

Supplementary Appendix

The Relationship between Average Glucose Levels and HbA1c Differs Across Racial Groups:

A Sub-study of the GRADE Randomized Trial

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B. Supplement Table S1. Discontinuation of study medications and use of non-study medications by racial/ethnic group

	All (n=1454)	Non-Hispanic White (n=534)	Non-Hispanic Black (n=389)	Hispanic White (n=327)	Other races (n=204)	p-value*
Permanent discontinuation of study medications up until CGM completion [†]	138 (9.5%)	35 (6.6%)	45 (11.6%)	28 (8.6%)	30 (14.7%)	0.003
Use of non-study medications up until CGM completion [‡]	89 (6.1%)	23 (4.3%)	31 (8.0%)	17 (5.2%)	18 (8.8%)	0.038
Permanent discontinuation of study medications [†] and/or use of non-study medications [‡] up until CGM completion	193 (13.3%)	48 (9.0%)	66 (17.0%)	39 (11.9%)	40 (19.6%)	<0.001
Use of non-study meds at time of CGM completion [‡]	47 (3.2%)	14 (2.6%)	13 (3.3%)	9 (2.8%)	11 (5.4%)	0.270
Proportion of participants with a change in therapy in the ~90 days prior to performance of CGM ^a						
New discontinuation of study medications ^b	35 (2.4%)	8 (1.5%)	7 (1.8%)	13 (4.0%)	7 (3.6%)	0.074
Change in non-study medications ^c	22 (1.5%)	5 (0.9%)	7 (1.8%)	5 (1.5%)	5 (2.5%)	0.439
Addition of per-protocol rescue insulin ^d	36 (2.5%)	12 (2.3%)	9 (2.3%)	9 (2.8%)	6 (3.0%)	0.919
New discontinuation of study medications ^b , change in non-study medications ^c , and/or addition of per-protocol rescue insulin ^d	90 (6.3%)	23 (4.4%)	23 (6.0%)	26 (8.0%)	18 (9.1%)	0.050

CGM- continuous glucose monitoring.

Other races- Asian American and Pacific Islanders, American Indian or race not identified.

* p-value from a chi-square test for differences in proportions among the four racial/ethnic groups.

[†] Permanent discontinuation of any of the protocol-specified study medications. This can include discontinuation of metformin, randomized study medication, and/or rescue insulin (if required per protocol due to meeting secondary/tertiary outcome). This does not include per protocol discontinuation of the randomized study medication due to meeting the secondary/tertiary outcome.

[‡] This does not include the use of non-study versions of an assigned study medication.

^a Assessed changes in therapy between the quarterly study visits before and after the CGM period. Excludes n=20 (1.4%) participants who were missing either the most recent quarterly visit prior to CGM or the next visit following CGM.

