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Integrity Check for the Epidemiology of Diabetes Interventions and Complications Study (EDIC) One Year Intima-media Wall Thickness (IMT) Datasets

As a partial check of the integrity of the EDIC One Year IMT datasets archived in the NIDDK data repository, a set of tabulations was performed to verify that published results can be reproduced using the archived datasets. Analyses were performed to duplicate published results for the data reported by the EDIC Research Group [1] in *Diabetes* in February 1999. The results of this integrity check are described below. The full text of the *Diabetes* article can be found in Attachment 1, and the SAS code for our tabulations is included in Attachment 2.

The intent of this DSIC is to provide confidence that the data distributed by the NIDDK repository is a true copy of the study data. Our intent is ***not*** to assess the integrity of the statistical analyses reported by study investigators. As with all statistical analyses of complex datasets, complete replication of a set of statistical results should not be expected on a first (or second) exercise in secondary analysis. This occurs for a number of reasons including differences in the handling of missing data, restrictions on cases included in samples for a particular analysis, software coding used to define complex variables, etc. Experience suggests that most discrepancies can ordinarily be resolved by consultation with the study data coordinating center (DCC), however this process is labor-intensive for both DCC and Repository staff. It is thus not our policy to resolve every discrepancy that is observed in an integrity check. Specifically, we do not attempt to resolve minor or inconsequential discrepancies with published results or discrepancies that involve complex analyses, *unless staff of the NIDDK Repository suspect that the observed discrepancy suggests that the dataset may have been corrupted in storage, transmission, or processing by repository staff.* We do, however, document in footnotes to the integrity check those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

Background. The Diabetes Control and Complications Trial (DCCT), 1983-1993, was a multi-center trial designed to determine whether intensive therapy to maintain blood glucose and glycosolated hemoglobin concentrations as close to the normal range as possible would prevent or delay long-term complications in patients with type 1 diabetes. This trial showed a markedly reduced risk of microvascular complications as compared with conventional therapy. Most participants were then enrolled in the EDIC study, a long-term observational study. One of the objectives of EDIC was to study the development and progression of atherosclerotic cardiovascular disease in type 1 diabetes. The published data describe the role of cardiovascular risk factors and antecedent therapy in the DCCT on carotid IMT in type 1 diabetes [1].

In summary, approximately 18 months after the end of the DCCT, high-resolution B-mode ultrasonography was used to assess the carotid arteries of 1,325 patients. An age- and sex-matched nondiabetic population (n=153) was studied with the same protocol [1].

Baseline Data. Table 1 of the 1999 *Diabetes* article reports on baseline characteristics. Variables summarized in this baseline table (Table 1. Baseline clinical characteristics of EDIC participants by sex and original treatment group assignment during the DCCT) are taken from the EDIC One Year IMT analysis dataset, EDICIMT1, created for this study. Original treatment group assignment was verified against the DCCT baseline dataset, BASELINE. Table A lists the variables used for replication of the Table 1 variables.

Table A: Variables Used to Replicate Table 1

Table 1 Variable	Variables Used in Replication
Sample size	group, sex
Attained age (years)	att_age
Attained duration of type 1 diabetes (months)	att_durn
Height (cm)	height
BMI (kg/m^2)	bmi
BMI > 27 (%)	bmi_27
Natural WHR	nwst_hip
sBP (mmHg)	sbp
dBP (mmHg)	dbp
Hypertensive (%)	ht
Total cholesterol (mg/dl)	tchol
HDL cholesterol (mg/dl)	hdl
LDL cholesterol (mg/dl)	ldl
Triglycerides (mg/dl)	trig
AER (mg/24 h)	aer
AER ≥ 40 mg/24 h (%)	aer_40
GFR	gfr
Insulin dose (U • kg^{-1} • day^{-1})	std_ins
Cigarette smoking (current) (%)	smoking
HbA_{1c}	hba1c
Mean HbA_{1c} during DCCT	avg_a1c
Framingham score	fscore
Note: The EDIC baseline (1994-1995) is after an average of 6.5 years of intensive treatment in DCCT. Hypertensive is defined as sitting sBP ≥ 140 mmHg and/or dBP ≥ 90 mmHg or the use of antihypertensive medication. Framingham score is defined as described by Anderson et al. (An Updated Coronary Risk Profile. *Circulation* 83:355-365, 1991).	

