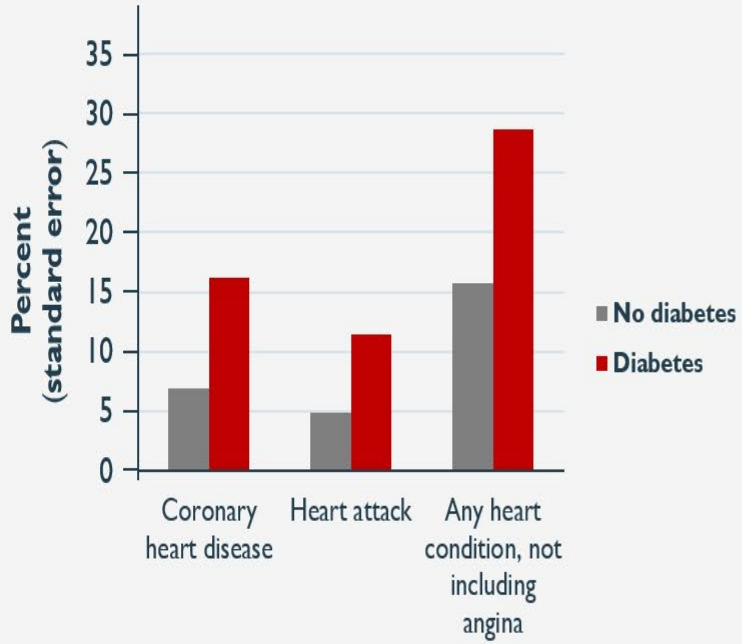
Age-Adjusted Estimated Prevalence of Diagnosed Diabetes by Race/Ethnicity Group and Sex for Adults Ages 18 and Older, US, 2017-2018



CDC, National Diabetes Statistics Report, 2021

PRIORITIZING CV RISK IN PATIENTS WITH T2DM IS ESSENTIAL[1]

Prevalence of history of CV disease among adults age ≥18 years, by diabetes status[2]
(NHIS, US, 2009-2010)



Adults with diabetes are

2×

more likely to die from CV disease than those without[3]

CV disease: the group of disorders of heart and blood vessels, including hypertension, coronary heart disease, cerebrovascular disease, and peripheral vascular disease.[4]

NHIS, National Health Interview Survey.

1. American Diabetes Association. *Diabetes Care*. 2023;46(suppl 1):S1-S291. 2. Barrett-Connor E, et al. In: Cowie C, et al, eds. *Diabetes in America*. 3rd ed. Bethesda, MD: NIDDK; 2018:18-1-18-30. NIH Pub No. 17-1468. 3. American Heart Association. Cardiovascular disease and diabetes. https://www.heart.org/en/health-topics/diabetes/diabetes-complications-and-risks/cardiovascular-disease--diabetes. Accessed October 26, 2022. 4. World Health Organization. Cardiovascular disease. June 11, 2021. https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds). Accessed October 26, 2022.

Health equity for people of color living with diabetes

>55% of Americans with diabetes are either Black, Native American, Hispanic or Asian.

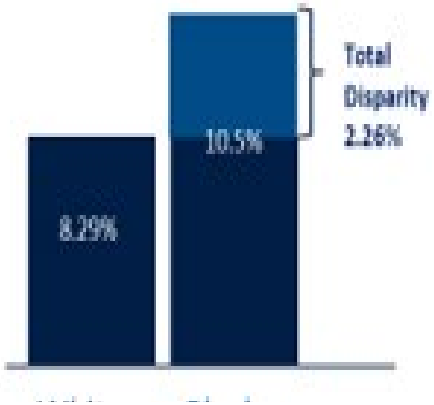
People of Color with type 1 diabetes are less likely to use diabetes-related technology as compared to White Americans.

Compared to White Americans

3x Black Americans are 3x less likely to use an insulin pump.

2x Black & Hispanic Americans are 2x less likely to use a CGM.

Higher A1C reported when compared Black vs. White individuals due to technology



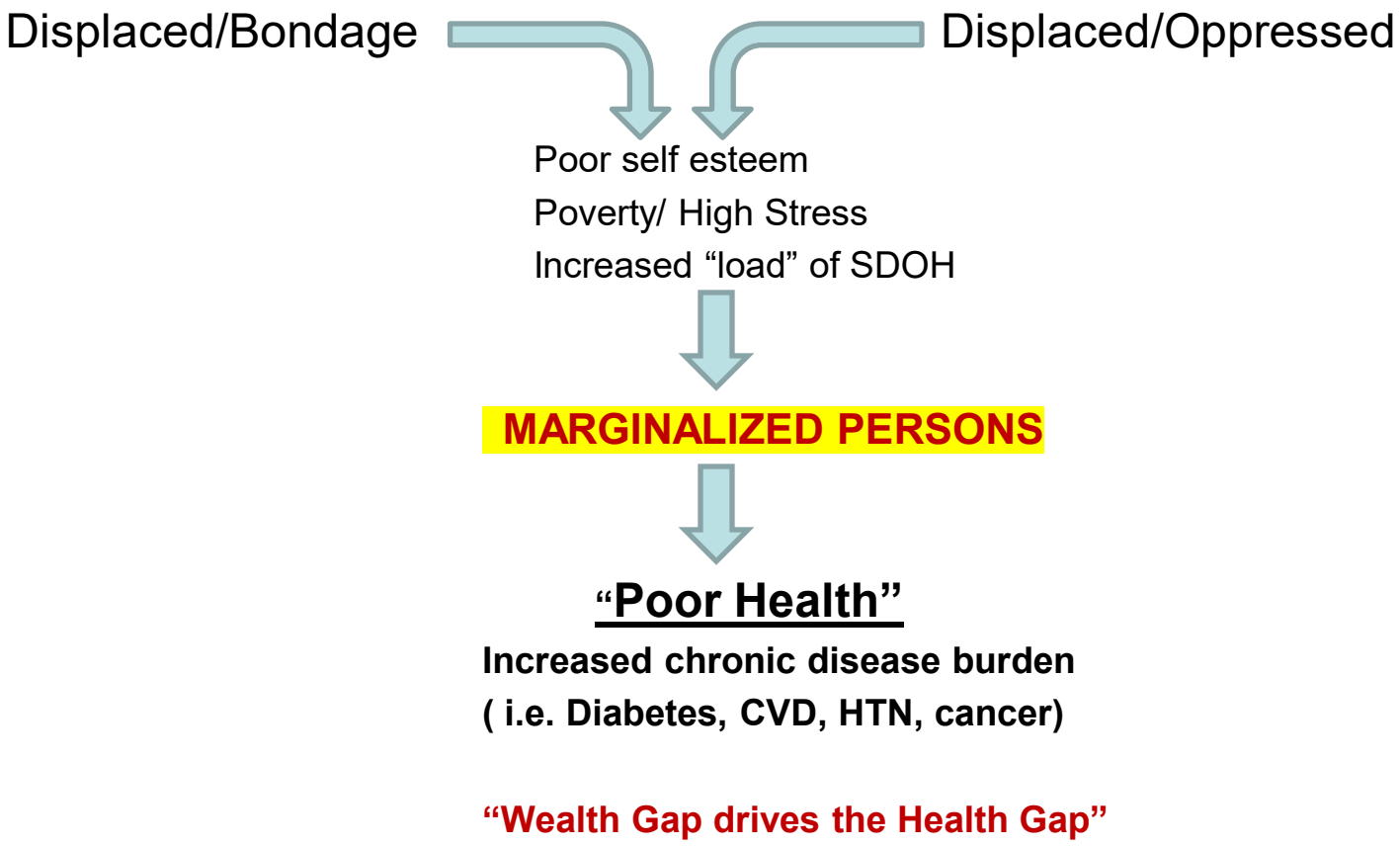
Higher rates of diabetes complications have been shown for people of color

2.0x more likely for Black and Hispanic individuals to **die from diabetes related complications.**

3.5x more likely for Black individuals to have **end stage renal disease.**

more likely for Hispanic individuals to

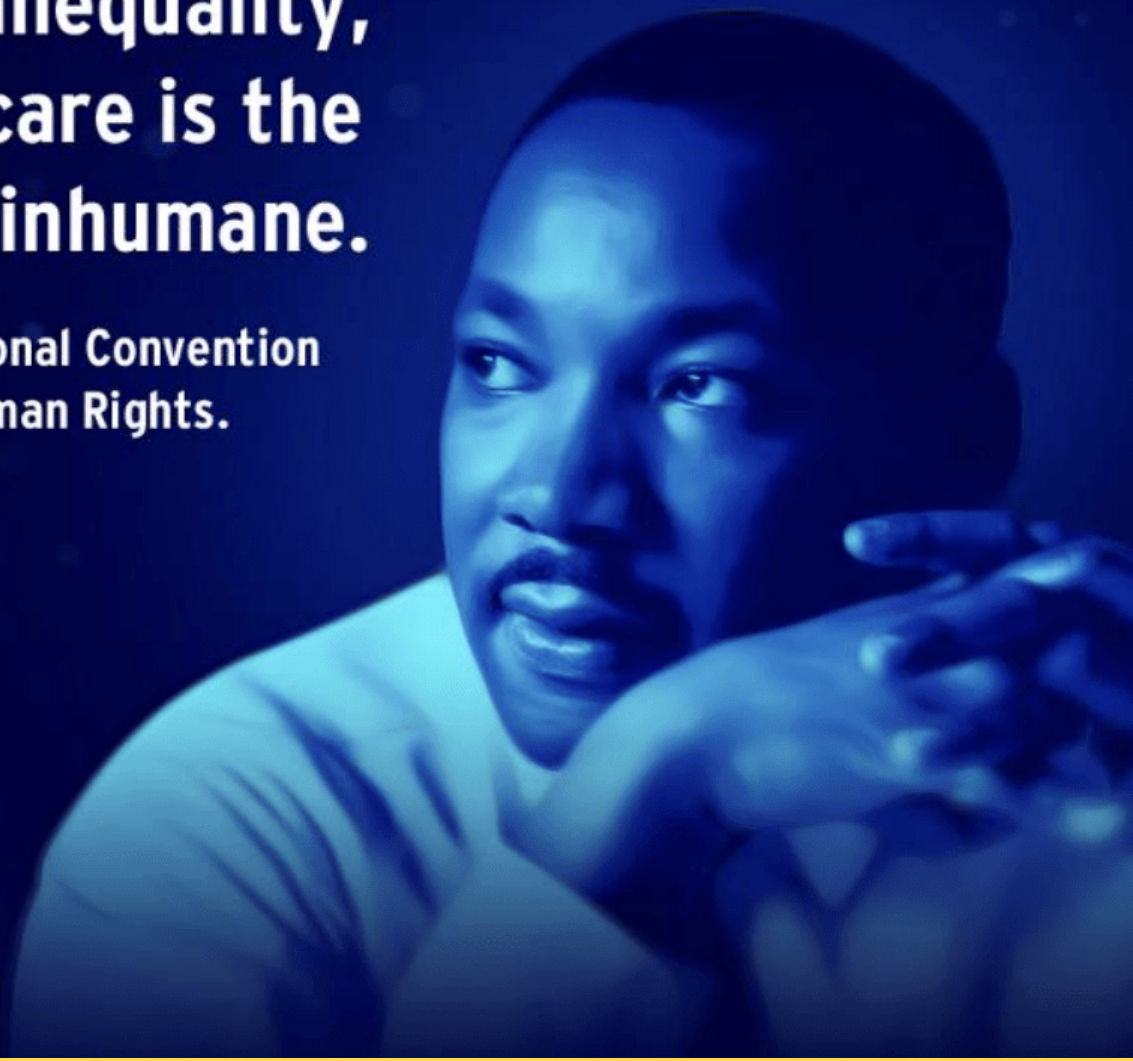
Diabetes: A Disease Risk for Marginalized People



MARTIN LUTHER KING

Of all the forms of inequality, injustice in health care is the most shocking and inhumane.

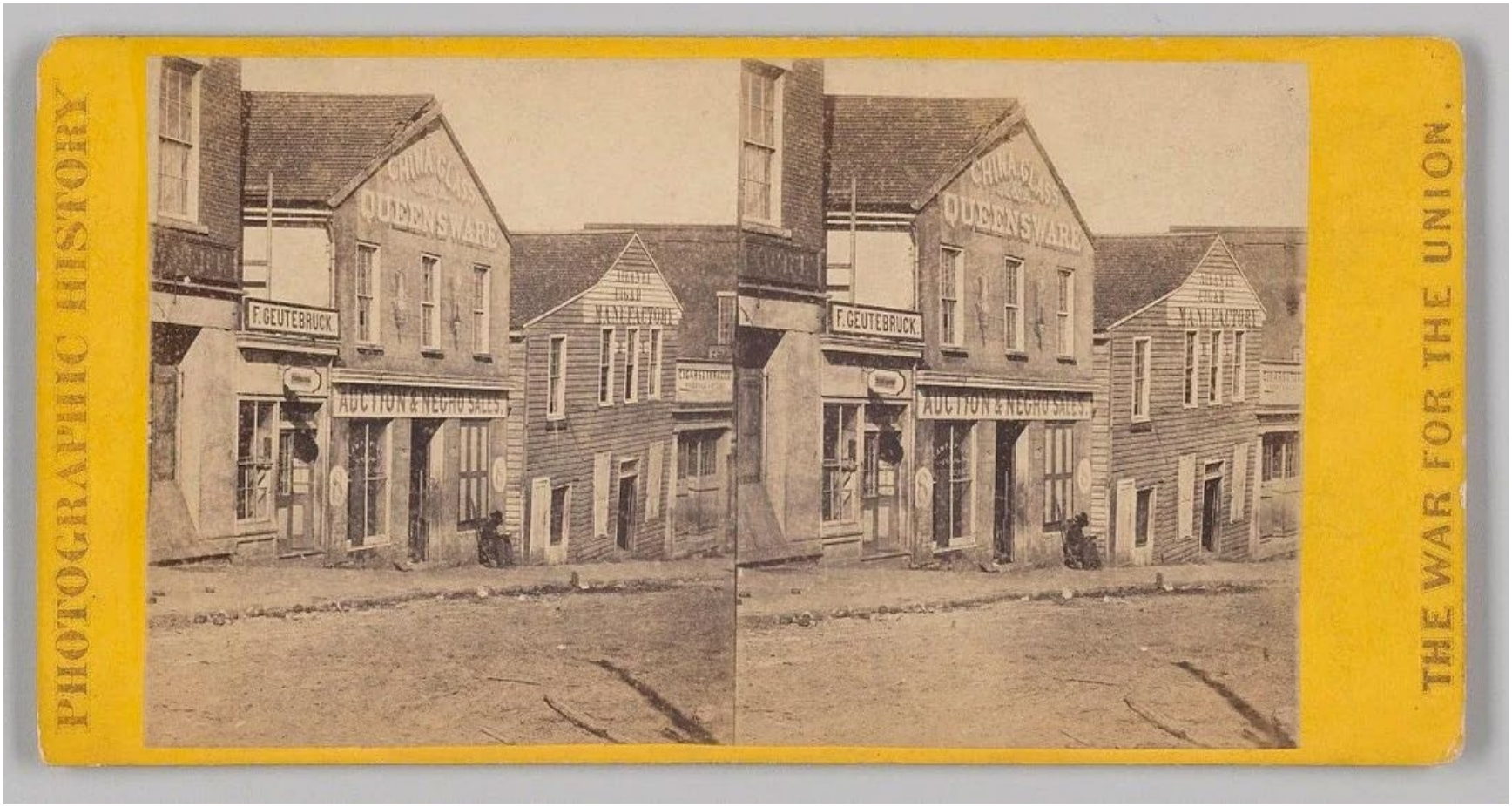
Speaking before the Second National Convention of the Medical Committee for Human Rights. Chicago, Illinois. March 25 1966.



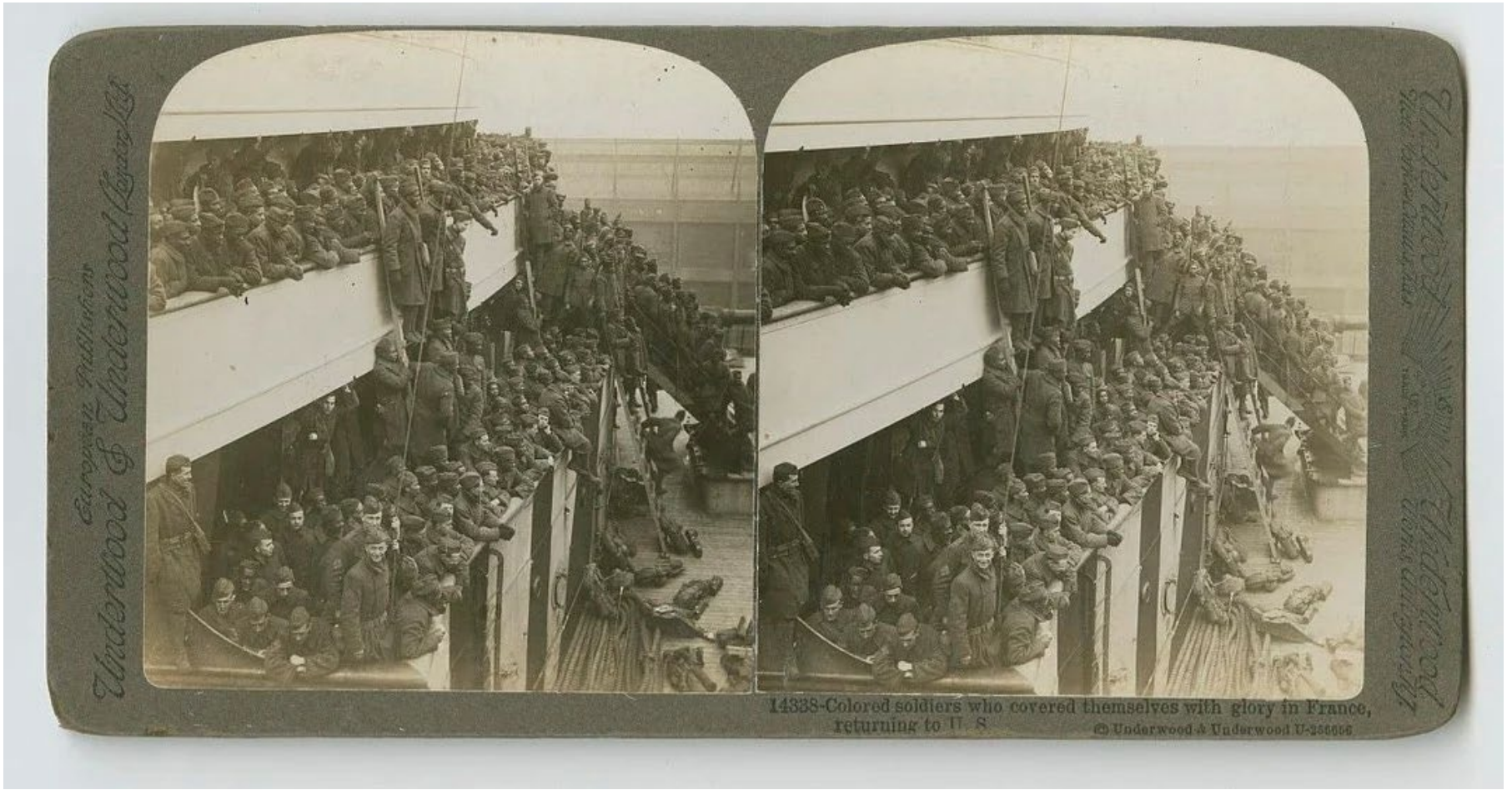
How Did We Get Here in U.S. Healthcare?