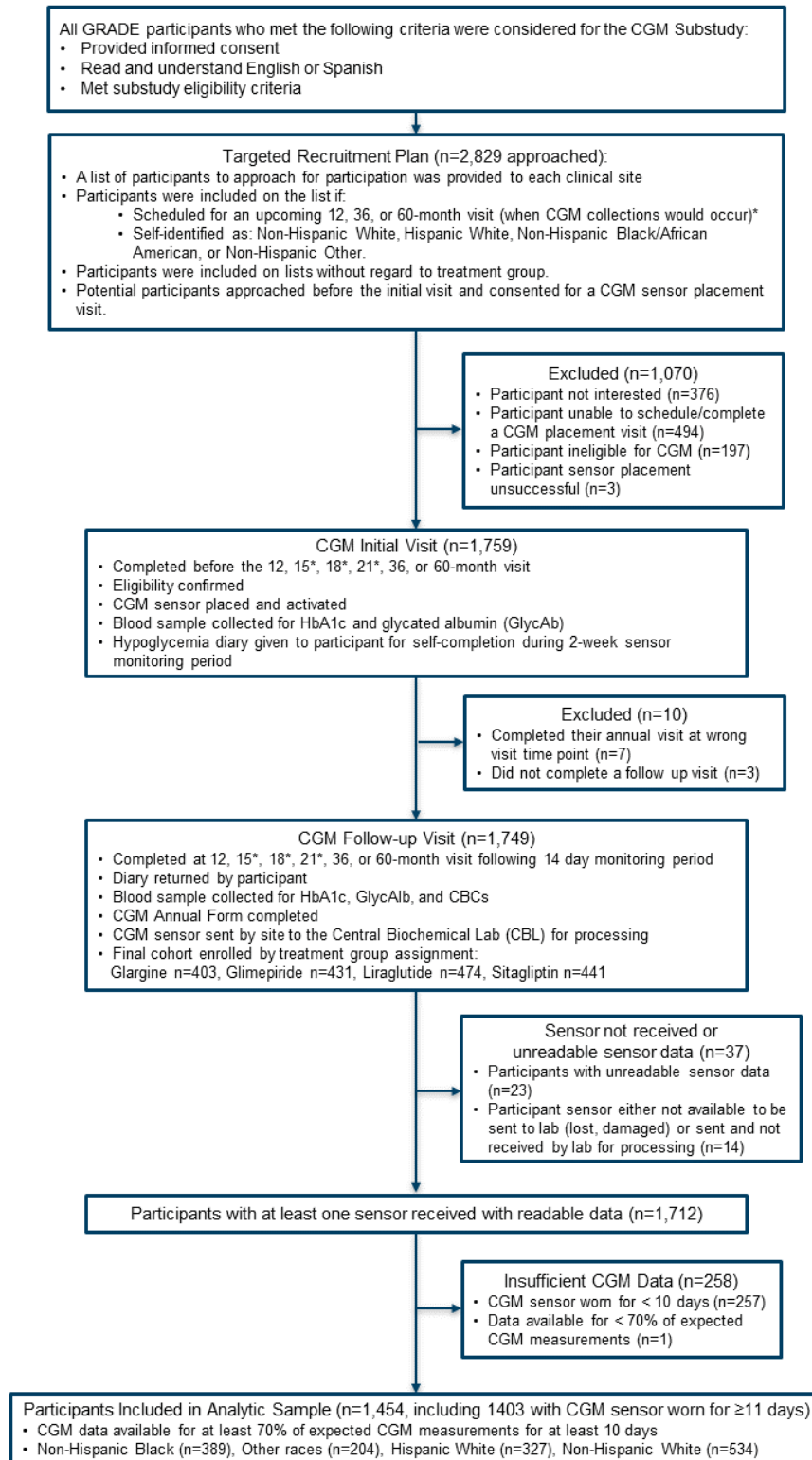
^b Stopping either metformin (does not count as a metformin discontinuation if participant is taking non-study metformin) and/or the randomly assigned medication between the study visits before and after the CGM.

^c Change in use of any of the non-study glucose-lowering/diabetes medications between the study visits before and after the CGM (e.g., using a non-study insulin at the visit before CGM but not at the visit after, not using a TZD at the visit before CGM but using a TZD at the visit after).

^d Started either glargine and/or aspart insulin between the study visits before and after the CGM.