In Table B, we compare the results for characteristics calculated from the archived dataset to the results published in the 1999 *Diabetes* article. As Table B shows, the results obtained from the archived data are the same as those in the published tabulations, with a few minor exceptions.

Table B: Comparison of Baseline Table Values Computed in Integrity Check to Reference Article Values

Table 1 Variable	Women, Treatment: Intensive		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
Sample size	321	321	0
Attained age (years)	35 ± 7	35 ± 7	0
Attained duration of type 1 diabetes (months)	168 ± 58	168 ± 58	0
Height (cm)	165 ± 6	165 ± 6	0
BMI (kg/m^2)	26.5 ± 4.6	26.5 ± 4.6	0
BMI > 27 (%)	39.7	39.7	0
Natural WHR	0.76 ± 0.07	0.76 ± 0.07	0
sBP (mmHg)	114 ± 12	114 ± 12	0
dBP (mmHg)	74 ± 9	74 ± 9	0
Hypertensive (%)	9.7	9.7	0
Total cholesterol (mg/dl)	188 ± 36	188 ± 36	0
HDL cholesterol (mg/dl)	59 ± 14	59 ± 14	0
LDL cholesterol (mg/dl)	113 ± 29	113 ± 29	0
Triglycerides (mg/dl)	84 ± 74	84 ± 74	0
AER (mg/24 h)	21.1 ± 63.2	21.1 ± 63.2	0
AER ≥ 40 mg/24 h (%)	6.9	6.9	0
GFR	117.5 ± 23.5	117.5 ± 23.5	0
Insulin dose ($U \cdot kg^{-1} \cdot day^{-1}$)	0.63 ± 0.21	0.63 ± 0.21	0
Cigarette smoking (current) (%)	19.7	19.8	0.1
HbA_{1c}	7.9 ± 1.4	7.9 ± 1.4	0
Mean HbA_{1c} during DCCT	7.3 ± 0.9	7.3 ± 0.9	0
Framingham score	0.018 ± 0.025	0.018 ± 0.025	0
Note: Data are means ± SD, n, or %			

Table B: Comparison of Baseline Table Values Computed in Integrity Check to Reference Article Values (cont.)

Table 1 Variable	Women, Treatment: Conventional		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
Sample size	313	313	0
Attained age (years)	34 ± 7	34 ± 7	0
Attained duration of type 1 diabetes (months)	170 ± 61	170 ± 61	0
Height (cm)	165 ± 6	165 ± 6	0
BMI (kg/m^2)	25.1 ± 3.6	25.1 ± 3.6	0
BMI > 27 (%)	27.5	27.5	0
Natural WHR	0.76 ± 0.07	0.76 ± 0.07	0
sBP (mmHg)	114 ± 13	114 ± 13	0
dBP (mmHg)	72 ± 10	72 ± 10	0
Hypertensive (%)	12.9	12.9	0
Total cholesterol (mg/dl)	188 ± 39	188 ± 39	0
HDL cholesterol (mg/dl)	59 ± 14	59 ± 14	0
LDL cholesterol (mg/dl)	113 ± 32	113 ± 32	0
Triglycerides (mg/dl)	82 ± 73	82 ± 73	0
AER (mg/24 h)	63.5 ± 313.9	63.5 ± 313.9	0
AER ≥ 40 mg/24 h (%)	16.0	16.0	0
GFR	119.3 ± 26.1	119.3 ± 26.1	0
Insulin dose ($U \cdot kg^{-1} \cdot day^{-1}$)	0.64 ± 0.19	0.64 ± 0.19	0
Cigarette smoking (current) (%)	18.1	18.1	0
HbA_{1c}	8.2 ± 1.5	8.2 ± 1.5	0
Mean HbA_{1c} during DCCT	9.0 ± 1.4	9.0 ± 1.4	0
Framingham score	0.017 ± 0.028	0.017 ± 0.028	0
Note: Data are means ± SD, n, or %			

Table B: Comparison of Baseline Table Values Computed in Integrity Check to Reference Article Values (cont.)