Historical Medical and Scientific Context of Health Disparities in the USA

Firmly anchored in the concepts of dehumanization and innate superiority, slaves were bought, sold, and traded in well-established markets--- as property



The Legacy of Being Seen and Treated as Property Has Generated Shameful Consequences



A Litany of Long-term, Consequential Legacies from our Bitter Past: Enduring Effects and a Constant Source of Engagement Across Our Institutions

Social/Financial

- Sharecropping
- Tyranny of unregulated debt
- "Owners" now serving as "employers"
- **Peonage**
- Vagrancy laws coupled with slave labor
- Withdrawal of Union soldiers after 1877**
- Lack of protection from segregationist laws
- **Intentional segregation of housing patterns**
- Redlining
- Roosevelt's New Deal
- Buchanan vs. Warley (1917) decision preventing Blacks from moving into majority white communities
- Issuance of sub-prime loans
- Denial of access to access to home ownership as the foundation of middle-class family wealth
- Denial of access to patent opportunities, training
- Denial of access to equal education opportunities
- **Corruption/fixation/biasing of attitudes**

Socioeconomic/Political

- Violence and Intimidation
- Opelousas, LA, Massacre, 1868
- Colfax, LA, Massacre, 1873
- Wilmington, NC, Massacre, 1898
- Atlanta, GA, Massacre, 1908
- Springfield, IL, Massacre, 1908
- East St. Louis MO, Massacre, 1917
- Elaine, AR, Massacre, 1919
- Tulsa, OK, Massacre, 1920
- Ocoee, FL, Massacre, 1920
- Rosewood, FL, Massacre, 1923
- **>4400 lynchings, 1865 - 1943**
- **Voter suppression laws/poll taxes**
- Denial of union membership/health/retirement
- Public services discrimination
- **Segregation of health/education facilities**
- **Exclusion from advancement opportunities**
- **Corruption/fixation/ biasing of attitudes**

HISTORICAL DISCRIMINATION AND RACISM DURING SLAVERY AND POST-CIVIL WAR

Medical and Scientific Contributors

- Eugenics Theory defining certain races and ethnicities as biologically inferior
- Closure of medical schools training black physicians in 1910s
- Experimentation on vulnerable groups without their consent

↓ Trust in medical establishment

Language and communication barriers

Healthcare provider bias toward minority patients

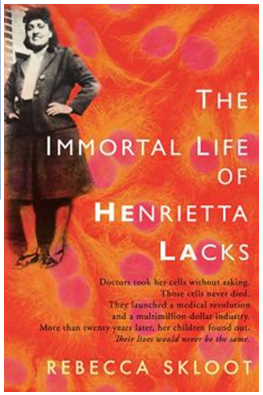
Healthcare Context

Poor access to care, ↓ quality of care, ↓ participatory decision-making in patient-provider relationships, ↓ health literacy

Golden et al. *J Clin Endocrinol Metab*, 2021

Dr. J. Marion Sims

- Experimented and repeatedly performed gynecological procedures on slave women without anesthesia
- Consent from owner, not slave



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,

Racial Disparities In Health Are Persistent Over Time and Our Urgent Challenge is to Discern *WHY*, in order to Inform Remedies!

How much are these differences driven by Biology vs Bias vs Behavior vs Other(s)?

THE MOST SIGNIFICANT CHANGES THAT DRIVE THE CURRENT TRENDS IN DIABETES AMONG HIGH-RISK MINORITIES HAVE LITTLE TO DO WITH CHANGES IN THE GENES!

OUR FOCUS SHOULD BE SHARPLY ON THOSE ELEMENTS OF *ENVIRONMENT* AND *BEHAVIOR* THAT WE CAN MODIFY---THAT'S WHERE POTENTIAL FOR CHANGE RESIDES

The "Causality Balance" in T2DM: Advantage Environment!

Case of Pima Indians: AZ and Mexico

- Present in region since ~300 B.C.
- Farmers due to presence of Gila River
- Loss of river's waters to settlers
- Reservation established in 1859
- 1st case of DM recorded in 1908
- Joslin documented 21 cases in 1937
- 10-fold increase reported by 1950's
- Prevalence of 46% by 1970's
- 8-fold lower prevalence in Pimas from same region who migrated to Northern Mexico within **40 years**
- Markedly different diets, BMI, physical activity, fat intake, CHO intake

Case of Japanese: TKYO and SEA

- Immigration began in 1800's
- Stopped by US government in 1924
- 2nd-generation Japanese (Nisei) revealed 2 to 3-fold higher rates of T2D than in Tokyo
- Nisei more overweight than Tokyo but not as much as US whites
- Nisei consumed similar amounts of food as Tokyo but less than US whites
- Nisei consumed more total fat and less CHO than Tokyo
- Marked differences in T2D prevalence had occurred in less than 40 years!

The Complexity of the Legacy of Marginalization: Meharry vs Johns Hopkins Comparison*

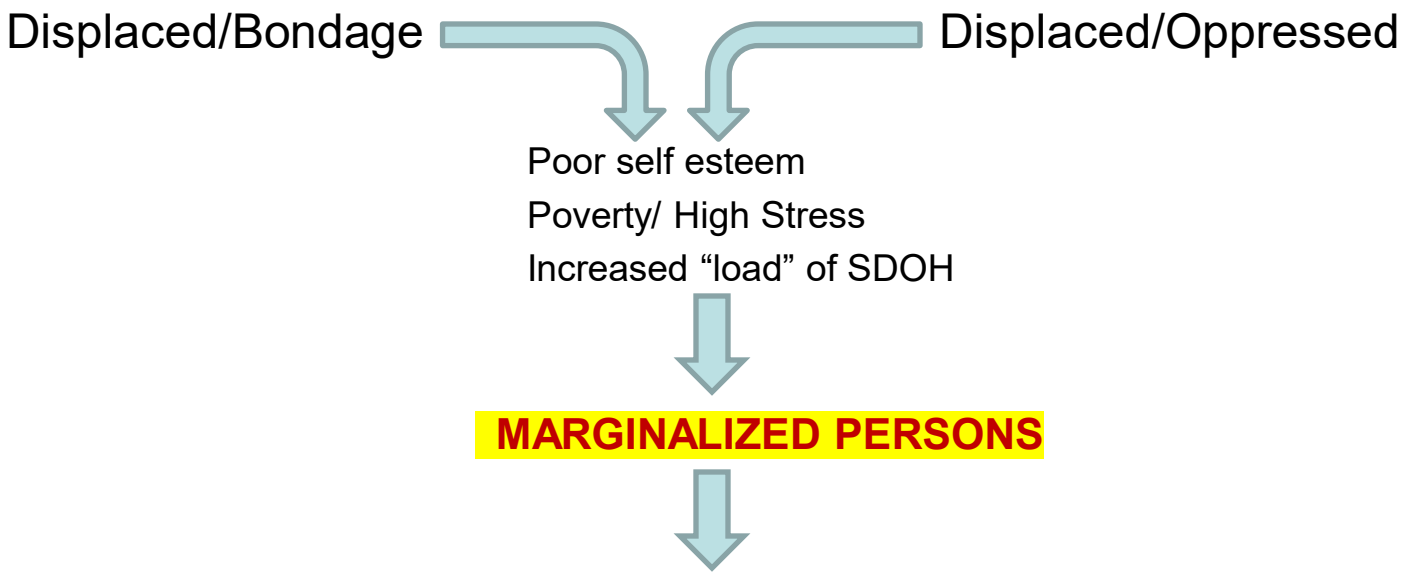
A 1958 – 65, all Black, cohort of Meharry Medical College MDs was compared with a 1957- 64, all White, cohort of Johns Hopkins MDs. 23-25 years later, the Black MDs were more likely to have:

- higher risk of CVD (RR=1.65)
- earlier onset of disease
- incidence rates of diabetes & hypertension that were twice as high
- higher incidence of coronary artery disease (1.4 times)
- higher case fatality (52% vs 9%)

Thomas et al., 1997 J. Health Care for Poor and Underserved

*While Black physicians were free from poverty, they lived largely in Black communities, received their health care from persons like themselves, and had lifestyles characterized by poor dietary habits, smoking, and inadequate regular physical activity.

Diabetes: A Disease Risk for Marginalized People



"Wealth Gap drives the Health Gap"

New Strategies and Often Different Strategies are Required to Improve Outcomes in Affected Groups

Successful Interventions for Reducing Diabetes Health Disparities

Level of intervention	Successful Components	Outcomes
Microsystem/health care organization	Disease management • Identification of diabetes population (registries) • ***Practice guidelines*** ****** • Health IT to track and monitor patients • Care management*	Improved diabetes outcomes
Community/health care system	• Culturally tailored patient education and empowerment • Community coalition building and advocacy • Community health workers • Provider audit and feedback • Quality improvement • Case management*	Improved minority health care Reduced racial and ethnic disparities in care

*Care management: Patient education addressing adherence barriers, ancillary services (labs), transportation

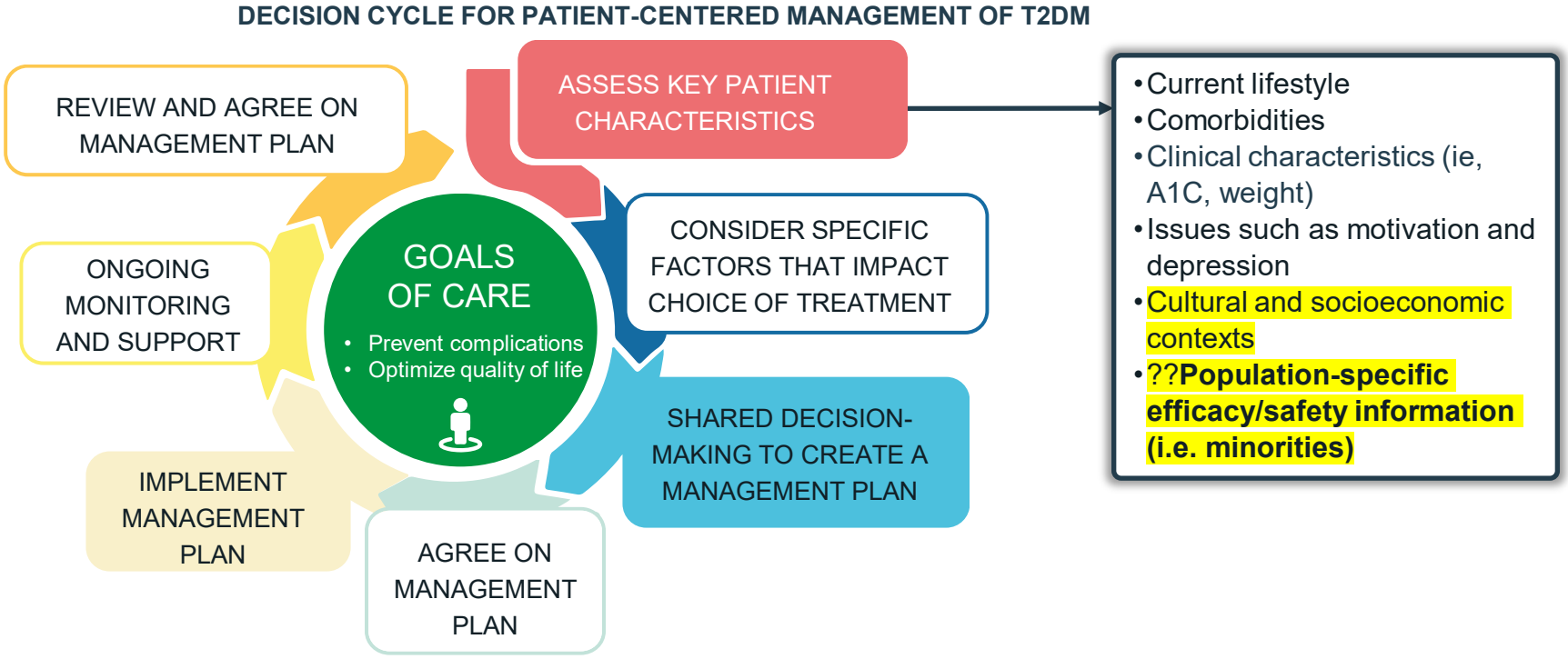
Golden et al, *J Clin Endocrinol Metab*, 2012

Long-standing urgency has been acknowledged for a key role of clinical guidelines in facilitating a reduction in a broad spectrum of health disparities in racial/ethnic groups

- Eliminating disparities will require aggressive efforts focused on risk assessment, guideline adherence, and risk-factor control in at-risk populations. As Lurie and colleagues noted, "improving quality of care through the **use of practice guidelines** can play an important role in addressing racial and ethnic disparities, as the combination of increasing awareness, improving quality, and increasing patient demand for and participation in high-quality care will likely contribute to addressing this important societal health issue".

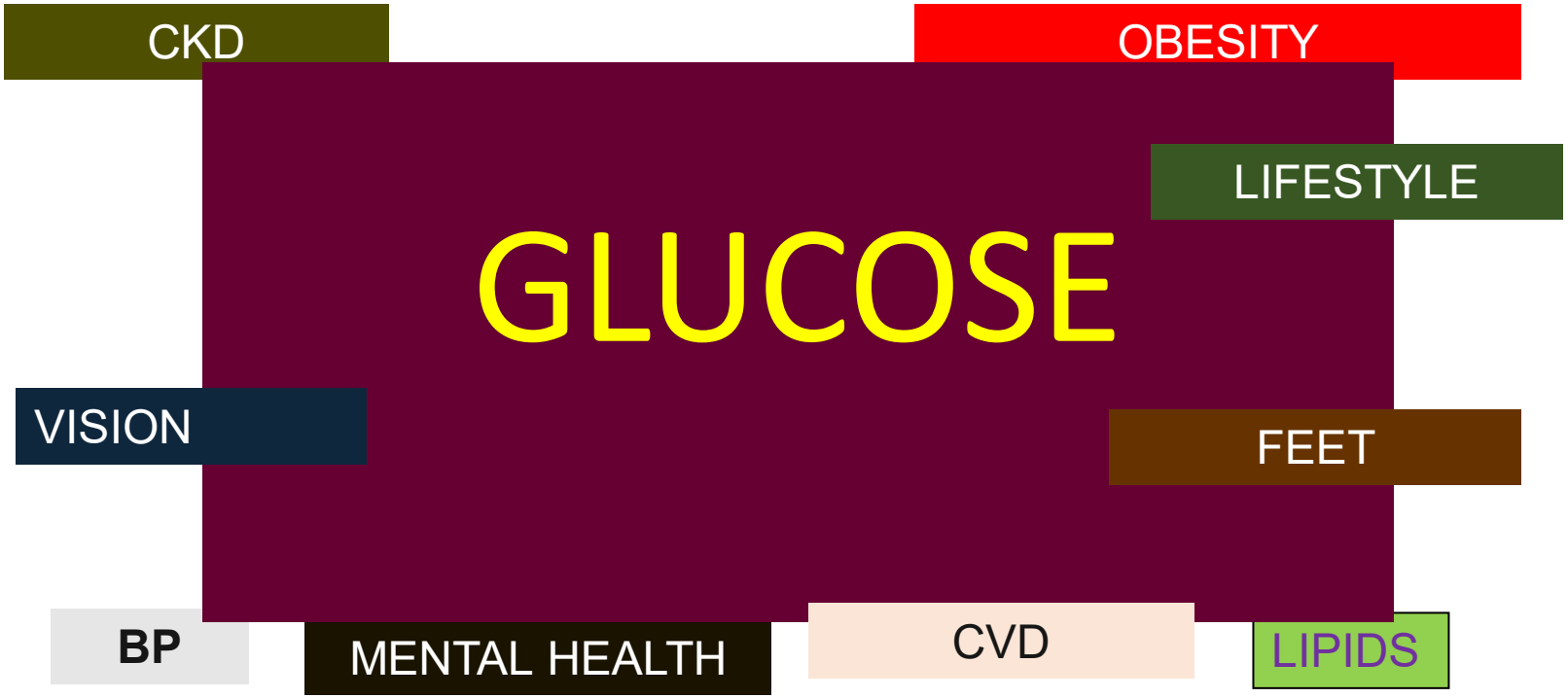
Lurie N., Fremont A., Jain A.K., Taylor S.L., McLaughlin R., Peterson E., Kong B.W., Ferguson T.B., Jr Racial and ethnic disparities in care: the perspectives of cardiologists. *Circulation.* 2005;**111**(10):1264–1269. doi: 10.1161/01.CIR.0000157738.12783.71.

2022 American Diabetes Association Standards of Medical Care in Diabetes—Abridged For Primary Care Providers



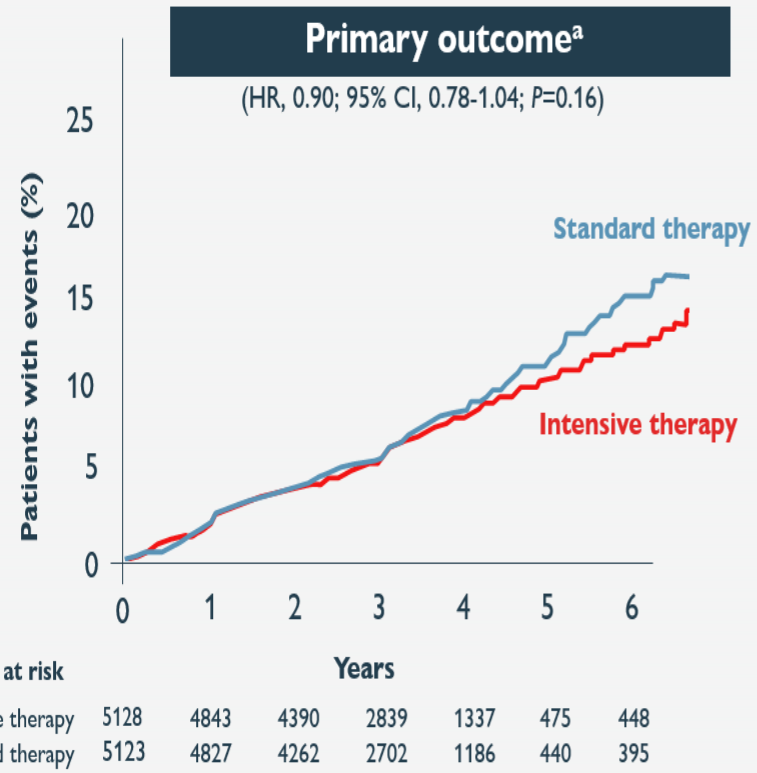
American Diabetes Association. *Clin Diabetes.* 2022;40(1):10-38.

THE “HISTORICAL” PROBLEM OF DIABETES CONTROL

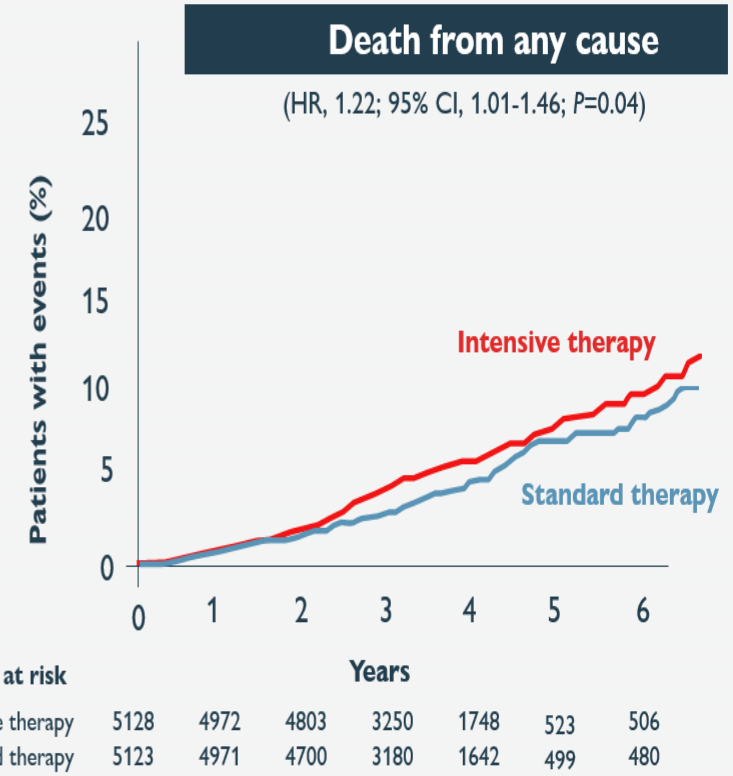


INTENSIVE GLUCOSE-LOWERING ALONE HAS NOT DEFINITIVELY BEEN SHOWN TO REDUCE CV EVENTS

- **10,251 patients (mean age, 62.2 years) with a median A1C of 8.1% were assigned to receive intensive therapy (targeting A1C <6%) or standard therapy (targeting 7%-7.9%)**



No. at risk							
Intensive therapy	5128	4843	4390	2839	1337	475	448
Standard therapy	5123	4827	4262	2702	1186	440	395



No. at risk							
Intensive therapy	5128	4972	4803	3250	1748	523	506
Standard therapy	5123	4971	4700	3180	1642	499	480

CI, confidence interval; HR, hazard ratio; MI, myocardial infarction. [a]First occurrence of nonfatal MI, nonfatal stroke, or death from CV events.