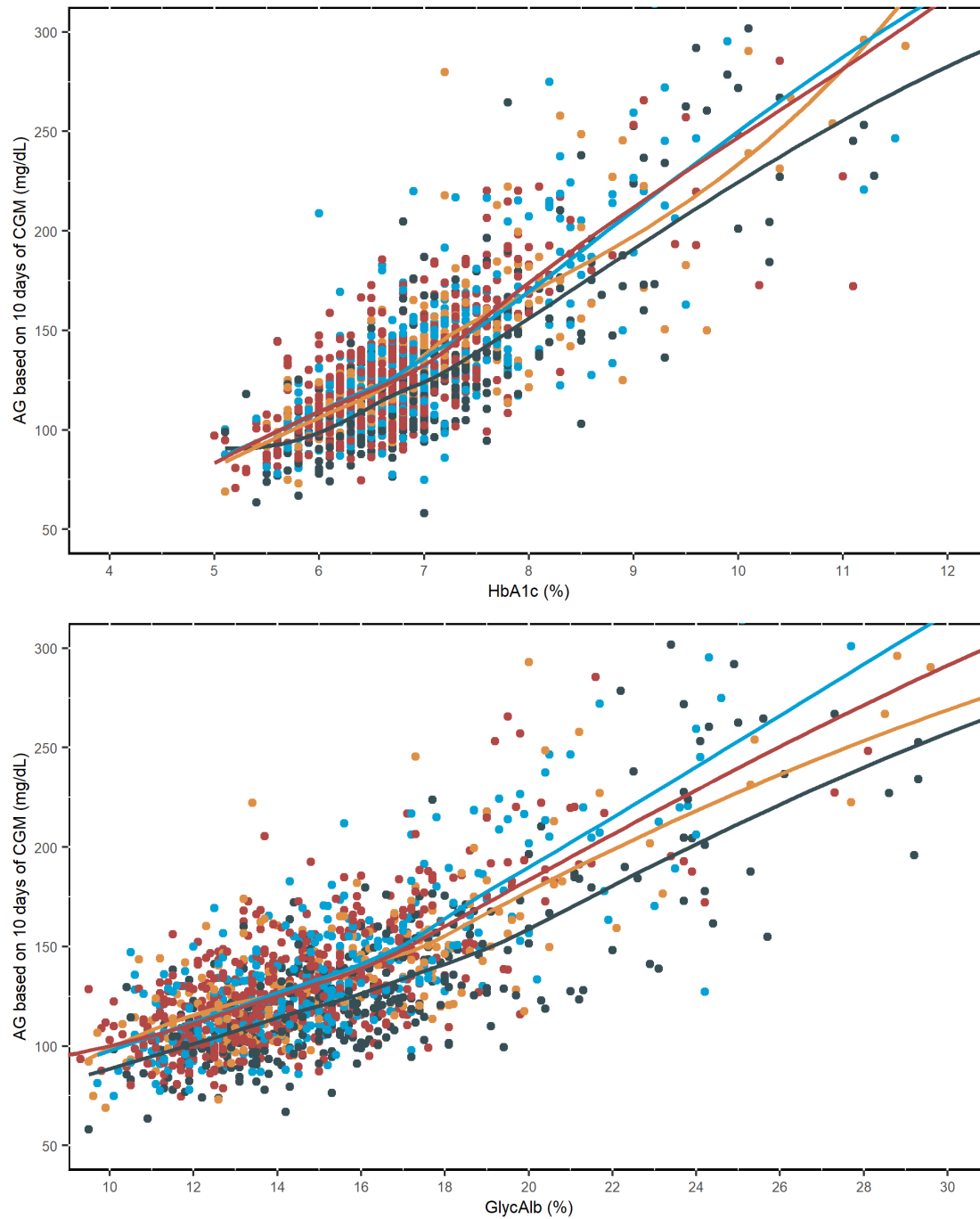
C. Supplement Figure S1. CONSORT Figure

Continuous Glucose Monitoring (CGM) Substudy



*Due to low numbers of upcoming 12-month visits, lists expanded to include 15, 18, and 21-month visits starting in May 2018

D. Supplement Figure S2. Relationship between HbA1c (top panel; %) and glycated albumin (bottom panel; %) with average glucose calculated from 10 days of CGM (mg/dL), with overlaid loess curves by race/ethnicity (n=1,454).



Red = Non-Hispanic White, Black = Non-Hispanic Black, Blue = Hispanic White, Orange = Other races.