Table 1 Variable	Women		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
Attained age (years)	0.042	0.042	0
Attained duration of type 1 diabetes (months)	0.722	0.722	0
Height (cm)	0.682	0.680	0.002
BMI (kg/m^2)	<0.001	<0.001	0
BMI > 27 (%)	0.001	0.001	0
Natural WHR	0.731	0.731	0
sBP (mmHg)	0.739	0.739	0
dBP (mmHg)	0.101	0.101	0
Hypertensive (%)	0.210	0.210	0
Total cholesterol (mg/dl)	0.495	0.495	0
HDL cholesterol (mg/dl)	0.737	0.737	0
LDL cholesterol (mg/dl)	0.542	0.542	0
Triglycerides (mg/dl)	0.427	0.427	0
AER (mg/24 h)	0.003	0.003	0
AER ≥ 40 mg/24 h (%)	<0.001	<0.001	0
GFR	0.069	0.069	0
Insulin dose (U • kg^{-1} • day^{-1})	0.801	0.800	0.001
Cigarette smoking (current) (%)	0.605	0.605	0
HbA_{1c}	0.009	0.009	0
Mean HbA_{1c} during DCCT	<0.001	<0.001	0
Framingham score	0.037	0.037	0
Note: Data are p-values			

Table B: Comparison of Baseline Table Values Computed in Integrity Check to Reference Article Values (cont.)

Table 1 Variable	Men, Treatment: Intensive		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
Sample size	340	340	0
Attained age (years)	36 ± 7	36 ± 7	0
Attained duration of type 1 diabetes (months)	167 ± 59	167 ± 59	0
Height (cm)	178 ± 7	178 ± 7	0
BMI (kg/m^2)	26.8 ± 4.2	26.8 ± 4.2	0
BMI > 27 (%)	41.2	41.2	0
Natural WHR	0.88 ± 0.08	0.88 ± 0.08	0
sBP (mmHg)	119 ± 11	119 ± 11	0
dBP (mmHg)	77 ± 9	77 ± 9	0
Hypertensive (%)	21.2	21.2	0
Total cholesterol (mg/dl)	187 ± 35	187 ± 35	0
HDL cholesterol (mg/dl)	49 ± 13	49 ± 13	0
LDL cholesterol (mg/dl)	119 ± 30	119 ± 30	0
Triglycerides (mg/dl)	98 ± 77	98 ± 77	0
AER (mg/24 h)	28.6 ± 112.9	28.6 ± 112.9	0
AER ≥ 40 mg/24 h (%)	7.4	7.4	0
GFR	115.3 ± 19.7	115.3 ± 19.7	0
Insulin dose ($U \cdot kg^{-1} \cdot day^{-1}$)	0.67 ± 0.24	0.67 ± 0.24	0
Cigarette smoking (current) (%)	19.3	19.4	0.1
HbA_{1c}	7.9 ± 1.2	7.9 ± 1.2	0
Mean HbA_{1c} during DCCT	7.2 ± 0.9	7.2 ± 0.9	0
Framingham score	0.039 ± 0.038	0.039 ± 0.038	0
Note: Data are means ± SD, n, or %			

Table B: Comparison of Baseline Table Values Computed in Integrity Check to Reference Article Values (cont.)