1. The Action to Control Cardiovascular Risk in Diabetes Study Group. *N Engl J Med*. 2008;358:2545-2559.

The Sustainable nature of disparities: Even with the Historical "**Glucocentric Approach**" African American A1c Levels were Uniformly Worse!

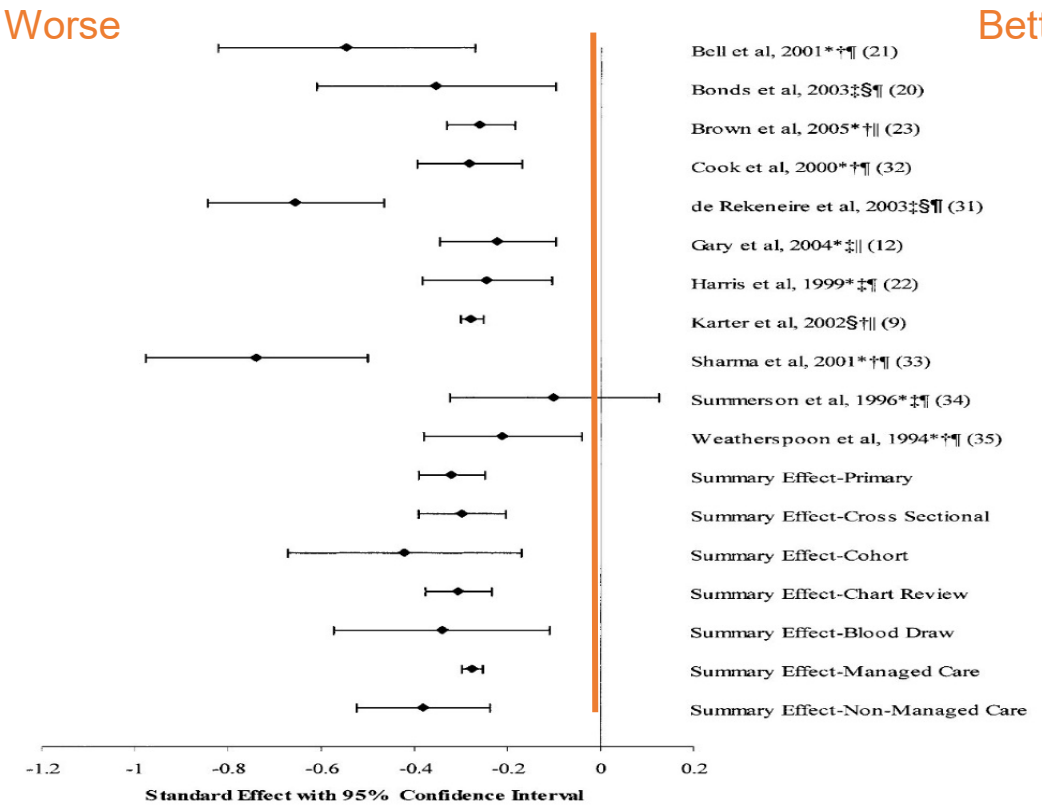
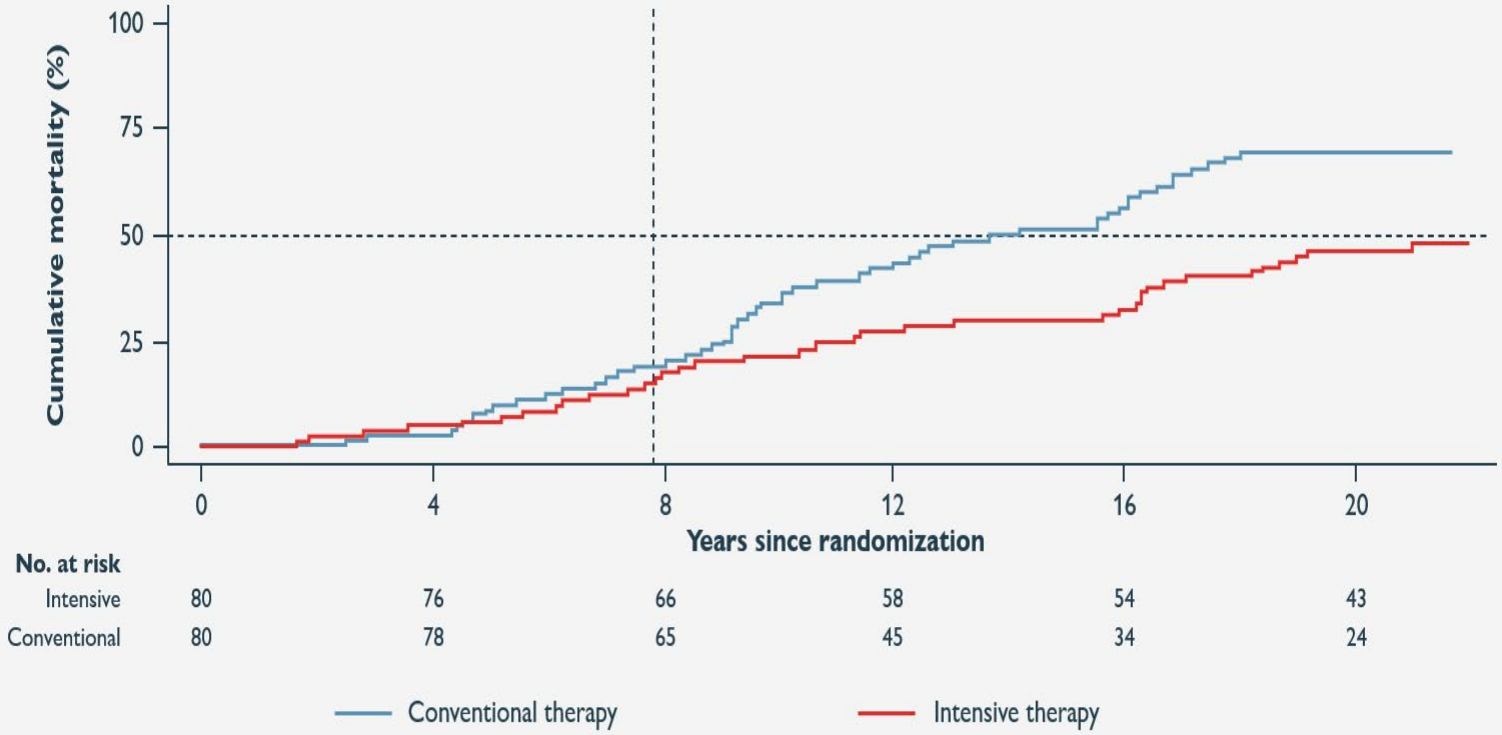


Figure 1—*Standard effect size summary for the difference between A1C in African Americans and non-Hispanic whites. *Cross-sectional study; †data obtained from chart review; ‡A1C sample from study-initiated blood draw; §prospective cohort study or clinical trial; ‖managed care; ¶nonmanged care.*

Kirk, et al. *Diabetes Care* 29:2130–2136, 2006

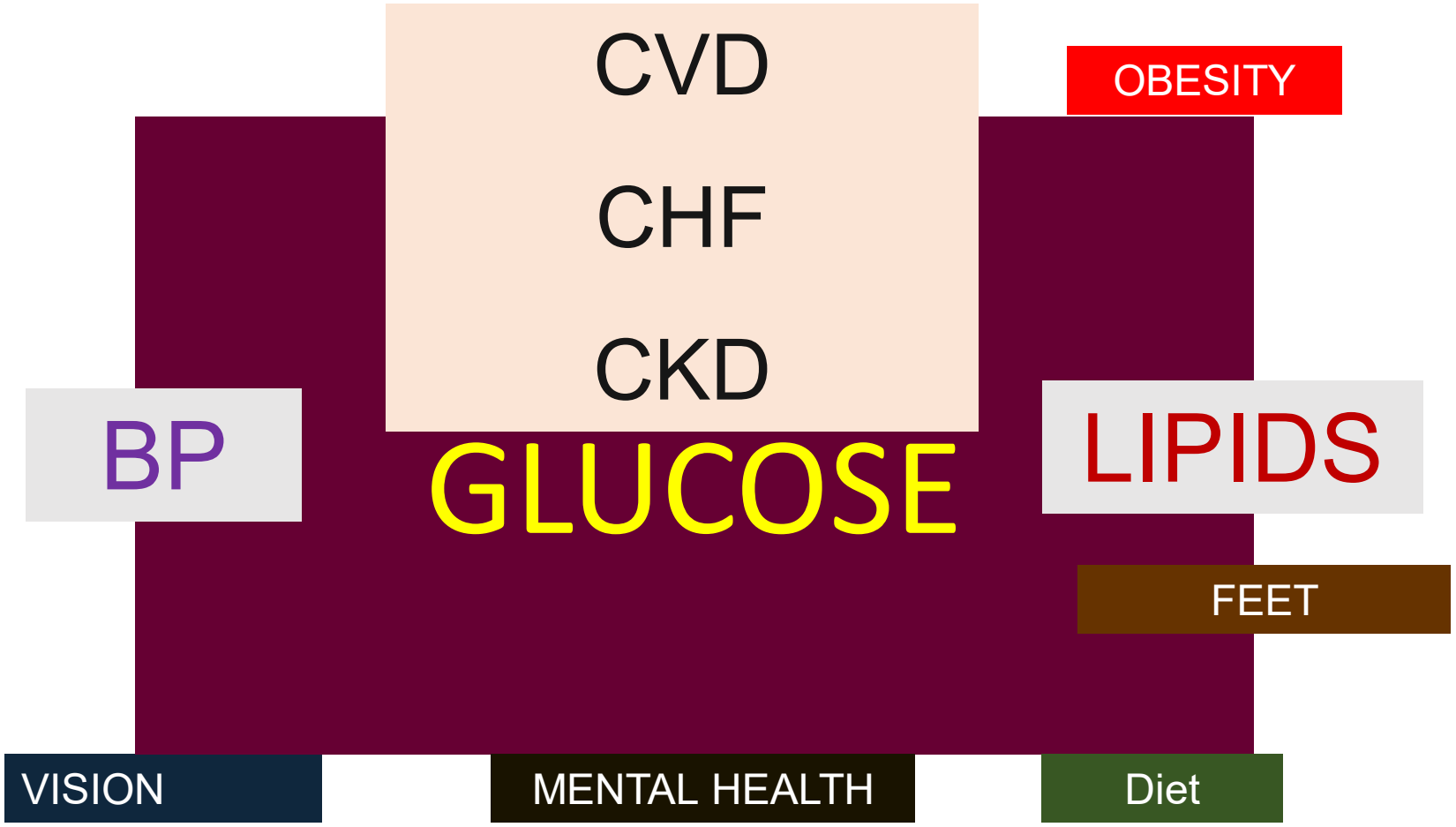
A MULTIDISCIPLINARY INTERVENTION IN PATIENTS WITH T2DM LED TO AN INCREASE IN LIFE SPAN

- Intensified treatment for 7.8 years was associated with **a 7.9-year longer median life span** over 21.2 years of follow-up

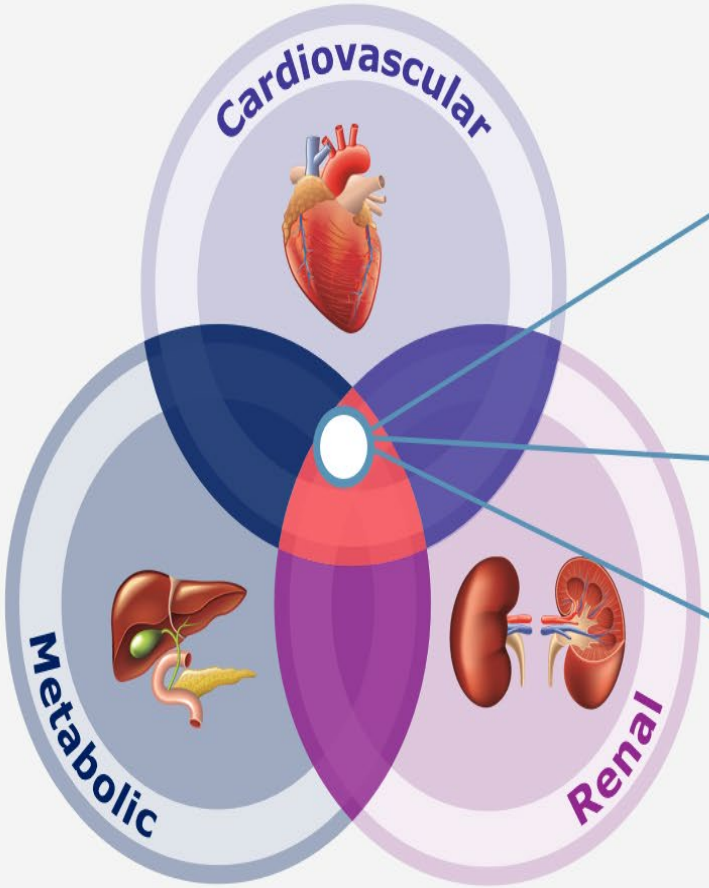


 1. Gæde P, et al. *Diabetologia*. 2016;59(11):2298-2307.

Evolution/understanding of T2DM as a Cardiometabolic Disease is the **REAL problem**, and it's <u>not evenly distributed</u>!



DISORDERS OF THE CRM SYSTEMS OFTEN COEXIST



CKD AFFECTS ≥40% OF T2DM PATIENTS
with more than half of these patients in the moderate to severe stages[3,4]

≥50% OF T2DM PATIENTS
have or are at high risk of developing CV disease[1]

~33% OF CKD PATIENTS
also have CV disease[2]

CKD, chronic kidney disease.

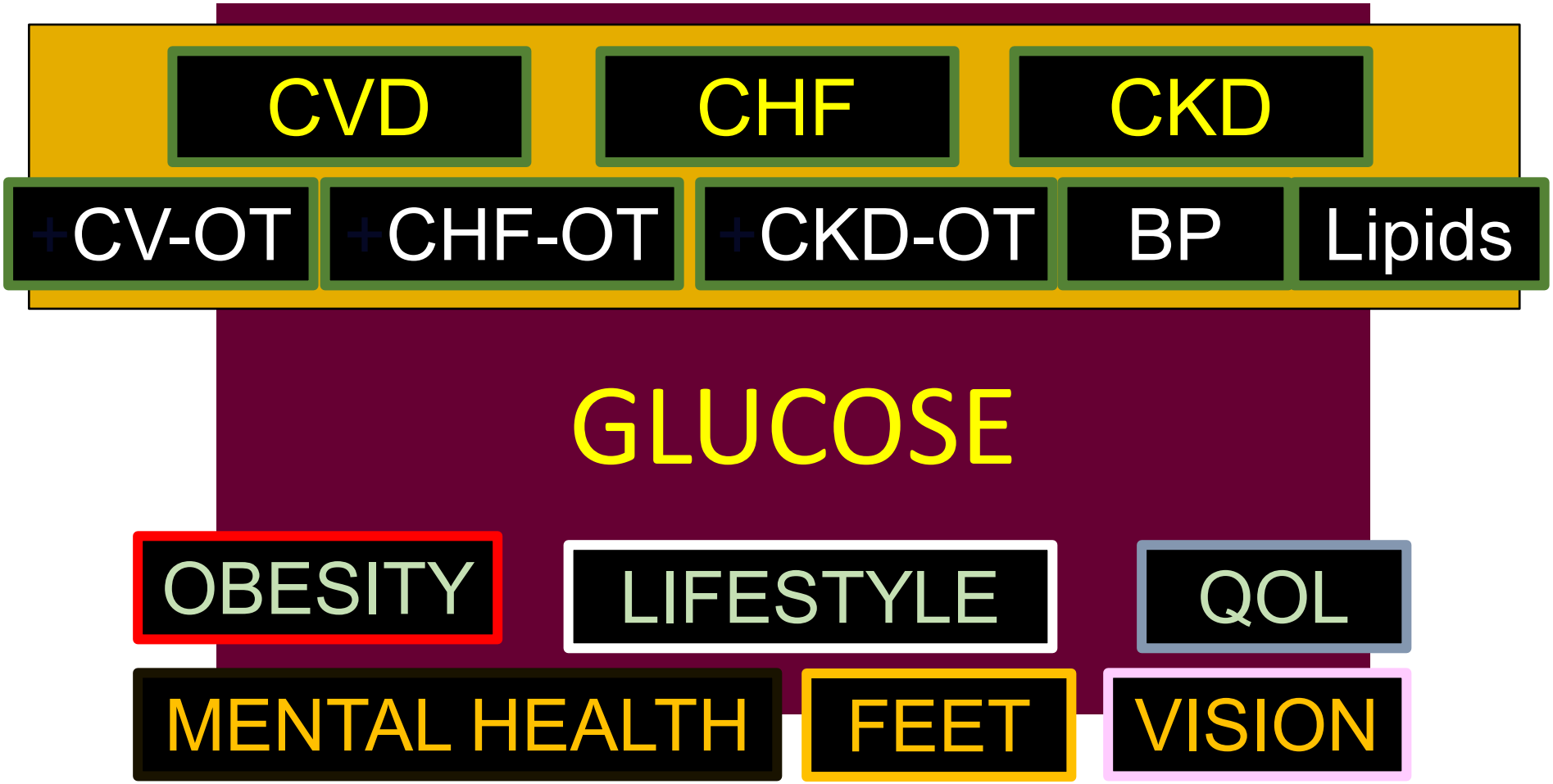
1. Wong K, et al. *J Diabetes Complications*. 2012;26:169-174. 2. Rahman M, et al. *Am J Nephrol*. 2014;40:399-407. 3. Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Atlanta, GA: CDC, US Dept of Health and Human Services; 2020. 4. International Diabetes Foundation. *IDF Diabetes Atlas*. 9th ed. http://www.diabetesatlas.org. Accessed July 17, 2020.