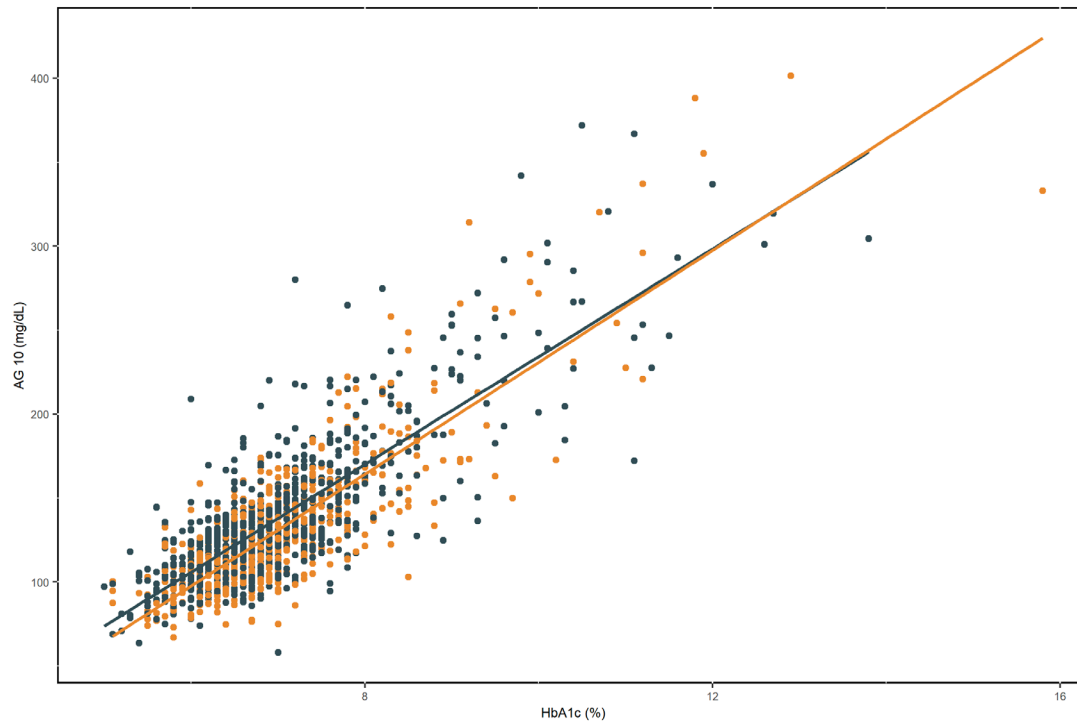
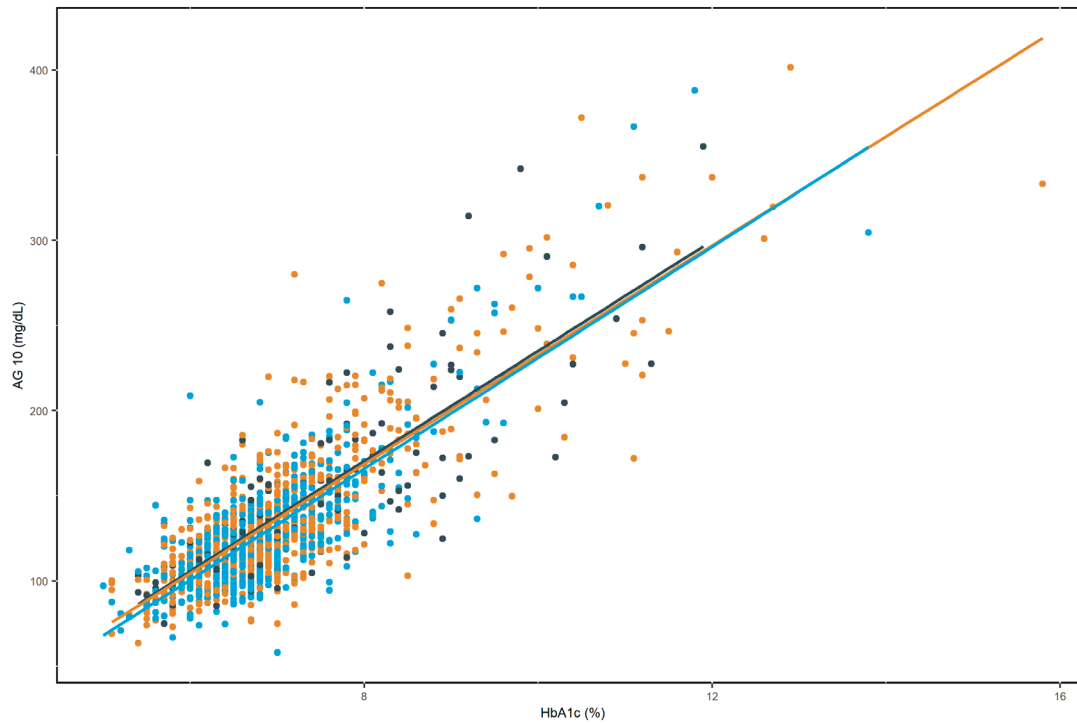
To convert values for HbA1c to mmol/mol, multiply by 10.93 and then subtract 23.5.

To convert values for glycated albumin to mmol/mol, add 0.4217 and then divide by 0.05652.

To convert values for glucose to mmol/L, multiply by 0.0555.

E. Supplement Figure S3 (top). Scatterplot of HbA1c vs. AG₁₀ by age, with age-specific regression lines overlaid (top). Black <45 years, orange 45-59 years, blue 60+ years. No significant difference between age groups.

Supplement Figure S3 (bottom). Scatterplot of HbA1c vs. AG₁₀ by sex, with sex-specific regression lines overlaid. Black is male, orange is female. The difference in the intercept and slope between sexes is highly significant (2-df joint test of equality, $p < 0.001$).