Table 1 Variable	Men, Treatment: Conventional		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
Sample size	351	351	0
Attained age (years)	36 ± 7	36 ± 7	0
Attained duration of type 1 diabetes (months)	159 ± 55	159 ± 55	0
Height (cm)	179 ± 7	179 ± 7	0
BMI (kg/m^2)	25.9 ± 3.2	25.9 ± 3.2	0
BMI > 27 (%)	34.5	34.5	0
Natural WHR	0.87 ± 0.09	0.87 ± 0.09	0
sBP (mmHg)	120 ± 12	120 ± 12	0
dBP (mmHg)	77 ± 8	77 ± 8	0
Hypertensive (%)	17.6	17.6	0
Total cholesterol (mg/dl)	184 ± 36	184 ± 36	0
HDL cholesterol (mg/dl)	50 ± 12	50 ± 12	0
LDL cholesterol (mg/dl)	115 ± 31	115 ± 31	0
Triglycerides (mg/dl)	97 ± 78	97 ± 78	0
AER (mg/24 h)	46.1 ± 123.2	46.1 ± 123.2	0
AER ≥ 40 mg/24 h (%)	17.9	18.0	0.1
GFR	116.1 ± 24.8	116.1 ± 24.8	0
Insulin dose ($U \cdot kg^{-1} \cdot day^{-1}$)	0.65 ± 0.20	0.65 ± 0.20	0
Cigarette smoking (current) (%)	18.4	18.4	0
HbA_{1c}	8.4 ± 1.3	8.4 ± 1.3	0
Mean HbA_{1c} during DCCT	9.0 ± 1.1	9.0 ± 1.1	0
Framingham score	0.037 ± 0.035	0.037 ± 0.035	0
Note: Data are means ± SD, n, or %			

Table B: Comparison of Baseline Table Values Computed in Integrity Check to Reference Article Values (cont.)

Table 1 Variable	Men		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
Attained age (years)	0.912	0.912	0
Attained duration of type 1 diabetes (months)	0.096	0.096	0
Height (cm)	0.076	0.076	0
BMI (kg/m^2)	0.016	0.016	0
BMI > 27 (%)	0.069	0.069	0
Natural WHR	0.101	0.101	0
sBP (mmHg)	0.186	0.186	0
dBP (mmHg)	0.446	0.446	0
Hypertensive (%)	0.240	0.240	0
Total cholesterol (mg/dl)	0.166	0.166	0
HDL cholesterol (mg/dl)	0.742	0.742	0
LDL cholesterol (mg/dl)	0.145	0.145	0
Triglycerides (mg/dl)	0.756	0.755	0.001
AER (mg/24 h)	0.038	0.038	0
AER ≥ 40 mg/24 h (%)	<0.001	<0.001	0
GFR	0.335	0.335	0
Insulin dose (U • kg^{-1} • day^{-1})	0.269	0.269	0
Cigarette smoking (current) (%)	0.750	0.750	0
HbA_{1c}	<0.001	<0.001	0
Mean HbA_{1c} during DCCT	<0.001	<0.001	0
Framingham score	0.704	0.704	0
Note: Data are p-values			

Nondiabetic Control Subject Data. Table 2 of the 1999 *Diabetes* article presents the IMT data including the average maximum of the common and internal carotid arteries stratified by sex and age decades for nondiabetic and type 1 diabetic subjects. Variables summarized in this follow-up table (Table 2. Comparison of IMT in nondiabetic subjects with EDIC type 1 diabetes cohort) are taken from both analysis datasets created for this study, EDICIMT1X (for the nondiabetic cohort) and EDICIMT1 (for the diabetic cohort). Table C lists the variables used for replication of the Table 2 variables.