A shift to GDMT has provided a highly-promising **approach to interrupting the cycle of poor outcomes** associated with the multiple cardiometabolic and renal comorbidities so prevalent in T2D---- facilitated by several important factors:

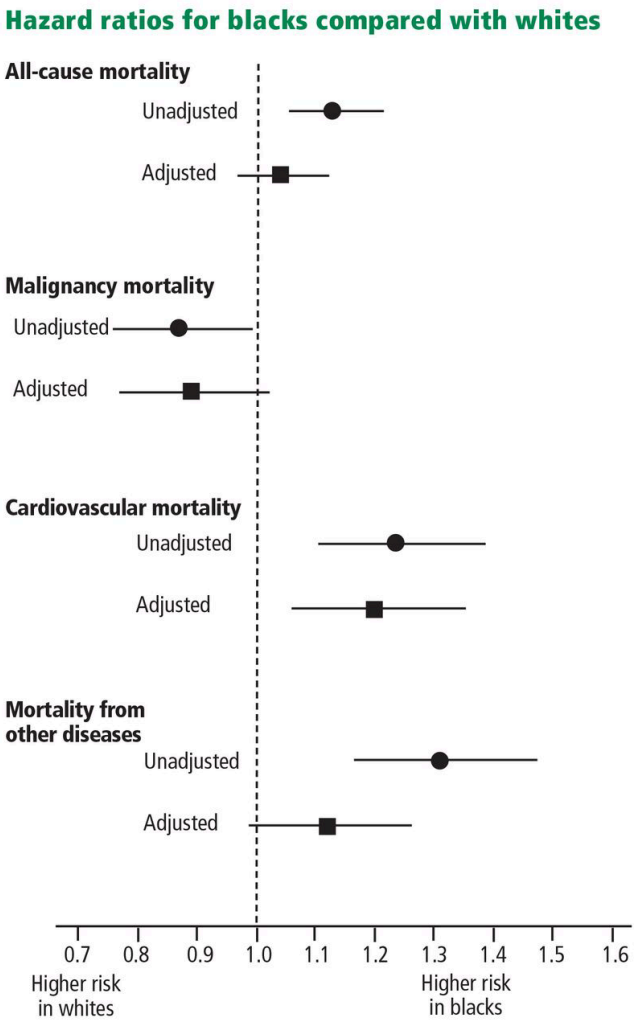
- Current guidelines advocate for treatments **targeted to specific risk factors** that are drivers of the major adverse outcomes of ASCVD, CHF, and CKD.
- Strategies focus on treatments that reduce risk of **cardiometabolic and renal dysfunction INDEPENDENT OF A1C** goal attainment, highlighting the "re-stratification" of T2D treatment approaches
- GDMT is built on the **validated evidence** from RCTs demonstrating how the use of medications, technologies, and lifestyle behaviors that lower glucose in T2DM can **reduce microvascular endpoints**, but **not macrovascular events**
- GDMT provides affirmation for the **re-stratification of diabetes management goals** from glucose-centric to cardiometabolic/cardiorenal-focused goals (although with an implicit assumption that "one size fits all")
- GDMT also affirms that additional clinical tools, when appropriately used (i.e. motivational interviewing, shared decision making) enhance goal attainment for patients with T2DM (complicated by the same implicit assumption)

****Important caveat:** The CVOTs that have provided the **evidence base**, the foundation for development of GDMT, have suffered from some crucial and often underreported shortcomings, all with the greatest impact on the high-risk populations!

Re-Stratification of T2D Priorities: Truly ***Urgent*** for Minorities!



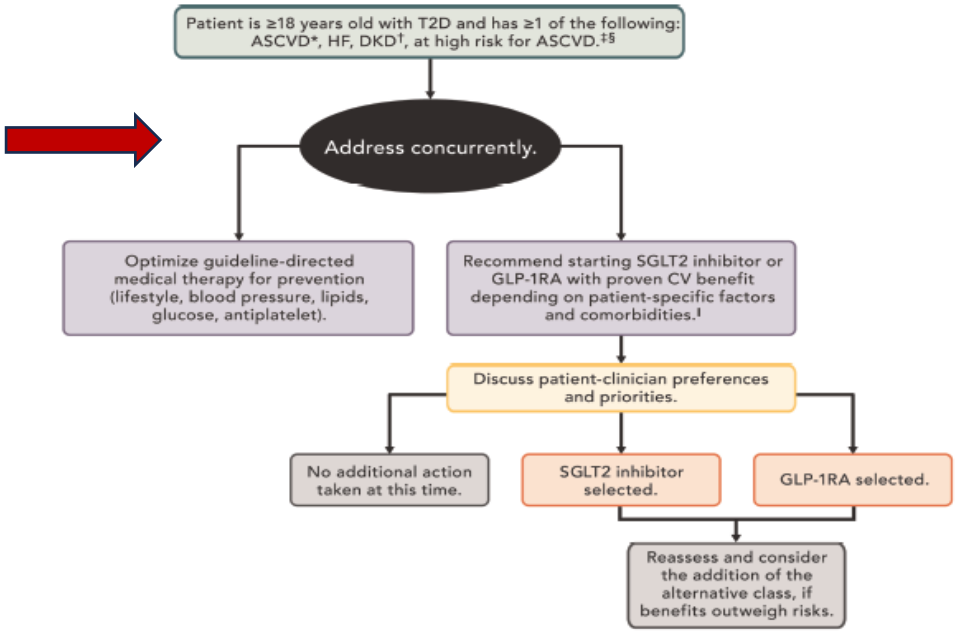
Risk for all-cause and major cause-specific death in black vs white patients



Joseph V. Nally, Jr CCJM 2017;84:855-862

CLEVELAND CLINIC JOURNAL OF MEDICINE

Re-Stratification of T2D Priorities has Radically Shifted the Roles of Newer Diabetes Therapies—Especially for the High-Risk Groups!



*ASCVD is defined as a history of an acute coronary syndrome or MI, stable or unstable angina, coronary heart disease with or without revascularization, other arterial revascularization, stroke, or peripheral artery disease assumed to be atherosclerotic in origin.

†DKD is a clinical diagnosis marked by reduced eGFR, the presence of albuminuria, or both.

‡ Consider an SGLT2 inhibitor when your patient has established ASCVD, HF, DKD or is at high risk for ASCVD. Consider a GLP-1RA when your patient has established ASCVD or is at high risk for ASCVD.

§ Patients at high risk for ASCVD include those with end organ damage such as left ventricular hypertrophy or retinopathy or with multiple CV risk factors (e.g., age, hypertension, smoking, dyslipidemia, obesity).

‖ Most patients enrolled in the relevant trials were on metformin at baseline as glucose-lowering therapy.

ASCVD = atherosclerotic cardiovascular disease; CV = cardiovascular; DKD = diabetic kidney disease; eGFR = estimated glomerular filtration rate; GLP-1RA = glucagon-like peptide-1 receptor agonist; HF = heart failure; MI = myocardial infarction; SGLT2 = sodium-glucose cotransporter-2; T2D = type 2 diabetes

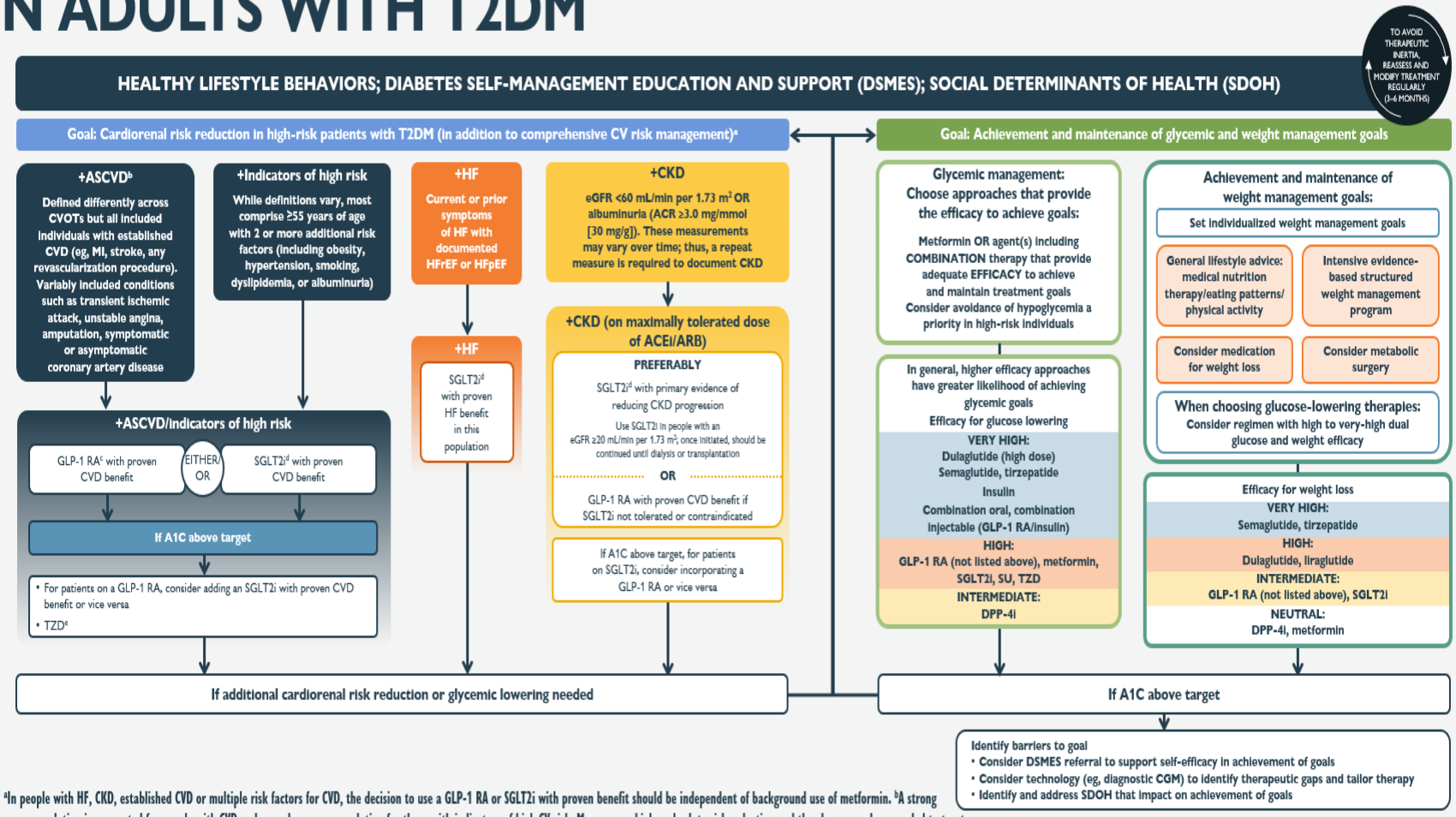
Figure 10.3—Approach to risk reduction with SGLT2 inhibitor or GLP-1 receptor agonist therapy in conjunction with other traditional, guideline-based preventive medical therapies for blood pressure, lipids, and glycemia and antiplatelet therapy. Reprinted with permission from Das et al. (220).

Figure 10.3—Approach to risk reduction with SGLT2 inhibitor or GLP-1 receptor agonist therapy in conjunction with other traditional, guideline-based preventive medical therapies for blood pressure, lipids, and glycemia and antiplatelet therapy

Question: What is the role of clinical guidelines for providing *specific-population evidence* of effectiveness of recommended therapies, rather than convey the implicit assumption of *broad-based efficacy* ("good for all")?

American Diabetes Association Professional Practice Committee. *Diabetes Care.* 2022;45(Suppl. 1):S144-S174.

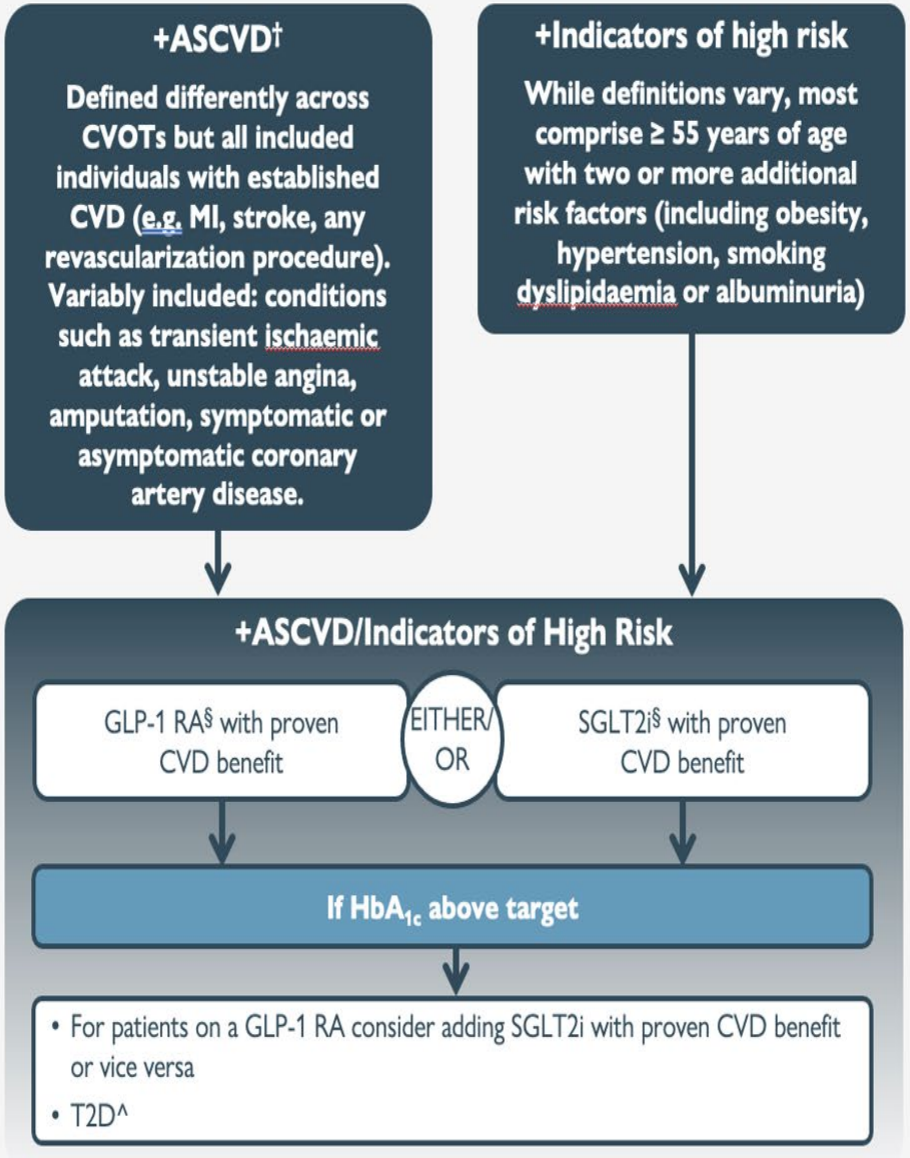
PHARMACOLOGIC TREATMENT OF HYPERGLYCEMIA IN ADULTS WITH T2DM

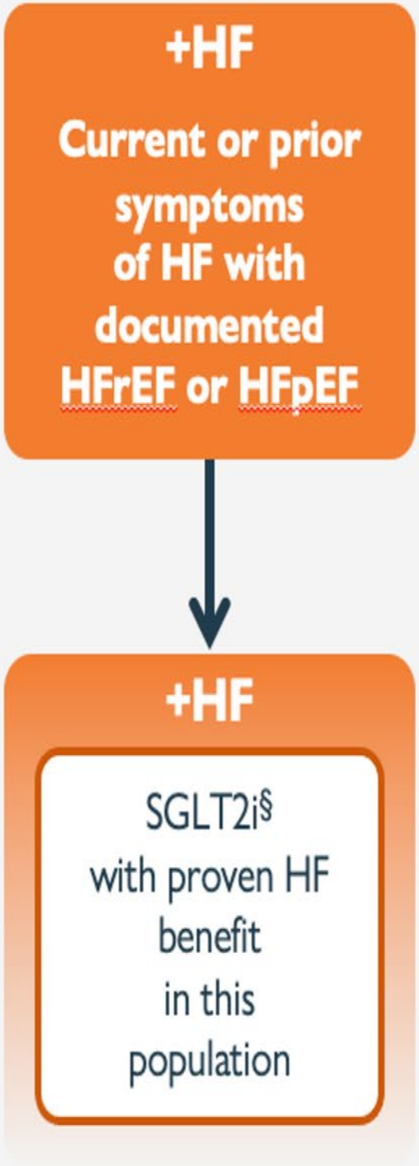


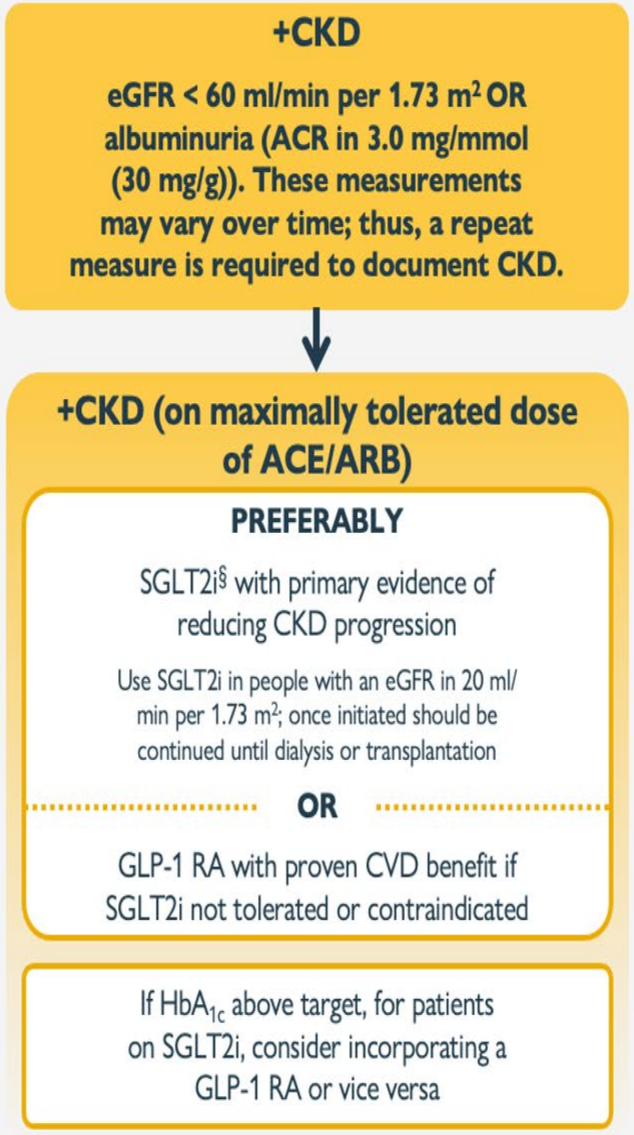
[a]In people with HF, CKD, established CVD or multiple risk factors for CVD, the decision to use a GLP-1 RA or SGLT2i with proven benefit should be independent of background use of metformin. [b]A strong recommendation is warranted for people with CVD and a weaker recommendation for those with indicators of high CV risk. Moreover, a higher absolute risk reduction and thus lower numbers needed to treat are seen at higher levels of baseline risk and should be factored into the shared decision-making process. [c]For GLP-1 RA, CVOTs demonstrate their efficacy in reducing composite MACE, CV death, all-cause mortality, MI, stroke, and renal endpoints in individuals with T2DM with established/high risk of CVD. [d]For SGLT2i, CV/renal outcomes trials demonstrate their efficacy in reducing the risk of composite MACE, CV death, all-cause mortality, MI, HHF, and renal outcomes in individuals with T2DM with established/high risk of CVD. [e]Low-dose TZD may be better tolerated and similarly effective.

CVOT, cardiovascular outcomes trial; DPP-4i, DPP-4 inhibitor; HF, heart failure; HFpEF, HF with preserved ejection fraction; HFrEF, HF with reduced ejection fraction; NPH, neutral protamine Hagedorn; SU, sulfonylurea; TZD, thiazolidinedione.

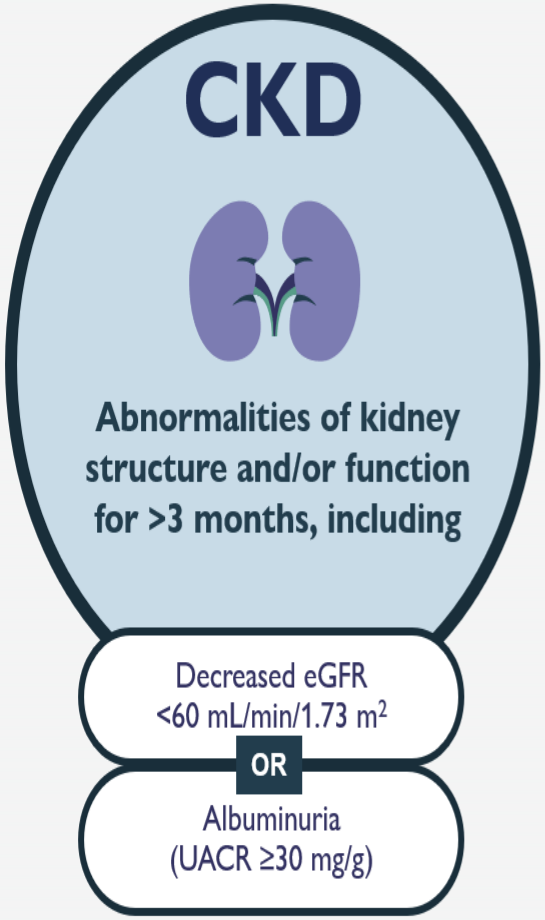
 1. Davies MJ, et al. *Diabetes Care*. 2022;45(11):2753-2786. 2. American Diabetes Association. *Diabetes Care*. 2020;43(suppl 1):S1-S212. 3. American Diabetes Association. *Diabetes Care*. 2023;46(suppl 1):S1-S291.