F: Supplement Table S2. Racial/ethnic differences in the relationships between glycated albumin (%) and average glucose calculated from 10 days of CGM (AG₁₀; mg/dL) in a linear regression model

Racial Group		
	p<0.001 [†]	
	Intercept	Slope
Non-Hispanic White	-1.2 (5.5)	9.1 (0.4)
Non-Hispanic Black	-4.7 (4.7)	8.4 (0.3)
Hispanic White	-20.6 (6.0)	10.6 (0.4)
Other races	13.4 (6.6)	8.2 (0.4)
Pairwise comparisons (p-values)		
Non-Hispanic White vs. Non-Hispanic Black	<0.001	
Non-Hispanic White vs. Hispanic White	0.01	
Non-Hispanic White vs. Other	0.23	
Non-Hispanic Black vs. Hispanic White	<0.001	
Non-Hispanic Black vs. Other	<0.001	
Hispanic White vs. Other	<0.001	

[†]p-value for a test of the difference among the four groups in the slopes and/or intercepts on 6 degrees of freedom. Other races- Asian American and Pacific Islanders, American Indian or race not identified.

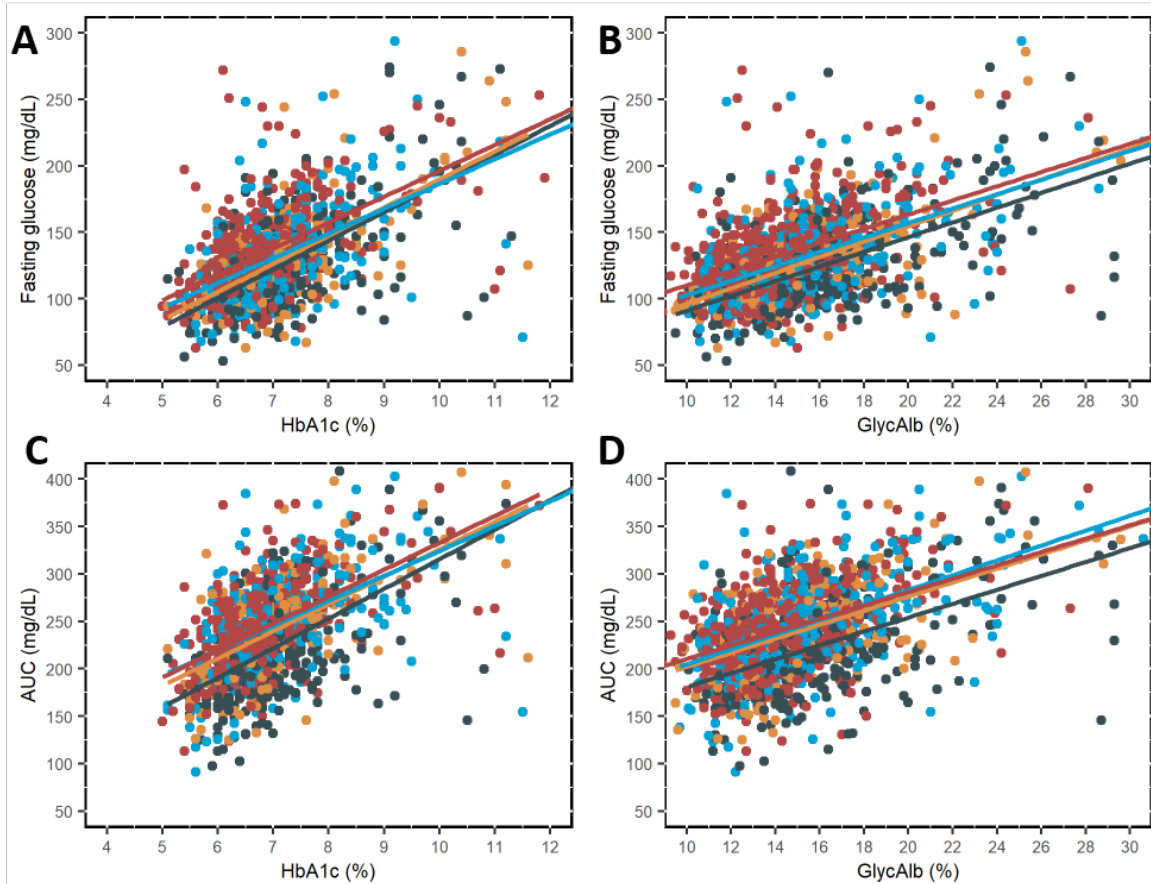
G. Supplement Table S3. Racial/ethnic differences in the relationships between HbA1c (%) and average glucose (AG) calculated from the full 14 days of CGM as available (AG₁₄; mg/dL) (n=1,454), fasting plasma glucose (FPG) from the OGTT, and glucose area under the curve (AUC) from the OGTT in linear regression models.