Table C: Variables Used to Replicate Table 2

Table 2 Variable	Variables Used in Replication
Sample size	EDICIMT1X dataset: include all subjects EDICIMT1 dataset : include all subjects where 'decade' variable has a value of '20 - 29', '30 - 39' or '40 - 49'
Sex	EDICIMT1X dataset: gender EDICIMT1 dataset: sex
Common carotid artery	EDICIMT1X dataset: common EDICIMT1 dataset: common
Internal carotid artery	EDICIMT1X dataset: internal EDICIMT1 dataset: internal
Age (by decade)	EDICIMT1X dataset: decade EDICIMT1 dataset: decade
Note: Nondiabetic data were obtained from six normal subjects without diabetes at each of the 29 clinics using the EDIC ultrasound scanning protocol and read at the Central Ultrasound Reading Unit. Data exclude six EDIC patients who were 19 years old when scanned and five who were aged 50 or 51 years old	

In Table D, we compare the follow-up results calculated from the archived dataset to the results published in the 1999 *Diabetes* article. As Table D shows, the results obtained from the archived data are the same as those in the published tabulations, with a few minor exceptions.

Table D: Comparison of Nondiabetic Control Subject Table Values Computed in Integrity Check to Reference Article Values

Table 2 Variable	Women, Common Carotid Artery IMT (mm)		
	Nondiabetic		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
20-29	25, 0.603 ± 0.062	25, 0.603 ± 0.062	0
30-39	27, 0.663 ± 0.074	27, 0.663 ± 0.074	0
40-49	25, 0.704 ± 0.078	25, 0.704 ± 0.078	0
	Type 1 diabetes		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
20-29	172, 0.616 ± 0.073	172, 0.616 ± 0.073	0
30-39	278, 0.657 ± 0.081	278, 0.657 ± 0.081	0
40-49	178, 0.696 ± 0.079	178, 0.696 ± 0.079	0
	p-value		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
20-29	0.471	0.473	0.002
30-39	0.453	0.448	0.005
40-49	0.622	0.622	0
Note: Data are sample size, mean ± standard deviation and p-values. P-values are from Wilcoxon rank-sum test after linear adjustment for covariance with age.			

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Table 2 Variable	Women, Internal Carotid Artery IMT (mm)		
	Nondiabetic		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
20-29	25, 0.547 ± 0.053	25, 0.547 ± 0.053	0
30-39	27, 0.632 ± 0.153	27, 0.632 ± 0.153	0
40-49	25, 0.655 ± 0.074	25, 0.655 ± 0.074	0
	Type 1 diabetes		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
20-29	172, 0.583 ± 0.092	172, 0.583 ± 0.092	0
30-39	278, 0.632 ± 0.147	278, 0.632 ± 0.147	0
40-49	178, 0.719 ± 0.226	178, 0.719 ± 0.226	0
	p-value		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
20-29	0.065	0.064	0.001
30-39	0.859	0.856	0.003
40-49	0.704	0.697	0.007
Note: Data are sample size, mean ± standard deviation and p-values. P-values are from Wilcoxon rank-sum test after linear adjustment for covariance with age.			

Table D: Comparison of Nondiabetic Control Subject Table Values Computed in Integrity Check to Reference Article Values (cont.)

Table 2 Variable	Men, Common Carotid Artery IMT (mm)		
	Nondiabetic		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
20-29	21, 0.648 ± 0.098	21, 0.648 ± 0.098	0
30-39	25, 0.657 ± 0.076	25, 0.657 ± 0.076	0
40-49	30, 0.741 ± 0.094	30, 0.741 ± 0.094	0
	Type 1 diabetes		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
20-29	125, 0.636 ± 0.059	125, 0.636 ± 0.059	0
30-39	350, 0.684 ± 0.083	350, 0.684 ± 0.083	0
40-49	211, 0.745 ± 0.104	211, 0.745 ± 0.104	0
	p-value		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
20-29	0.971	0.973	0.002
30-39	0.103	0.104	0.001
40-49	0.925	0.924	0.001
Note: Data are sample size, mean ± standard deviation and p-values. P-values are from Wilcoxon rank-sum test after linear adjustment for covariance with age.			