+ASCVD†
Defined differently across CVOTs but all included individuals with established CVD (e.g. MI, stroke, any revascularization procedure). Variably included: conditions such as transient ischaemic attack, unstable angina, amputation, symptomatic or asymptomatic coronary artery disease.
+Indicators of high risk
While definitions vary, most comprise ≥ 55 years of age with two or more additional risk factors (including obesity, hypertension, smoking dyslipidaemia or albuminuria)
+ASCVD/Indicators of High Risk
GLP-1 RA§ with proven CVD benefit
EITHER/ OR
SGLT2i§ with proven CVD benefit
If HbA1c above target
• For patients on a GLP-1 RA consider adding SGLT2i with proven CVD benefit or vice versa
• T2D^


+HF
Current or prior symptoms of HF with documented HFrEF or HFpEF
+HF
SGLT2i§ with proven HF benefit in this population


+CKD
eGFR < 60 ml/min per 1.73 m² OR albuminuria (ACR in 3.0 mg/mmol (30 mg/g)). These measurements may vary over time; thus, a repeat measure is required to document CKD.
+CKD (on maximally tolerated dose of ACE/ARB)
PREFERABLY
SGLT2i§ with primary evidence of reducing CKD progression
Use SGLT2i in people with an eGFR in 20 ml/min per 1.73 m²; once initiated should be continued until dialysis or transplantation
OR
GLP-1 RA with proven CVD benefit if SGLT2i not tolerated or contraindicated
If HbA1c above target, for patients on SGLT2i, consider incorporating a GLP-1 RA or vice versa

CRITERIA FOR DIAGNOSIS AND RISK STRATIFICATION OF CKD REQUIRE BOTH eGFR AND UACR[1,2]



KDIGO: Classification and prognosis of CKD				Persistent albuminuria categories Description and range		
				A1	A2	A3
				Normal to mildly increased	Moderately increased	Severely increased
				<30 mg/g <3 mg/mmol	30-300 mg/g 3-30 mg/mmol	>300 mg/g >30 mg/mmol
eGFR categories (mL/min/1.73 m²) Description and range	G1	Normal or high	≥90	Low	Moderately increased	High
	G2	Mildly decreased	60-89	Low	Moderately increased	High
	G3a	Mildly to moderately decreased	45-59	Moderately increased	High	Very high
	G3b	Moderately to severely decreased	30-44	High	Very high	Very high
	G4	Severely decreased	15-29	Very high	Very high	Very high
	G5	Kidney failure	<15	Very high	Very high	Very high

Risk of progression

Risk of progression

KDIGO classification reprinted from *Kidney International*,[1] Vol 98 (suppl), Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group, "KDIGO 2020 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease," Pages S1-S115, Copyright 2020, with permission from Elsevier. 1. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. *Kidney Int.* 2020;98(suppl):S1-S115. 2. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. *Kidney Int.* 2022;102(5S):S1-S127.

DIAGNOSIS AND TREATMENT OF CKD INVOLVES MULTIPLE SPECIALTIES STARTING WITH PCPs AND ENDING WITH NEPHROLOGISTS

Appropriate monitoring, treatment, and timely referral from PCPs to nephrology can be determined using the **KDIGO Heat Map**

CKD is classified based on: **•Cause (C)** **•GFR (G)** **•Albuminuria (A)**				Albuminuria categories Description and range		
				A1	A2	A3
				Normal to mildly increased	Moderately increased	Severely increased
				<30 mg/g <3 mg/mmol	30-299 mg/g 3-29 mg/mmol	≥300 mg/g ≥30 mg/mmol
GFR categories (mL/min/ 1.73 m^2) Description and range	G1	Normal or high	≥90	**Screen 1**	**Treat 1**	**Treat and refer 3**
	G2	Mildly decreased	60-89	**Screen 1**	**Treat 1**	**Treat and refer 3**
	G3a	Mildly to moderately decreased	45-59	**Treat 1**	**Treat 2**	**Treat and refer 3**
	G3b	Moderately to severely decreased	30-44	**Treat 2**	**Treat and refer 3**	**Treat and refer 3**
	G4	Severely decreased	15-29	**Treat and refer* 3**	**Treat and refer* 3**	**Treat and refer 4+**
	G5	Kidney failure	<15	**Treat and refer 4+**	**Treat and refer 4+**	**Treat and refer 4+**

Low risk (if no other markers of kidney disease, no CKD)

High risk

Moderately increased risk

Very high risk

*Referring clinicians may wish to discuss with their nephrology service, depending on local arrangements regarding treating or referring.

Figure from *Diabetes Care*,[1] reprinted from *American Journal of Medicine*, Vol 129, Issue 2, Vassalotti JA, et al; National Kidney Foundation Kidney Disease Outcomes Quality Initiative, "Practical Approach to Detection and Management of Chronic Kidney Disease for the Primary Care Clinician," Pages 153-162.e7, Copyright 2016, with permission from Elsevier, and from KDIGO classification reprinted from *Kidney International*, Vol 98 (suppl), Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group, "KDIGO 2020 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease," Pages S1-S115, Copyright 2020, with permission from Elsevier.

1. American Diabetes Association Professional Practice Committee. *Diabetes Care*. 2022;45(suppl 1):S175-S184.

RECOMMENDATIONS FOR CKD SCREENING

Screening should include[1,2]

Measurements of **UACR** in a spot urine sample

Measurement of **serum creatinine and eGFR**

Screening recommendations[1-3]

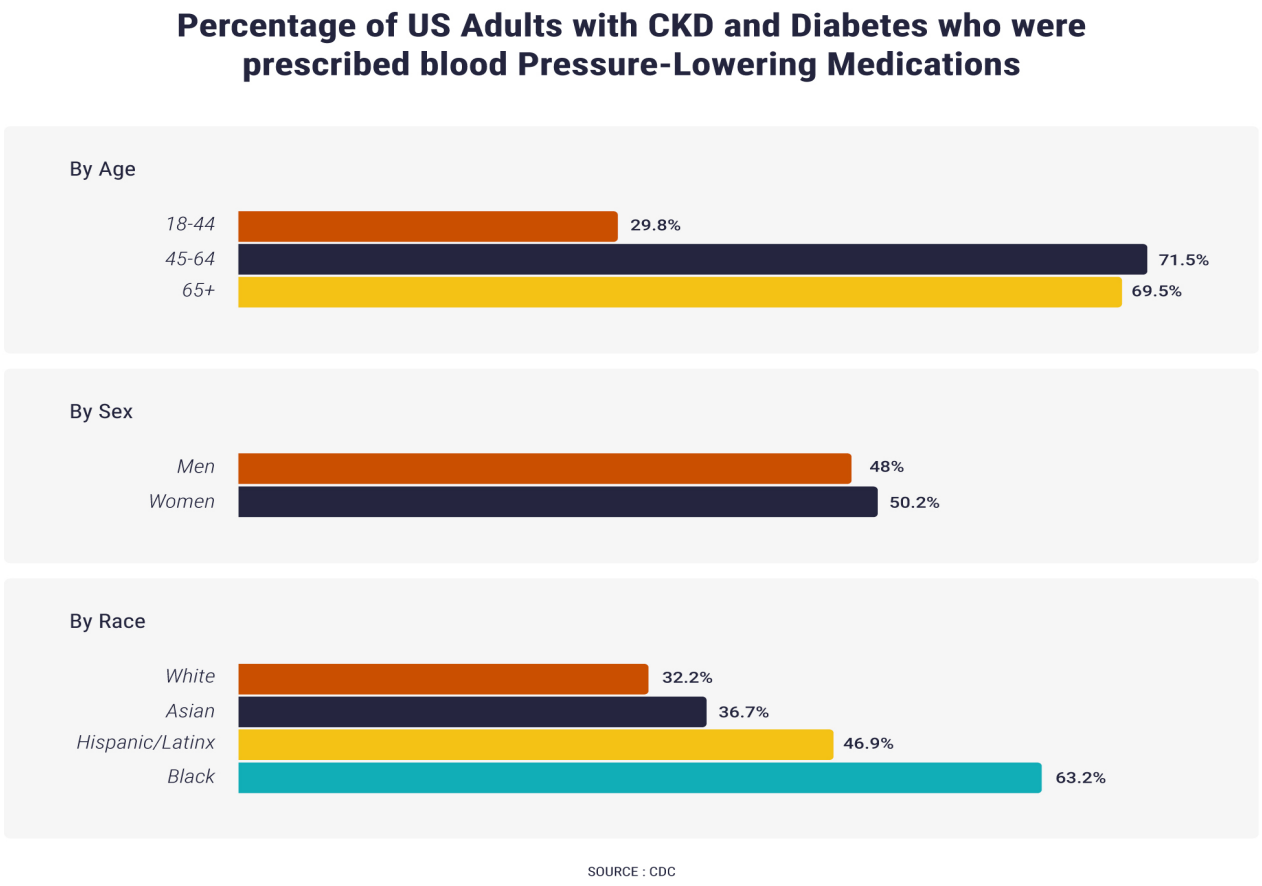
- **Measure UACR and eGFR at least once a year in all patients with T2DM, regardless of treatment**
- Other high-risk individuals,[a] including those with hypertension or CV disease
  - Initiation, frequency, and cessation of CKD screening should be individualized based on kidney and CV risk profiles

[a]Older age, race/ethnicity, systemic diseases that impact kidneys, family history of kidney disease, genetic risk factors, poor access to healthcare or low socioeconomic status, high-risk occupations and environmental exposures, prior AKI, preeclampsia, exposure to nephrotoxins, and obesity.

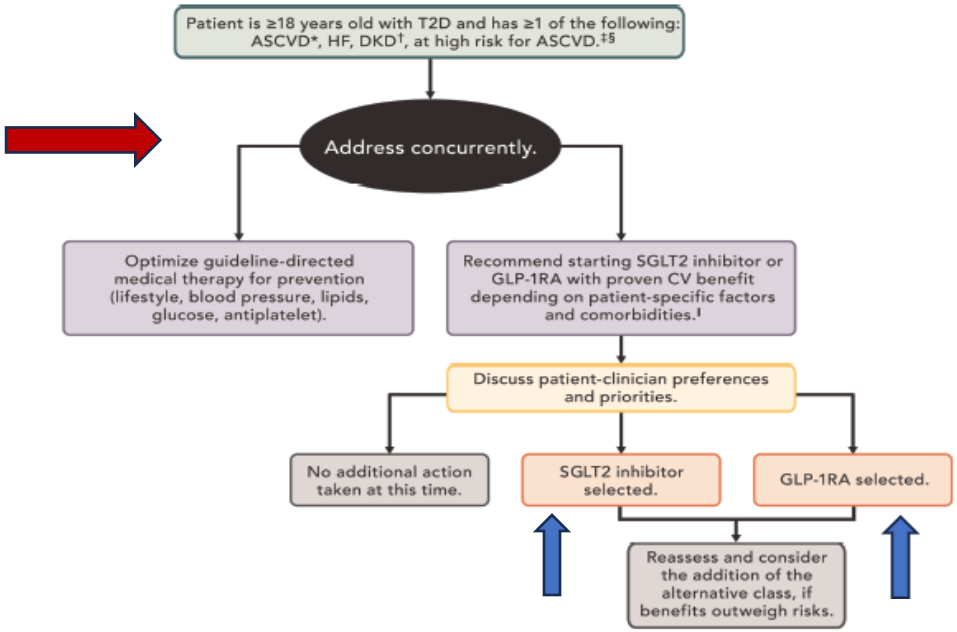
AKI, acute kidney injury.

1. American Diabetes Association. *Diabetes Care*. 2023;46(suppl 1):S1-S291. 2. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. *Kidney Int*. 2022;102(5S):S1-S127. 3. Berns JS. *Clin J Am Soc Nephrol*. 2014;9:1988-1992.

CKD is Disproportionately Higher in African Americans



Re-Stratification of T2D Priorities has Radically Shifted the Roles of Newer Diabetes Therapies—Especially for the High-Risk Groups!



*ASCVD is defined as a history of an acute coronary syndrome or MI, stable or unstable angina, coronary heart disease with or without revascularization, other arterial revascularization, stroke, or peripheral artery disease assumed to be atherosclerotic in origin.

†DKD is a clinical diagnosis marked by reduced eGFR, the presence of albuminuria, or both.

‡ Consider an SGLT2 inhibitor when your patient has established ASCVD, HF, DKD or is at high risk for ASCVD. Consider a GLP-1RA when your patient has established ASCVD or is at high risk for ASCVD.

§ Patients at high risk for ASCVD include those with end organ damage such as left ventricular hypertrophy or retinopathy or with multiple CV risk factors (e.g., age, hypertension, smoking, dyslipidemia, obesity).

‖ Most patients enrolled in the relevant trials were on metformin at baseline as glucose-lowering therapy.

ASCVD = atherosclerotic cardiovascular disease; CV = cardiovascular; DKD = diabetic kidney disease; eGFR = estimated glomerular filtration rate; GLP-1RA = glucagon-like peptide-1 receptor agonist; HF = heart failure; MI = myocardial infarction; SGLT2 = sodium-glucose cotransporter-2; T2D = type 2 diabetes

Figure 10.3—Approach to risk reduction with SGLT2 inhibitor or GLP-1 receptor agonist therapy in conjunction with other traditional, guideline-based preventive medical therapies for blood pressure, lipids, and glycemia and antiplatelet therapy. Reprinted with permission from Das et al. (220).

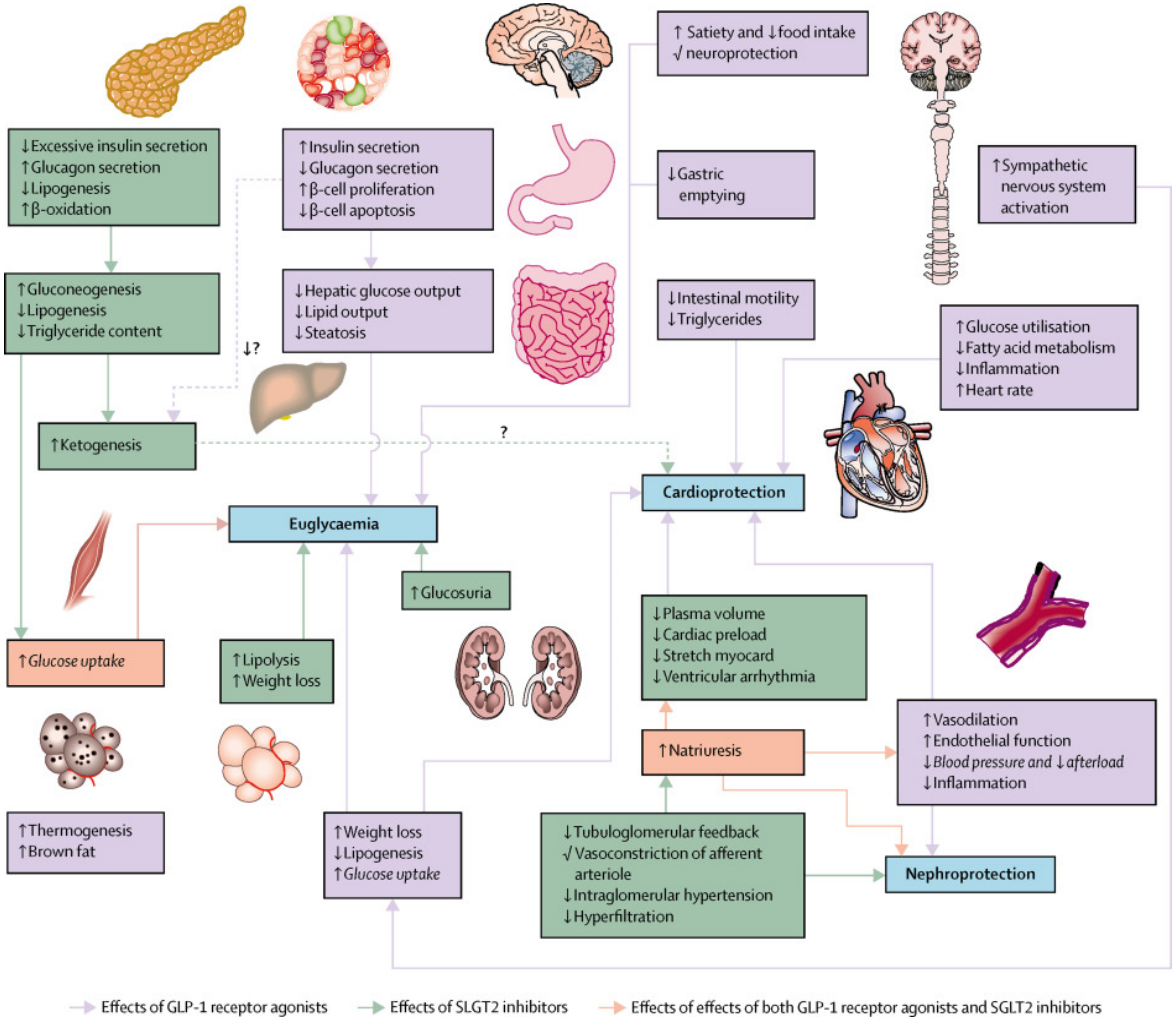
Figure 10.3—Approach to risk reduction with SGLT2 inhibitor or GLP-1 receptor agonist therapy in conjunction with other traditional, guideline-based preventive medical therapies for blood pressure, lipids, and glycemia and antiplatelet therapy

Question: What is the role of clinical guidelines for providing *specific-population evidence* of effectiveness of recommended therapies, rather than convey the implicit assumption of *broad-based efficacy* ("good for all")? How urgent is their use in high-risk populations?****

American Diabetes Association Professional Practice Committee. *Diabetes Care.* 2022;45(Suppl. 1):S144-S174.

To Optimize Beneficial Effects of the Newer Agents in the Highest –Risk Groups We Must Invest Trust in the Science!

The science of the MOA for SGLT2i's and GLP-1 RAs is well-established and presumed to be uniformly applicable



SGLT2 Inhibitors: a Powerful and Flexible New Class in Management of T2D

Summary of findings for clinical CV outcomes for the SGLT2 inhibitors

Table 1

CV Outcomes With SGLT2 Inhibitors in Recent Trials[a]

Outcome	Canagliflozin	Dapagliflozin	Empagliflozin
CV death, nonfatal MI, or nonfatal stroke	0.86 (0.75-0.97)[b]	0.93 (0.84-1.03)	0.86 (0.74-0.95)
CV death	0.87 (0.72-1.06)	0.98 (0.81-1.17)	0.62 (0.49-0.77)
CV death or HHF	0.78 (0.67-0.91)	0.83 (0.73-0.95)	0.66 (0.55-0.79)
All-cause mortality	0.87 (0.74-1.01)	0.93 (0.82-1.04)	0.68 (0.57-0.82)
HHF	0.67 (0.52-0.87)	0.73 (0.61-0.88)	0.65 (0.50-0.85)
MI	0.89 (0.73-1.09)	0.89 (0.77-1.01)	0.87 (0.70-1.09)
Stroke	0.87 (0.69-1.09)	1.01 (0.84-1.21)	1.18 (0.89-1.56)

[a] Results of the VERTIS (ertugliflozin) trial are not included because they have not been published yet.
[b] Results are given as HRs, with CIs in parentheses.
CV: cardiovascular; HF: heart failure; HFF: hospitalization for HF; HR: hazard ratio; MI: myocardial infarction; SGLT2: sodium-glucose cotransporter 2.
Source: References 9, 20, 22.

***The effects on outcomes show variability, but overall are reflective of clinical benefit. However, these data do not address the lack of demonstrated benefit in minority populations in the RCTs to date. Do we advise their use?**
MOST CERTAINLY YES!