Racial Group	AG ₁₄		FPG		Glucose AUC	
	p<0.001 [†]		p<0.001 [†]		p<0.001 [†]	
	Intercept	Slope	Intercept	Slope	Intercept	Slope
Non-Hispanic White	-86.2 (7.8)	31.7 (1.1)	1.4 (8.8)	19.5 (1.3)	49.5 (15.3)	28.3 (2.2)
Non-Hispanic Black	-90.6 (7.3)	31.0 (1.0)	-29.0 (8.5)	21.6 (1.2)	3.4 (13.8)	31.2 (1.9)
Hispanic White	-101.4 (9.0)	34.1 (1.2)	-0.1 (10.2)	18.7 (1.4)	61.8 (15.7)	26.3 (2.2)
Other races	-91.6 (10.8)	32.5 (1.5)	-21.6 (12.4)	21.1 (1.7)	38.4 (19.4)	28.8 (2.7)
Pairwise comparisons (p-values)						
Non-Hispanic White vs. Non-Hispanic Black	<0.001		<0.001		<0.001	
Non-Hispanic White vs. Hispanic White	0.61		0.001		0.61	
Non-Hispanic White vs. Other	0.92		<0.001		0.07	
Non-Hispanic Black vs. Hispanic White	<0.001		<0.001		<0.001	
Non-Hispanic Black vs. Other	<0.001		0.19		<0.001	
Hispanic White vs. Other	0.61		0.15		0.27	

[†]p-value for a test of the difference among the four groups in the slopes and/or intercepts on 6 degrees of freedom.

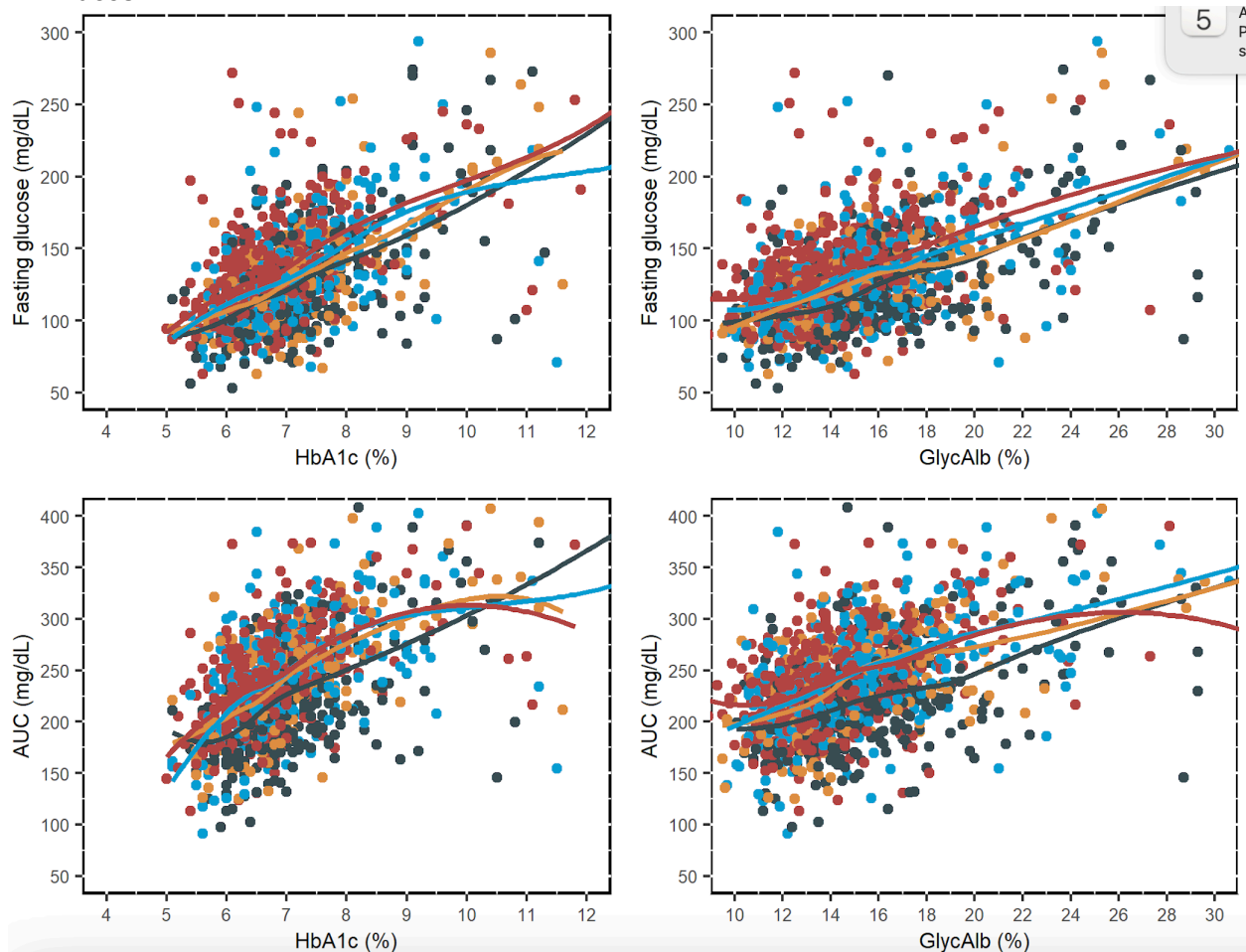
Other races- Asian American and Pacific Islanders, American Indian or race not identified.