Table 2 Variable	Men, Internal Carotid Artery IMT (mm)		
	Nondiabetic		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
20-29	21, 0.588 ± 0.085	21, 0.588 ± 0.085	0
30-39	25, 0.645 ± 0.104	25, 0.645 ± 0.104	0
40-49	30, 0.741 ± 0.147	30, 0.741 ± 0.147	0
	Type 1 diabetes		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
20-29	125, 0.629 ± 0.083	125, 0.629 ± 0.083	0
30-39	350, 0.684 ± 0.114	350, 0.684 ± 0.114	0
40-49	211, 0.806 ± 0.261	211, 0.806 ± 0.261	0
	p-value		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
20-29	0.032	0.032	0
30-39	0.071	0.071	0
40-49	0.437	0.437	0
Note: Data are sample size, mean ± standard deviation and p-values. P-values are from Wilcoxon rank-sum test after linear adjustment for covariance with age.			

Univariate Correlation Data. Table 3 of the 1999 *Diabetes* article presents univariate Spearman correlations of various clinical characteristics with average maximum wall thickness for the common and internal carotid arteries. Variables summarized in this follow-up table (Table 3. Spearman correlation coefficients of clinical characteristics with average maximum IMT) are taken from the EDICIMT1 analysis dataset created for this study. Table E lists the variables used for replication of the Table 3 variables.

Table E: Variables Used to Replicate Table 3

Table 3 Variable	Variables Used in Replication
Sex	sex
Attained age (years)	att_age
Attained duration of type 1 diabetes (months)	att_durn
Height (cm)	height
BMI (kg/m^2)	bmi
WHR	nwst_hip
sBP (mmHg)	sbp
dBP (mmHg)	dbp
Total cholesterol (mg/dl)	tchol
HDL cholesterol (mg/dl)	hdl
LDL cholesterol (mg/dl)	ldl
Triglycerides (mg/dl)	trig
Smoking (total pack-years)	cum_smok
Insulin dose ($U \cdot kg^{-1} \cdot day^{-1}$)	std_ins
HbA_{1c}	hba1c
Mean HbA_{1c} during the DCCT	avg_a1c
Framingham risk score	fscore
AER (mg/24 h)	aer
GFR	gfr

In Table F, we compare the follow-up results calculated from the archived dataset to the results published in the 1999 *Diabetes* article. As Table F shows, the results obtained from the archived data are the same as those in the published tabulations, with a few minor exceptions.

Table F: Comparison of Univariate Correlation Table Values Computed in Integrity Check to Reference Article Values