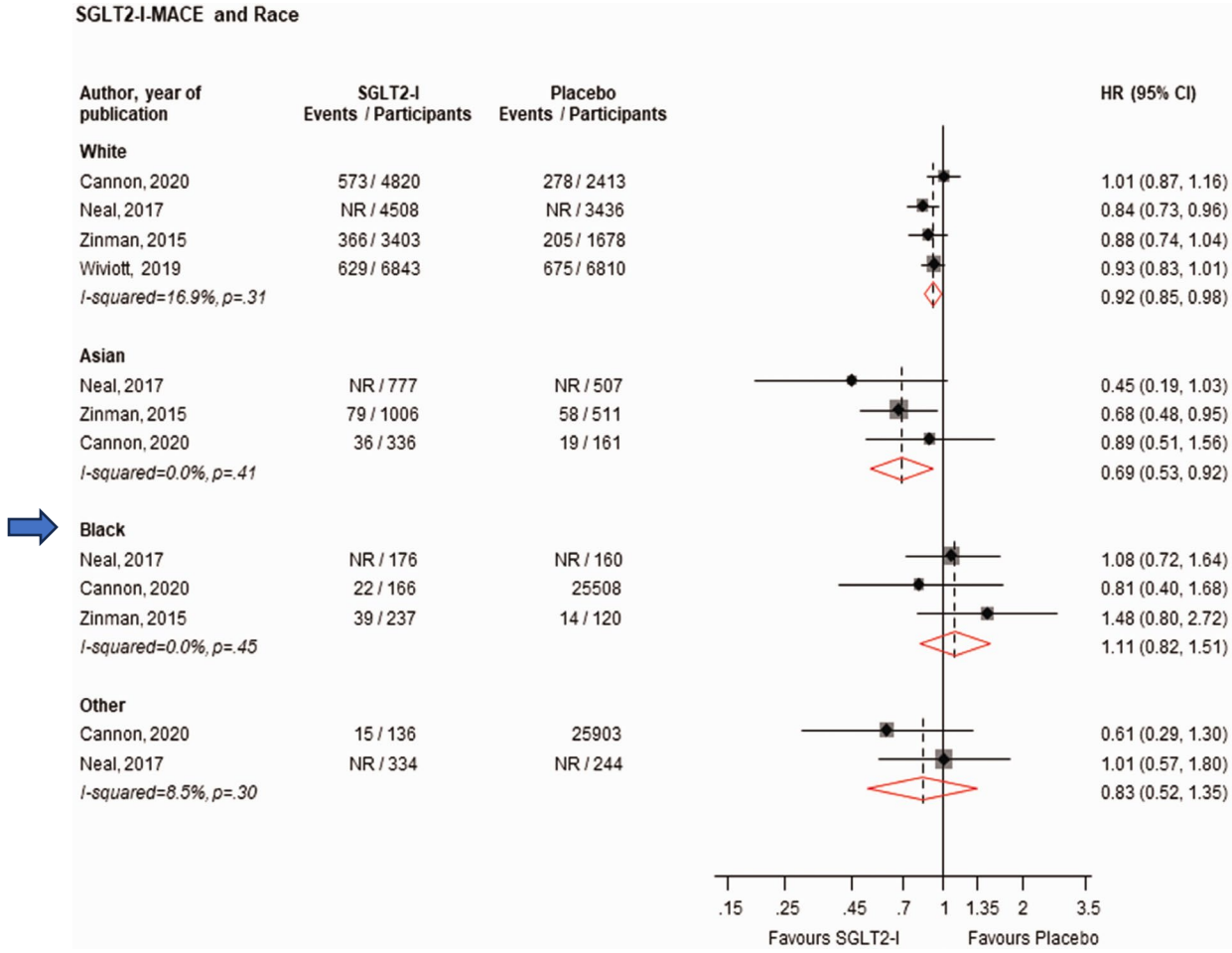
SGLT2 Inhibitors now have impressively expanded indications

Medication	Expanded Indications
Bexagliflozin	—
Canagliflozin	…to reduce to reduce the risk of MACE* in adults with T2DM and established CVD …to reduce the risk of ESKD, doubling of serum creatinine, CV death, and hospitalization for HF in adults with T2DM and diabetic nephropathy with albuminuria
Dapagliflozin	…to reduce the risk of hospitalization for HF in adults with T2DM and established CVD or multiple CV risk factors …to reduce the risk of CV death and hospitalization for HF, and urgent HF visit in adults with heart failure …to reduce the risk of sustained eGFR decline, ESKD, CV death, and hospitalization for HF in adults with CKD at risk of progression
Empagliflozin	…to reduce the risk of CV death and hospitalization for HF in adults with HF …to reduce the risk of CV death in adults with T2DM and established CVD
Ertugliflozin	—
Sotagliflozin	…to reduce the risk of CV death, hospitalization for HF, and urgent HF visit in adults with HF or T2DM with CKD and other CV risk factors

CKD, chronic kidney disease

*Composite of CV death, nonfatal MI, nonfatal strok

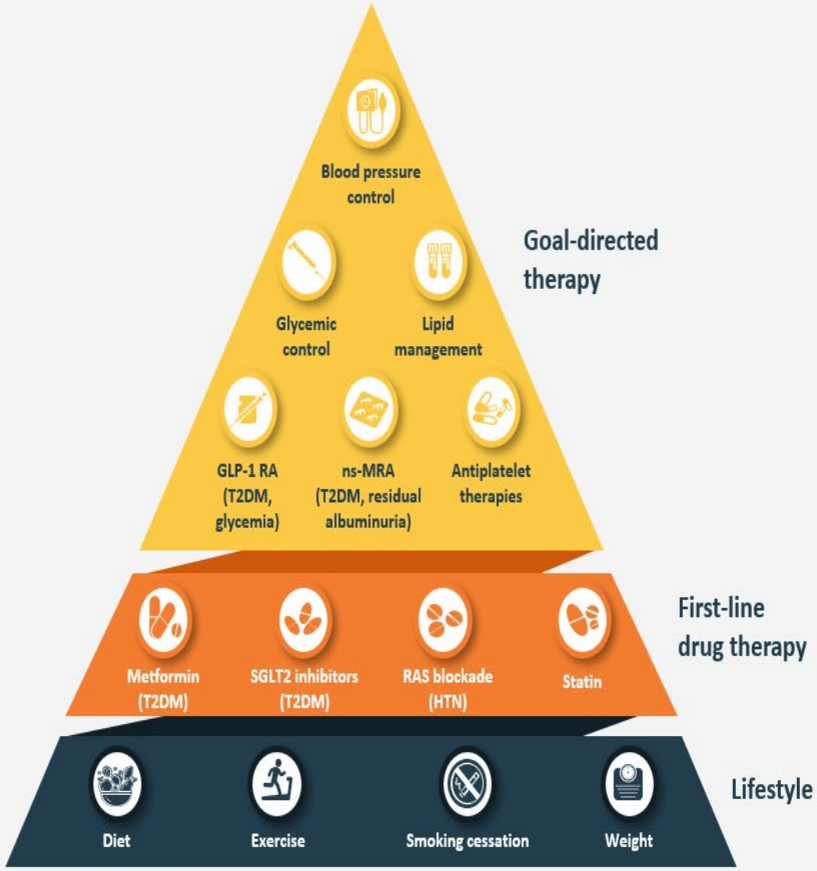
Impact of SGLT2 inhibitors in minority populations studied in RCTs*



***The trend for Blacks is toward *no clinical impact*, but is confounded by wide variability, perhaps once again secondary to small numbers.**

PATIENTS WITH CKD AND T2DM SHOULD BE TREATED USING A COMPREHENSIVE APPROACH

KDIGO 2022 Draft Clinical Practice Guideline for Diabetes Management in CKD

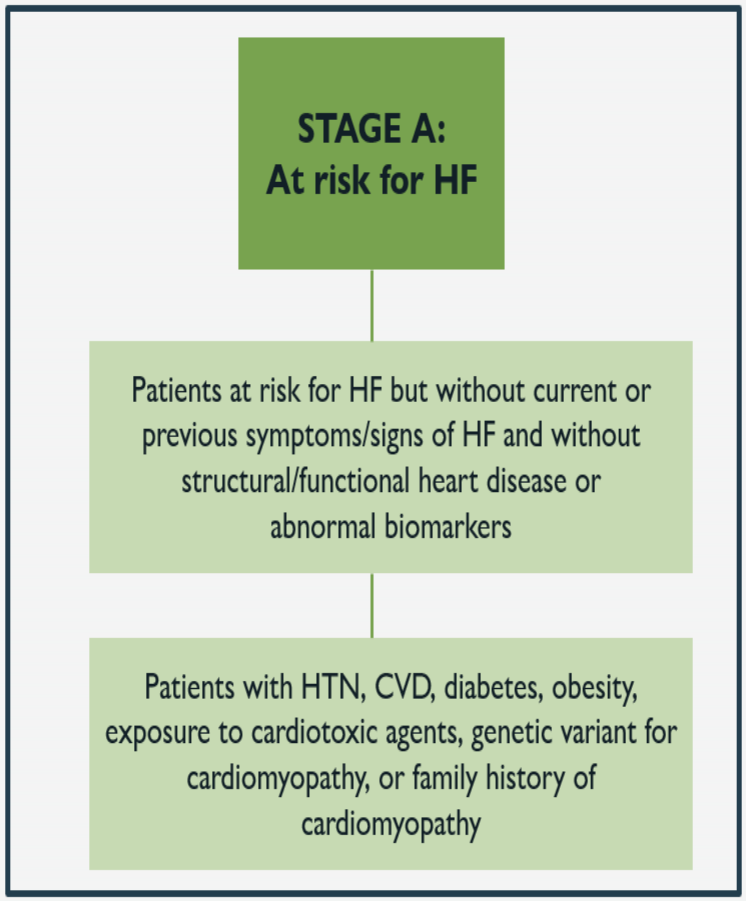


HTN, hypertension; ns-MRA, nonsteroidal mineralocorticoid receptor antagonist; RAS, renin-angiotensin system.

Adapted from Kidney International,[1] Vol 102, Issue 55 Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group, "KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease," Pages S1-S127, Copyright 2022, with permission from Elsevier.

1. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. *Kidney Int.* 2022;102(5S):S1-S127.

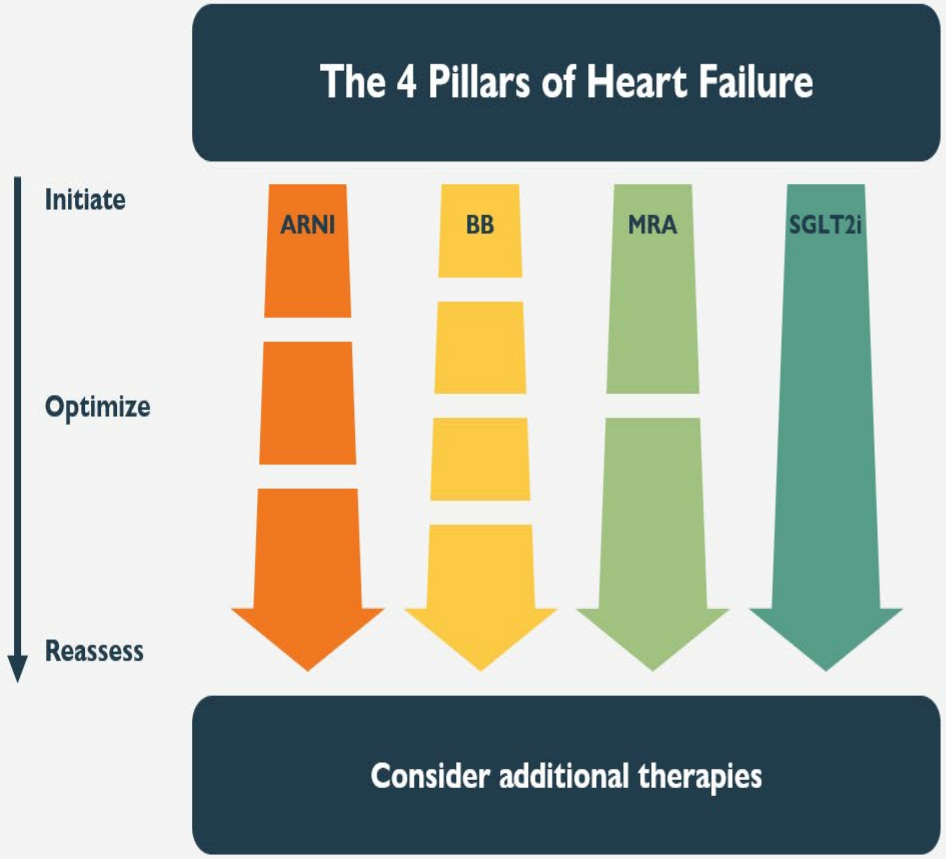
ACC/AHA RECOMMENDATIONS FOR PATIENTS AT RISK FOR HF (STAGE A: PRIMARY PREVENTION)



From Heidenreich, PA et al.[1] Reprinted with permission. *Circulation*. 2022;145:e876-e895. ©2022 American Heart Association, Inc.

1. Heidenreich PA, et al. *Circulation*. 2022;145(18):e876-e894.

A FOUR PILLAR APPROACH TO MANAGING T2DM COMPLICATIONS



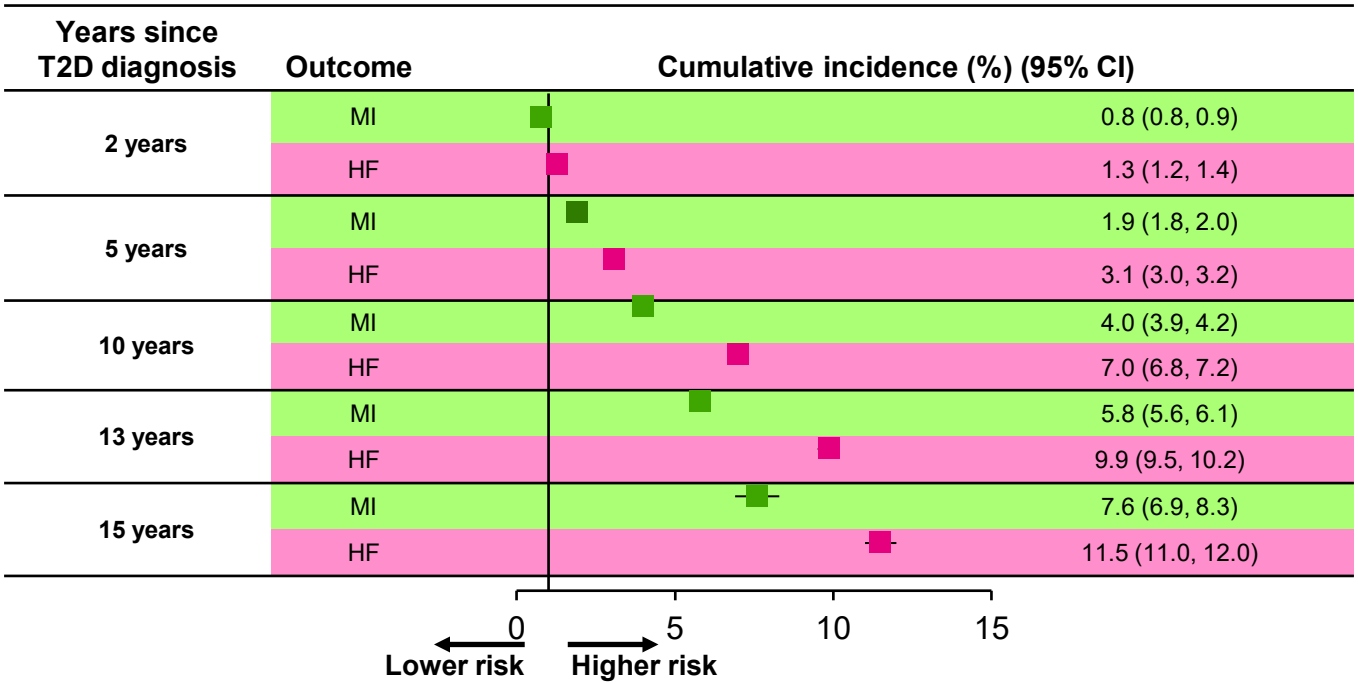
- In **patients with HF and T2DM, the use of SGLT2i is recommended** for the management of hyperglycemia and to reduce HF-related morbidity and mortality
- In patients with **T2DM and either established CVD or at high CV risk, SGLT2i should be used** to prevent hospitalizations for HF

ARNI, angiotensin receptor-neprilysin inhibitors; BB, beta blocker; MRA, mineralocorticoid receptor antagonists.

1. Straw S, et al. *Open Heart*. 2021;8(1):e001585.

HF is more incident than MI in patients with T2D irrespective of the duration of disease

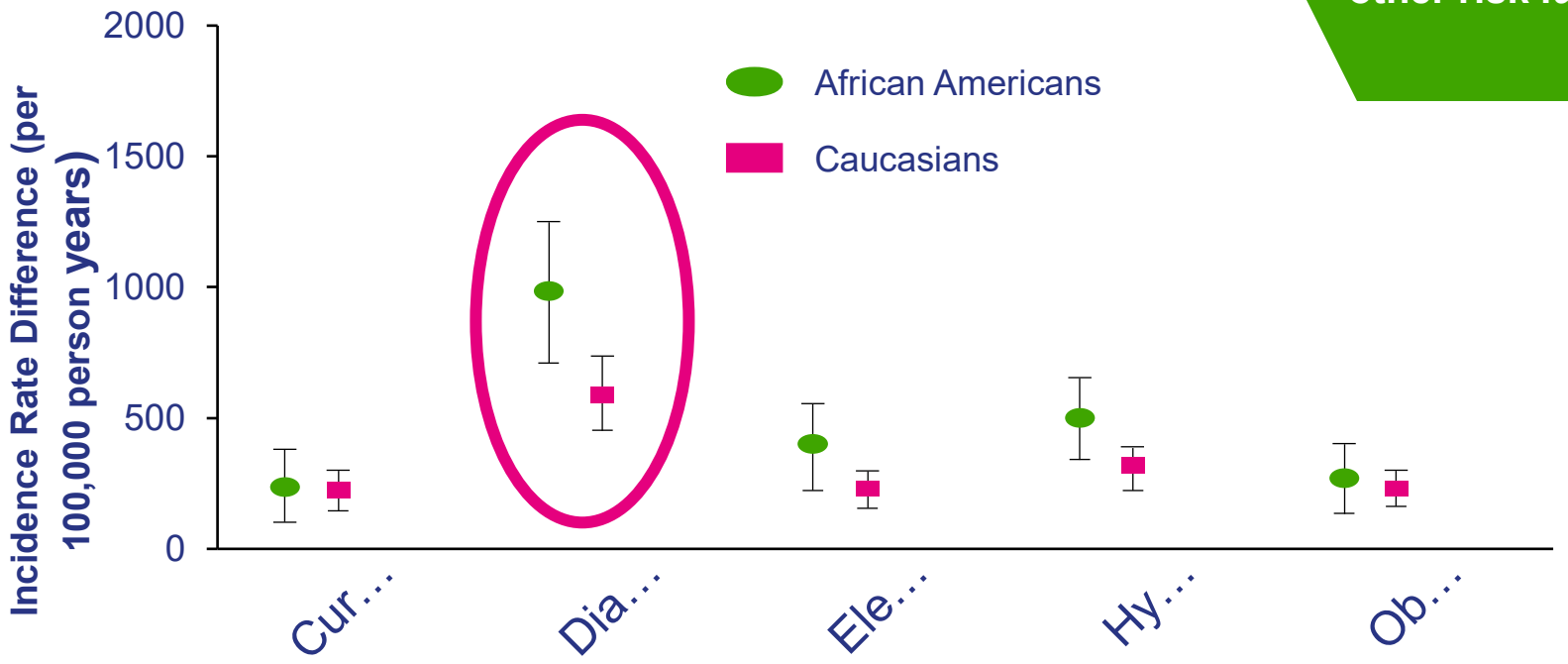
- Estimated cumulative incidence of MI and HF in 135,199 T2D patients from a large US integrated healthcare delivery system at different periods post-T2D diagnosis



CI, confidence interval; HF, heart failure; MI, myocardial infarction; T2D, Type 2 diabetes
Jejin An, et al. Presented at 79th Scientific Sessions of the American Diabetes Association; June 7th–11th, 2019; San Francisco, CA, USA; poster 422-P

The ARIC study: Population burden of HF is attributable to modifiable risk factors---greater urgency for the African American population!