H. Supplement Figure S4. Relationship of (A) HbA1c (%) and (B) glycated albumin (%) with fasting glucose (mg/dl) and of (C) HbA1c and (D) glycated albumin with area under the curve glucose derived from the oral glucose tolerance tests, all by race/ethnicity. Red = Non-Hispanic White, Black = Non-Hispanic Black, Blue = Hispanic White, Orange = Other races. Each of the 4 differences in the intercept and slope comparing NHW and NHB are highly significant ($p < .001$ for each 2-df joint test of equality).



To convert values for HbA1c to mmol/mol, multiply by 10.93 and then subtract 23.5.
 To convert values for glycated albumin to mmol/mol, add 0.4217 and then divide by 0.05652.
 To convert values for glucose to mmol/L, multiply by 0.0555.

I. Supplement Figure S5. Loess curves of the relationship of (A) HbA1c (%) and (B) glycated albumin (%) with fasting glucose levels (mg/dl) and of (C) HbA1c and (D) glycated albumin with area under the curve glucose derived from the oral glucose tolerance tests, all by race/ethnicity. Red = Non-Hispanic White, Black = Non-Hispanic Black, Blue = Hispanic White, Orange = Other races.



To convert values for HbA1c to mmol/mol, multiply by 10.93 and then subtract 23.5.
 To convert values for glycated albumin to mmol/mol, add 0.4217 and then divide by 0.05652.
 To convert values for glucose to mmol/L, multiply by 0.0555

J. Table S4. Racial/ethnic differences in the relationships between glycated albumin and average glucose (AG) calculated from 14 days of CGM (AG₁₄; mg/dL), fasting plasma glucose (FPG) from the OGTT, and glucose area under the curve (AUC) from the OGTT in linear regression models.

Racial Group	AG ₁₄		FPG		Glucose AUC	
	p<0.001 [†]		p<0.001 [†]		p<0.001 [†]	
	Intercept	Slope	Intercept	Slope	Intercept	Slope
Non-Hispanic White	-0.4 (5.3)	9.0 (0.4)	56.7 (6.2)	5.3 (0.4)	140.1 (10.3)	7.0 (0.7)
Non-Hispanic Black	-4.1 (4.6)	8.3 (0.3)	35.7 (5.4)	5.5 (0.3)	107.8 (8.7)	7.3 (0.5)
Hispanic White	-18.5 (5.8)	10.3 (0.4)	48.4 (6.7)	5.4 (0.4)	126.8 (10.6)	7.8 (0.7)
Other races	7.5 (6.4)	8.5 (0.4)	37.7 (7.5)	5.8 (0.5)	128.0 (11.9)	7.4 (0.7)
Pairwise comparisons (p-values)						
Non-Hispanic White vs. Non-Hispanic Black	<0.001		<0.001		<0.001	
Non-Hispanic White vs. Hispanic White	0.014		0.002		0.624	
Non-Hispanic White vs. Other	0.633		<0.001		0.188	
Non-Hispanic Black vs. Hispanic White	<0.001		<0.001		<0.001	
Non-Hispanic Black vs. Other	<0.001		0.012		<0.001	
Hispanic White vs. Other	0.004		0.193		0.381	

[†]p-value for a test of the difference among the four groups in the slopes and/or intercepts on 6 degrees of freedom.
Other races- Asian American and Pacific Islanders, American Indian or race not identified.