Table 3 Variable	Common Carotid Artery		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
Attained age (years)	M: 0.46, <0.001 F: 0.42, <0.001	M: 0.46, <0.001 F: 0.42, <0.001	M: 0 F: 0
Attained duration of type 1 diabetes (months)	M: 0.13, <0.001 F: 0.08, 0.04	M: 0.13, <0.001 F: 0.08, 0.04	M: 0 F: 0
Height (cm)	M: 0.17, <0.001 F: 0.12, 0.003	M: 0.17, <0.001 F: 0.12, 0.002	M: 0 F: 0, 0.001
BMI (kg/m^2)	M: 0.15, <0.001 F: 0.06, 0.12	M: 0.15, <0.001 F: 0.06, 0.11	M: 0 F: 0, 0.01
WHR	M: 0.22, <0.001 F: 0.01, 0.89	M: 0.22, <0.001 F: 0.01, 0.90	M: 0 F: 0, 0.01
sBP (mmHg)	M: 0.21, <0.001 F: 0.14, <0.001	M: 0.21, <0.001 F: 0.14, <0.001	M: 0 F: 0
dBP (mmHg)	M: 0.11, 0.004 F: 0.07, 0.08	M: 0.11, 0.003 F: 0.07, 0.08	M: 0, 0.001 F: 0
Total cholesterol (mg/dl)	M: 0.21, <0.001 F: 0.09, 0.04	M: 0.21, <0.001 F: 0.09, 0.03	M: 0 F: 0, 0.01
HDL cholesterol (mg/dl)	M: -0.03, 0.37 F: 0.00, 0.96	M: -0.03, 0.36 F: 0.00, 0.96	M: 0, 0.01 F: 0
LDL cholesterol (mg/dl)	M: 0.24, <0.001 F: 0.08, 0.06	M: 0.24, <0.001 F: 0.08, 0.06	M: 0 F: 0
Triglycerides (mg/dl)	M: 0.07, 0.06 F: 0.06, 0.14	M: 0.07, 0.05 F: 0.06, 0.14	M: 0, 0.01 F: 0
Smoking (total pack-years)	M: 0.21, <0.001 F: 0.15, <0.001	M: 0.21, <0.001 F: 0.15, <0.001	M: 0 F: 0
Insulin dose ($U \cdot kg^{-1} \cdot day^{-1}$)	M: -0.06, 0.10 F: -0.08, 0.06	M: -0.06, 0.09 F: -0.08, 0.05	M: 0, 0.01 F: 0, 0.01
HbA_{1c}	M: 0.07, 0.07 F: -0.02, 0.62	M: 0.07, 0.06 F: -0.02, 0.62	M: 0, 0.01 F: 0
Mean HbA_{1c} during the DCCT	M: 0.06, 0.12 F: -0.11, 0.008	M: 0.06, 0.11 F: -0.11, 0.007	M: 0, 0.01 F: 0, 0.001
Framingham risk score	M: 0.47, <0.001 F: 0.42, <0.001	M: 0.47, <0.001 F: 0.42, <0.001	M: 0 F: 0
AER (mg/24 h)	M: 0.10, 0.01 F: -0.01, 0.76	M: 0.10, 0.01 F: -0.01, 0.75	M: 0 F: 0, 0.01
GFR	M: -0.01, 0.76 F: -0.05, 0.25	M: -0.01, 0.77 F: -0.05, 0.24	M: 0, 0.01 F: 0, 0.01
Note: Data are Spearman correlations and p-values.			

Table F: Comparison of Univariate Correlation Table Values Computed in Integrity Check to Reference Article Values (cont.)