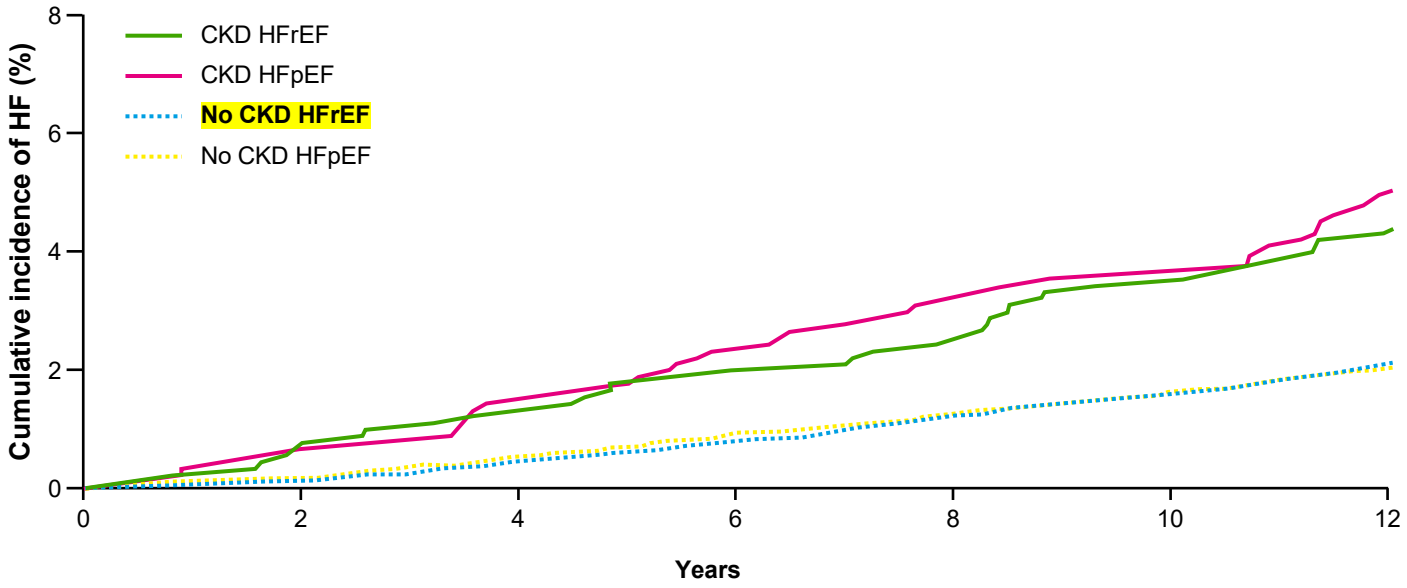
Diabetes was the most important determinant of development of HF compared to other risk factors



ARIC, Atherosclerosis Risk in Communities; HF, heart failure.
Avery CL et al. J Am Coll Cardiol. 2012;60:1640-6.

Declining renal function has been shown to increase the risk of both HFpEF and HFrEF--- An Urgent Problem in High-risk populations!

Incidence rates of HF are higher in those with CKD compared with those without



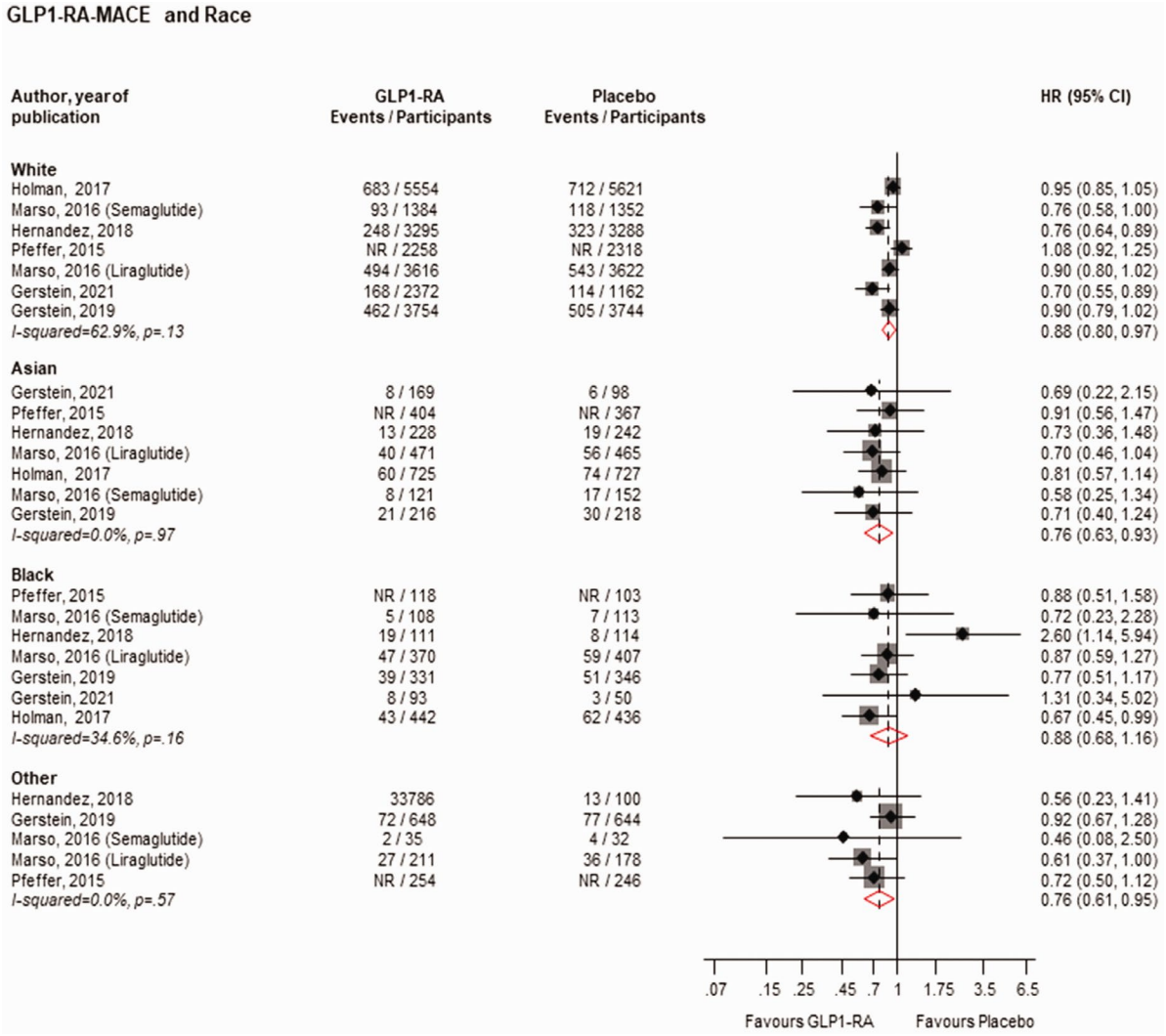
CKD, chronic kidney disease; HF, heart failure; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction
Nayor M, et al. *Eur J Heart Fail* 2017;19:615–623

GLP-1 RAs: Now with Expanded Indications

Medication	Expanded Indications
Dulaglutide	…to reduce the risk of MACE* in adults with T2DM who have established CVD or multiple CV risk factors
Exenatide once-weekly	—
Liraglutide	…to reduce the risk of MACE* in adults with T2DM and established CVD
Lixisenatide	—
Semaglutide/SC	…to reduce the risk of MACE* in adults with T2DM and established CVD
Semaglutide/PO	—

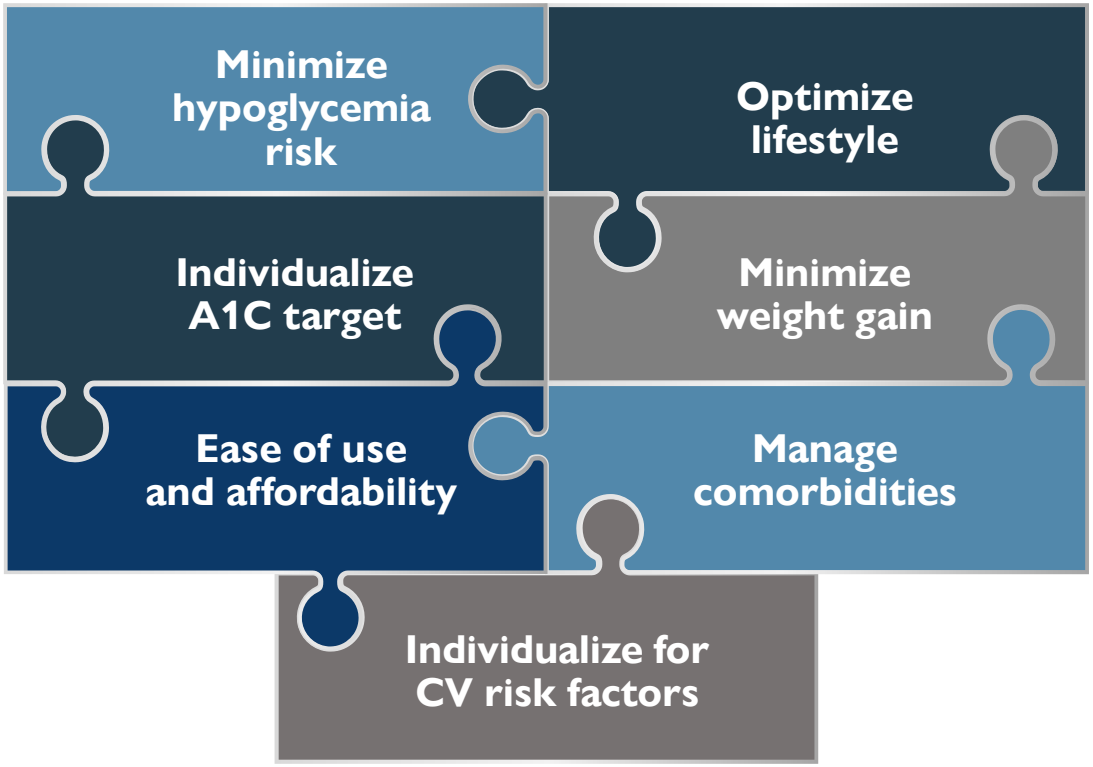
*Composite of CV death, nonfatal MI, nonfatal stroke

Impact of GLP-RAs in minority populations studied in RCTs*



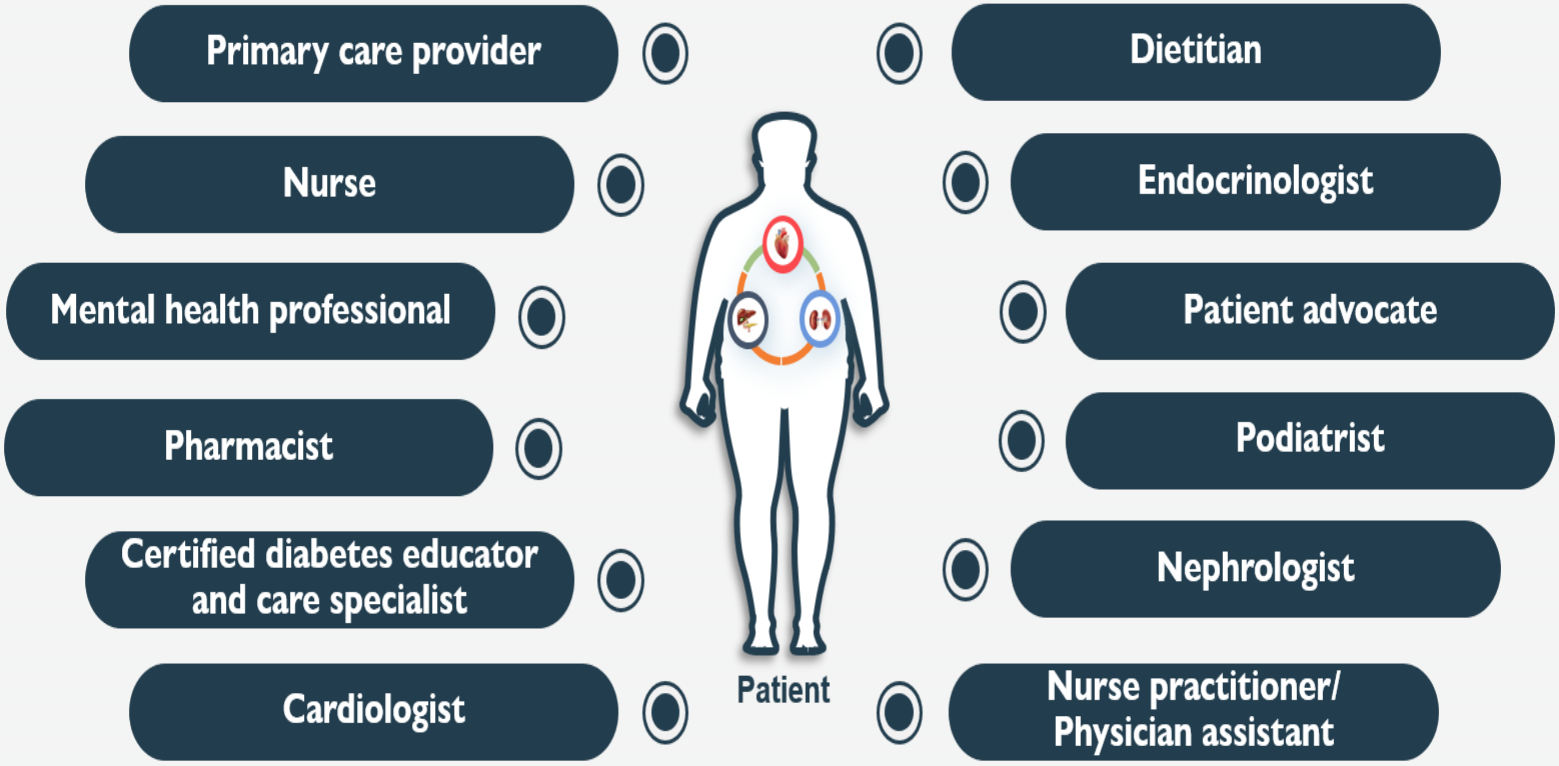
***The certainty of clinical impact for Blacks is confounded by wide variability, perhaps secondary to small numbers.**

Principles of Care for High-risk Patients Must Be Comprehensive and Multifactorial



Garber AJ et al. *Endocr Pract.* 2020;26:107-139.

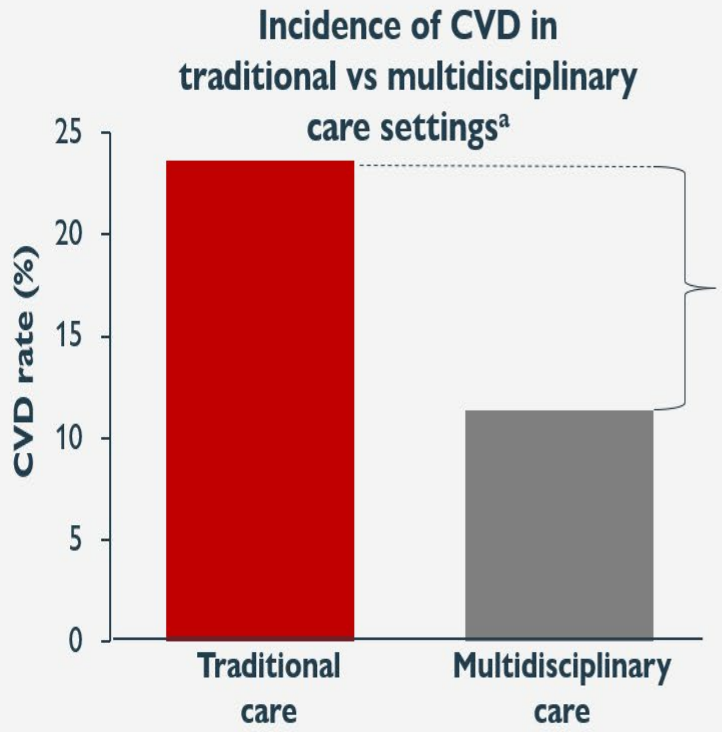
A COLLABORATIVE MULTIDISCIPLINARY TEAM SHOULD DRIVE PATIENT CARE[1,2]



1. American Diabetes Association. *Diabetes Care*. 2023;46(suppl 1):S1-S291. 2. Das SR, et al. *J Am Coll Cardiol*. 2020;76:1117-1145.

Based on a fictional patient developed for this presentation.

A MULTIDISCIPLINARY APPROACH IMPROVES CV OUTCOMES IN PATIENTS WITH T2DM[1,2]



Patients treated using a multidisciplinary approach had a

52% lower

incidence rate of CVD

[a]RAMP-DM (Risk Assessment and Management Programme–Diabetes Mellitus), which included intervention by an advanced practice nurse, family medicine specialist, and hospital specialists as needed.[2]

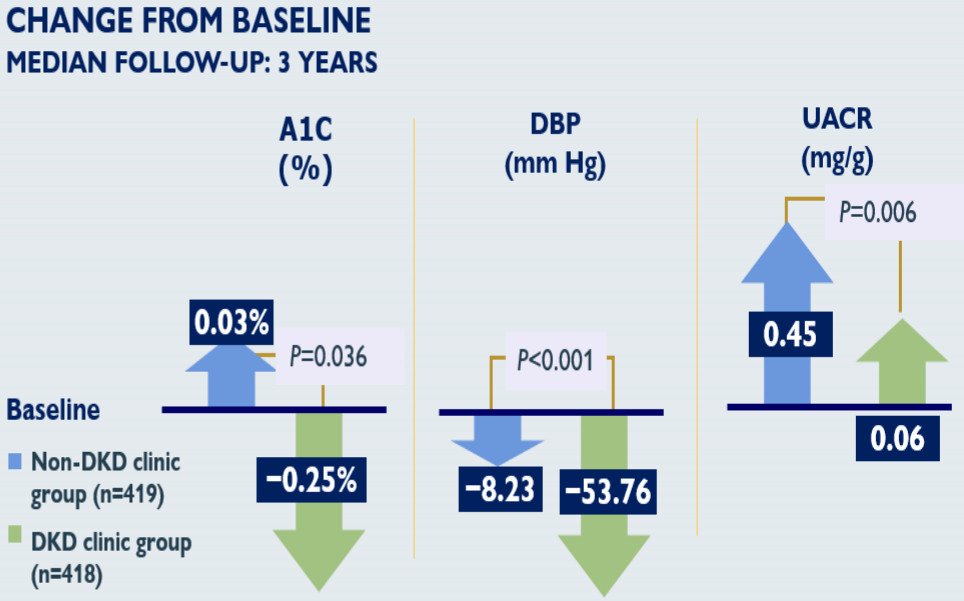
1. Wan EYF, et al. *Diabetes Care*. 2018;41:49-59. 2. Fung CS, et al. *BMC Fam Pract*. 2012;13:116.

COLLABORATION BETWEEN SPECIALISTS IS ASSOCIATED WITH IMPROVEMENT IN CLINICAL OUTCOMES IN DKD

DKD CLINIC

- Endocrinologist
- Dietitian
- Advanced practice nurse
- Nephrologist
- Clinical pharmacist
- Social worker

Patients referred to a multidisciplinary clinic experienced significant reductions in A1C, DBP, and UACR



- **Multidisciplinary care reduced the risk** of progression to stage 5 CKD by **45%** (*P*=0.004)[a]

[a]Hazard ratio„ 0.55 (95% CI, 0.36-0.83) vs care only in a diabetes center. Multivariable Cox regression adjusted for demographics and clinical factors. CKD stage 3 or 4 at baseline. N=837 patients with care initiated at a diabetes center in Singapore.
DBP, diastolic blood pressure; DKD, diabetic kidney disease.
Low S, et al. *J Diabetes*. 2018;10:572-580.