K. Table S5. Predicted average glucose levels (AG₁₀; mmol/L) for given predicted HbA1c (mmol/mol) by race/ethnicity

HbA1c (mmol/mol)	All (n=1454)	Non-Hispanic White (n=534)	Non-Hispanic Black (n=389)	Hispanic White (n=327)	Other races (n=204)
Average glucose (mmol/L) with 95% prediction interval*					
42	5.7 (3.1, 8.3)	5.8 (3.3, 8.4)	5.3 (2.7, 7.9)	5.8 (3.2, 8.3)	5.8 (3.3, 8.4)
48	6.6 (4.0, 9.2)	6.7 (4.2, 9.3)	6.2 (3.6, 8.8)	6.7 (4.2, 9.3)	6.7 (4.2, 9.3)
53	7.5 (4.9, 10.2)	7.7 (5.1, 10.2)	7.0 (4.5, 9.7)	7.7 (5.1, 10.3)	7.6 (5.1, 10.2)
58	8.4 (5.8, 11.0)	8.5 (6.0, 11.2)	7.9 (5.4, 10.5)	8.7 (6.1, 11.3)	8.5 (5.9, 11.1)
64	9.3 (6.7, 11.9)	9.4 (6.9, 12.0)	8.8 (6.3, 11.4)	9.7 (7.0, 12.2)	9.4 (6.8, 12.0)
69	10.2 (7.6, 12.8)	10.4 (7.8, 12.9)	9.7 (7.2, 12.3)	10.6 (8.0, 13.2)	10.3 (7.7, 12.9)
75	11.1 (8.5, 13.8)	11.3 (8.7, 13.9)	10.6 (8.0, 13.2)	11.6 (9.0, 14.2)	11.2 (8.6, 13.8)
80	12.0 (9.4, 14.7)	12.2 (9.6, 14.8)	11.5 (8.9, 14.1)	12.5 (9.9, 15.2)	12.0 (9.4, 14.7)
86	12.9 (10.3, 15.5)	13.1 (10.5, 15.7)	12.4 (9.8, 15.0)	13.5 (10.9, 16.2)	12.9 (10.3, 15.6)

AG₁₀- average glucose derived from 10 days of continuous glucose monitoring. Other races- Asian American and Pacific Islanders, American Indian or race not identified. Hemoglobin values (A1C) <6.0 % were not included due to the paucity of observations in that range.

*95% prediction intervals estimate an individual's AG₁₀ (mg/dL) based solely upon observation of their HbA1c and racial/ethnic group.

L. Supplement Table S6. Predicted HbA1c levels (mmol/mol) for given predicted AG₁₀ (mmol/L) by race/ethnicity

	All (n=1454)	Non-Hispanic White (n=534)	Non-Hispanic Black (n=389)	Hispanic White (n=327)	Other races (n=204)
Predicted HbA1c (mmol/mol) with 95% prediction interval ⁺					
AG ₁₀ (mmol/L)					
5.6	45 (32, 58)	44 (31, 56)	46 (34, 60)	45 (32, 58)	45 (32, 57)
6.9	51 (38, 64)	50 (37, 62)	53 (40, 65)	51 (38, 63)	51 (38, 63)
8.3	56 (43, 69)	55 (42, 67)	58 (46, 72)	55 (43, 68)	56 (44, 69)
9.7	62 (49, 75)	61 (48, 74)	65 (52, 78)	61 (49, 74)	62 (50, 75)
11.1	67 (54, 80)	66 (53, 79)	70 (58, 84)	66 (53, 78)	68 (55, 80)
12.5	73 (61, 86)	72 (58, 85)	77 (64, 90)	70 (58, 84)	74 (61, 87)
13.9	79 (66, 92)	77 (65, 90)	84 (70, 96)	76 (63, 89)	79 (67, 92)

AG₁₀- average glucose derived from 10 days of continuous glucose monitoring. Other races- Asian American and Pacific Islanders or American Indian or race not identified.

* 95% prediction intervals estimate an individual's HbA1c (%) based solely upon observation of their AG and racial/ethnic group.