New Strategies of Care for High-risk Patients Must Be Creative, Comprehensive, and Multifactorial

Unlock a world of care and support with the HOVMD Mobile Medical Clinics

Medication Management & Refill Clinics

Our Pharmacists provide medication therapy management & refills, to ensure patients receive the right medications and achieve optimal health outcomes.

Nutrition & Cooking Demonstrations

With our dedicated team of dieticians, we offer comprehensive nutrition counseling that is designed specifically for the patients' unique needs.

Remote Monitoring

We offer remote patient monitoring services, allowing patients to stay connected to their providers through NO COST Cellular Blood Glucose and Blood Pressure Monitors.

New Strategies of Care for High-risk Patients Must Be Creative, Comprehensive, and Multifactorial

HOVMD

Healing Our Village Concierge Medical Services

Bringing healthcare to your doorstep with our Mobile Medical Van

Our mobile clinic offers health screenings to help your residents optimize their health. Our experienced medical professionals will provide your residents with a comprehensive assessment, annual wellness visits, full laboratory services, EKGs & more..

We understand that accessibility is key when it comes to healthcare. Bringing healthcare to your community will decrease needless Emergency Room Visits.

NEW Pattern Management Approach

Table 3—Pattern care strategy

- Earlier use of home blood glucose monitoring to guide management
- Use of basal insulin earlier in the natural history

1. Home glucose monitoring and A1C measurements:
   - Keeping A1C <5.7% or <5.5% (39 or 37 mmol/mol) may be sufficient if these goals can be met by management with lifestyle change + metformin.
   - In patients requiring additional medication treatment, some home glucose monitoring will likely be needed to determine whether therapy in individual patients needs to be directed toward fasting vs. postprandial glucose levels.
   - Target glucose levels: fasting <100 mg/dL, 2-h postprandial <140 mg/dL
   - Early in the natural history, some monitoring of fasting glucose levels along with measurement of A1C levels is likely to be sufficient.
2. Management according to glucose patterns:

Fasting glucose <100 mg/dL	Postprandial glucose <140 mg/dL
Metformin	DPP-4 inhibitors
Basal insulin given in the evening	GLP-1 analogs
• Glargine—before supper	Pioglitazone
• Detemir—at bedtime	SGLT-2 inhibitors
Glipizide (1.25–5.0 mg) at bedtime	α-Glucosidase inhibitors
	Glinides before meals
	Short-acting insulin analogs before meals

3. It is difficult to achieve near-normal glucose levels with the use of either mealtime insulin, long-acting sulfonylureas, or premixed insulin, due to problems with hypoglycemia.

Phillips LS et al. Diabetes Care 2014; 37:2668-2676

REMOTE MONITORING – SECRET TO REDUCING HOPSITALIZATIONS

- Practice Expense CPT Codes for RPM:
- 99453 Patient Onboarding (one-time use) $19.43
- 99454 Remote Patient Monitoring (monthly) $64.15
-
- Professional Services CPT Codes for RPM:
- 99457 Medical Doctor / Qualified Health Professional – 30 minutes (monthly) $51.54 non-facility and $32.44 facility


FORA® 6 Connect
Blood Glucose and β-Ketone Monitoring System
FORA 6
Gold Advance
Connect
Multi-Functional Monitoring System
Bluetooth
β-Ketone + Blood Glucose
Gold technology for High Accuracy
LCD Backlight
FORA
LANCETAS ESTÉRILES
100
FORA
0.5 µL / 5 seconds
50
FORA 6 Connect
M
• FORA 6 Connect Meter • 50 Blood Glucose Test Strips • 100 FORA Lancets
• FORA Painless Design Lancing Device • Owner's Manual & Carry Case

Technology Enabled Care
Digital Health – Diabetes Education / Medication Review

TEST N'GO VOICE

- Pharmacists and CDEs work with patients on BG Pattern Management
- E-visits performed at home, in pharmacies and/or clinics
- Dual Platform Bluetooth Connectivity
- Talking Functionality – hear results in English or Spanish
  Connects to iFORA on iOS and Android mobile devices
- Provide easy to understand report card that is shared with PCP, Patient and Family Advocate

Advanced GDH-FAD strip
No-coding, 0.5uL and 5 seconds
Capillary and Venous blood
No interference from Maltose

LCD Backlight
Easy to read even in a dim environment

Larger Easy-to-Read Display

Speaks in Spanish and English

AAA Batteries - Easy to find and replace

PRICES – INCLUDE PHARMACIST CONSULTATION - PRIVATE
$25 USD – Bluetooth VOICE meter
$25 USD – 50 Strips
TENDER – determined by country

JOIN THE HEALING OUR VILLAGE (HOV) PHARMACY NETWORK

Healing Our Village *provides disease state management and medicaton reconciliation to Medicaid Managed Care organizatons, physician offices, hospitals and community health centers for the past 10 years. We are now expanding our operation Nationwide. We are looking for clinical pharmacists and independent pharmacies to join the HOV Network. By joining the network you will receive the following:*

- *Discounted web based training in chronic disease management with a focus on; Diabetes,CAD, COPD/ASTHMA, Heart Failure, Obesity, Depression, HIV/AIDS, Medicaton Errors, Drug Abuse Preventon*
- *Access to HOV University with webinars on setting up Specialty Pharmacy Practces; Diabetes Care Center, 340B pharmacy and much, much more*
- *Access to HOV educational materials (i.e. books, videos, flip charts, brochures, etc.)*
- *Assess to "Ask the Expert" portal for patient consultation*
- *Participation as a Network Pharmacy in our Managed Medicaid Programs in your state. This will provide extra revenue for every patient provided with a Comprehensive Medicaton Review. (CMR)*

In order to participate in the HOV Pharmacy Network you must be willing to:

- *Sign a Business Associates Agreement with Healing Our Village to cover all Privacy and HIPPA requirements*
- *Be willing to carry the Foracare bluetooth meter and strips as part of your inventory*
- *Be available to schedule patient consultation during business hours and off hours (minimum of 10 hours per week)*
- *Be willing to provide point of care testing in your pharmacy to include: blood pressure checks and blood glucose testing (Note: based on CLIA regulations in your state)*
- *Willing to set up an "education corner" in your pharmacy for videos and print materials*

Are you interested in Minority Health and Eliminating health Disparities?

Are you interested in MTM and Diabetes Education?

Are you interested in increasing your pharmacy revenue through patient consultation?

Healing Our Village is a minority owned business based in Atlanta Georgia with operations in Washington DC and Los Angeles, California. HOV was founded in 2009 by Dr Lenore T. Coleman with the intent to eliminate health disparities worldwide. Dr. Coleman has devoted her career to improving the health and wellbeing of minority populations. With an emphasis on health education and advocacy, Healing our Village provides disease management/medication therapy management to African American and Latino populations throughout the United States, Caribbean and Africa. HOV has AADE certified diabetes education centers and CDC approved DPP sites providing "live" and web-based classes on diabetes, nutrition and chronic disease management.

FOR MORE INFORMATION; CONTACT DR. LENORE T. COLEMAN AT 800 788 0941

Case Presentation

John, age 58

Patient Case of Uncontrolled Type 2 Diabetes

John, age 58

John is a 58-year-old African American diagnosed with T2DM six years ago.

He feels well and expresses no concerns at today's routine office visit.

He is compliant with his current medications

He checks his FPG "sometimes" and reports a range of 180-350 mg/dL

He tries to exercise 2-3 times a week but has trouble finding the time; expresses concerns about his weight

Patient Case of Uncontrolled Type 2 Diabetes

John, age 58

Medical history:

T2DM x 6 years

HTN

HLD

Obesity

BPH

CKD (Stage ?

Father, paternal Uncle died of CVD, <62 y.o.

Surgical History:

Lasik

Appendectomy

Social History:

~2 drinks/week

Denies tobacco

Stages of Chronic Kidney Disease

Stage of CKD	eGFR result	What it means
Stage 1	90 or higher	- Mild kidney damage - Kidneys work as well as normal
Stage 2	60-89	- Mild kidney damage - Kidneys still work well
Stage 3a	45-59	- Mild to moderate kidney damage - Kidneys don't work as well as they should
Stage 3b	30-44	- Moderate to severe damage - Kidneys don't work as well as they should
Stage 4	15-29	- Severe kidney damage - Kidneys are close to not working at all
Stage 5	less than 15	- Most severe kidney damage - Kidneys are very close to not working or have stopped working (failed)

Patient Case of Uncontrolled Type 2 Diabetes

John, age 58

Vitals:

Temp 98.7 F (37 C)

HR 56 bpm

RR 16

BP 150/90 mmHg

Ht 72 inches (183 cm)

Wt 250 lbs (113.4 kg)

BMI 34 kg/m²

WC 45 inches (114 cm)

Patient Case of Uncontrolled Type 2 Diabetes

John, age 58

Medications	
Metformin 1000 mg BID	Atorvastatin 40mg QD
Glimepide 4mg BID	Tamsulosin 0.4mg QD
Lisinopril 40mg QD	Aspirin 81 mg QD
Metoprolol 100mg BID	

Allergies: NKA

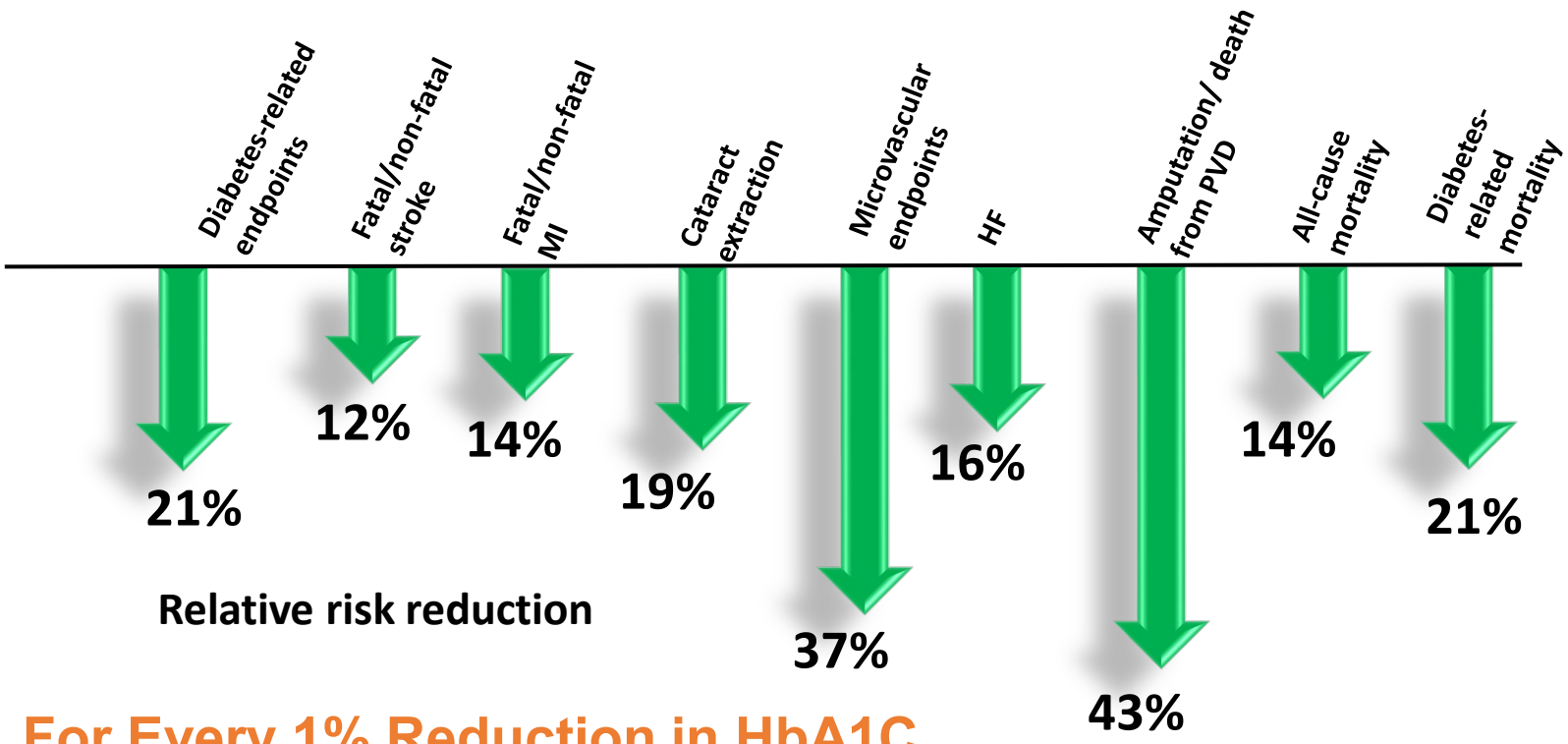
Patient Case of Uncontrolled Type 2 Diabetes

John, age

RELEVANT LABS (FASTING)	
Hemoglobin A1C	8.8%
LDL	120 mg/dL
HDL	45 mg/dL
Glucose	220 mg/dL
BUN	N20 mg/dL
Creatinine	1.4 mg/dL

Allergies: NKA

What are we trying to accomplish? Importance of Glycemic Control---*UKPDS*



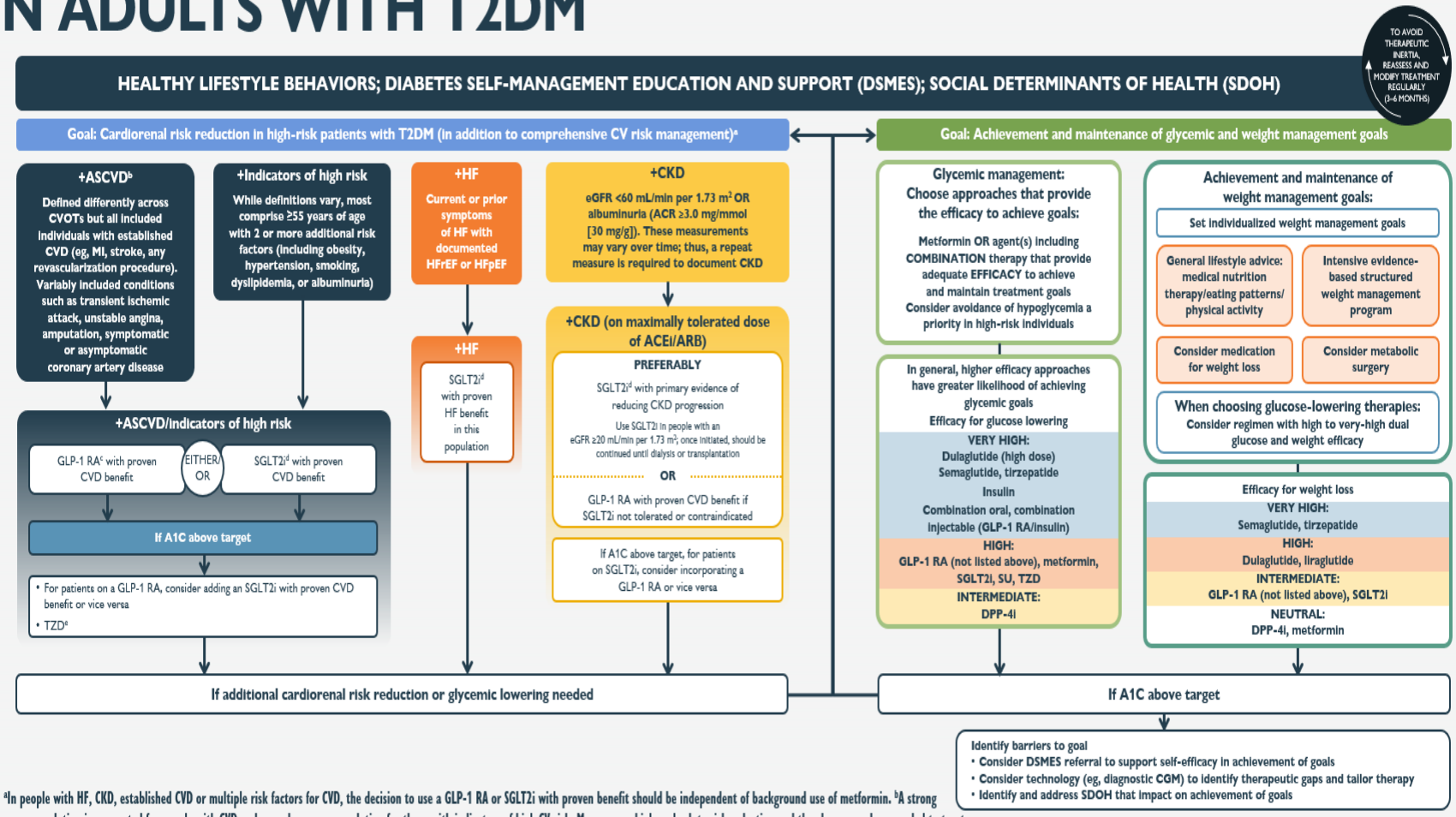
For Every 1% Reduction in HbA1C

Stratton IM et al. *BMJ*. 2000;321:405–412.

Setting Up a Framework for John's Treatment

1. What are the major issues that frame "individualization" of John's case?
2. What are your most urgent outcomes for John?
3. How does his current treatment plan align with the likelihood of achieving treatment goals?
4. Where does John "fit" with the current treatment recommendations? (ADA or AACE)
5. Do recent study results provide new insight into what might be preferred treatment for John?
6. What Would **You** do Next to Treat John's T2DM? Why?
7. What do you anticipate will be the greatest barriers?

PHARMACOLOGIC TREATMENT OF HYPERGLYCEMIA IN ADULTS WITH T2DM



[a]In people with HF, CKD, established CVD or multiple risk factors for CVD, the decision to use a GLP-1 RA or SGLT2i with proven benefit should be independent of background use of metformin. [b]A strong recommendation is warranted for people with CVD and a weaker recommendation for those with indicators of high CV risk. Moreover, a higher absolute risk reduction and thus lower numbers needed to treat are seen at higher levels of baseline risk and should be factored into the shared decision-making process. [c]For GLP-1 RA, CVOTs demonstrate their efficacy in reducing composite MACE, CV death, all-cause mortality, MI, stroke, and renal endpoints in individuals with T2DM with established/high risk of CVD. [d]For SGLT2i, CV/renal outcomes trials demonstrate their efficacy in reducing the risk of composite MACE, CV death, all-cause mortality, MI, HHF, and renal outcomes in individuals with T2DM with established/high risk of CVD. [e]Low-dose TZD may be better tolerated and similarly effective.

CVOT, cardiovascular outcomes trial; DPP-4i, DPP-4 inhibitor; HF, heart failure; HFpEF, HF with preserved ejection fraction; HFrEF, HF with reduced ejection fraction; NPH, neutral protamine Hagedorn; SU, sulfonylurea; TZD, thiazolidinedione.

 1. Davies MJ, et al. *Diabetes Care*. 2022;45(11):2753-2786. 2. American Diabetes Association. *Diabetes Care*. 2020;43(suppl 1):S1-S212. 3. American Diabetes Association. *Diabetes Care*. 2023;46(suppl 1):S1-S291.

Urgency for New Strategies in T2DM Management for the Highest Risk Groups

- Disease reflects interplay between genetics, social history, and environment (where and how people live, work, play)
- Risk factor burden is higher and CV complications more prevalent (with earlier onset)
- SDOH play a highly important role (access to services, affordability)
- A **collaborative model of care** (team-based, community oriented) is considered essential (with earlier interventions)
- There is pressing need for **creative strategies** of care delivery!

Summary and Conclusions
"New Strategies for Diabetes Management: Making it Work for the Highest Risk Groups"

- T2D and its related complications are common occurrences especially in populations of high-risk, marginalized persons
- Reduce reliance on a "one size fits all" approach to treatments and assure that the evidence base for clinical guidelines is **broadly rigorous**
- Strengthen and broaden the use of collaborative care strategies, using new and where necessary, creative approaches!
- Adjust the guidelines narrative to accommodate "gap" areas in the evidence base, and strongly encourage the generation and collection of RWE in minorities who are recipients of newer therapies that may offer the prospect of ***improved outcomes*** for high-risk minorities
- Provide adequate emphasis on the role(s) of the SDOH and include them in clinical decision-making, including acknowledgement of bias!

Questions