Table 3 Variable	Internal Carotid Artery		
	***Diabetes* (1999)**	**Integrity Check**	**Difference**
Attained age (years)	M: 0.38, <0.001 F: 0.35, <0.001	M: 0.38, <0.001 F: 0.35, <0.001	M: 0 F: 0
Attained duration of type 1 diabetes (months)	M: 0.12, 0.002 F: 0.12, 0.004	M: 0.12, 0.002 F: 0.12, 0.004	M: 0 F: 0
Height (cm)	M: 0.05, 0.19 F: -0.04, 0.36	M: 0.05, 0.19 F: -0.04, 0.36	M: 0 F: 0
BMI (kg/m^2)	M: 0.09, 0.02 F: 0.02, 0.56	M: 0.09, 0.02 F: 0.02, 0.56	M: 0 F: 0
WHR	M: 0.14, <0.001 F: 0.01, 0.85	M: 0.14, <0.001 F: 0.01, 0.85	M: 0 F: 0
sBP (mmHg)	M: 0.14, <0.001 F: 0.11, 0.007	M: 0.14, <0.001 F: 0.11, 0.007	M: 0 F: 0
dBP (mmHg)	M: 0.13, <0.008 F: 0.07, 0.09	M: 0.13, 0.008 F: 0.07, 0.08	M: 0 F: 0, 0.01
Total cholesterol (mg/dl)	M: 0.23, <0.001 F: 0.13, 0.002	M: 0.23, <0.001 F: 0.13, 0.001	M: 0 F: 0, 0.001
HDL cholesterol (mg/dl)	M: 0.00, 0.92 F: 0.03, 0.41	M: 0.00, 0.92 F: 0.03, 0.41	M: 0 F: 0
LDL cholesterol (mg/dl)	M: 0.26, <0.001 F: 0.13, 0.001	M: 0.26, <0.001 F: 0.13, 0.001	M: 0 F: 0
Triglycerides (mg/dl)	M: 0.05, 0.19 F: 0.00, 0.94	M: 0.05, 0.18 F: 0.00, 0.94	M: 0, 0.01 F: 0
Smoking (total pack-years)	M: 0.09, 0.02 F: 0.16, <0.001	M: 0.09, 0.02 F: 0.16, <0.001	M: 0 F: 0
Insulin dose ($U \cdot kg^{-1} \cdot day^{-1}$)	M: -0.10, 0.02 F: -0.05, 0.20	M: -0.10, 0.01 F: -0.05, 0.20	M: 0, 0.01 F: 0
HbA_{1c}	M: 0.02, 0.56 F: 0.02, 0.68	M: 0.02, 0.56 F: 0.02, 0.68	M: 0 F: 0
Mean HbA_{1c} during the DCCT	M: -0.02, 0.57 F: -0.07, 0.07	M: -0.02, 0.56 F: -0.07, 0.06	M: 0, 0.01 F: 0, 0.01
Framingham risk score	M: 0.38, <0.001 F: 0.35, <0.001	M: 0.38, <0.001 F: 0.35, <0.001	M: 0 F: 0
AER (mg/24 h)	M: 0.07, 0.09 F: 0.01, 0.85	M: 0.07, 0.09 F: 0.01, 0.84	M: 0 F: 0, 0.01
GFR	M: 0.02, 0.54 F: -0.02, 0.65	M: 0.02, 0.54 F: -0.02, 0.65	M: 0 F: 0
Note: Data are Spearman correlations and p-values.			

Multivariate Analyses Data. Table 4 of the 1999 *Diabetes* article presents multiple linear regression analyses. Variables summarized in this follow-up table (Table 4. Summary of multiple regression models for common carotid IMT and internal carotid IMT) are taken from the EDICIMT1 analysis dataset created for this study. Selected results were spot-checked and found to be consistent with the published results.

Treatment Group Difference Data. Table 5 of the 1999 *Diabetes* article presents IMT by sex, age, and treatment group. Variables summarized in this follow-up table (Table 5. Average maximum IMTs by age and randomized treatment assignment) are taken from the EDICIMT1 analysis dataset created for this study. Selected results were spot-checked and found to be consistent with the published results. There were, in fact, no differences in any of the means or standard deviations.

The repository has high confidence in the integrity of the EDIC One Year IMT analysis datasets.

Notes

1. Both analysis datasets related to the EDIC One Year Intima-media Wall Thickness (IMT) follow-up were examined in this replication analysis: EDICIMT1Xfor the nondiabetic cohort and EDICIMT1 for the diabetic cohort.

References

1. The EDIC Research Group, Effect of Intensive Diabetes Treatment on Carotid Artery Wall Thickness in the Epidemiology of Diabetes Interventions and Complications, Diabetes, February 1999; Volume 48: 383-390.

ATTACHMENT 1

The EDIC Research Group, Effect of Intensive Diabetes Treatment on Carotid Artery Wall Thickness in the Epidemiology of Diabetes Interventions and Complications, Diabetes, February 1999; Volume 48: 383-390.

The full text of the article referenced will be provided to approved requestors along with the data archive.

ATTACHMENT 2

SAS Code for Baseline, Nondiabetic Control Subject, Univariate Correlation, Multivariate Analyses, and Treatment Group Difference Tabulations from EDIC One Year IMT Datasets in the NIDDK Repository

```
/*****************************************************************************************/
/*
/* Program: R:\05_Users\Norma\EDIC\Carotid Artery\getdata.sas
/* Author:  Norma Pugh
/* Date:    01 February 2008
/* Purpose: Create SAS datasets from the SAS transport files provided to the repository.
/*****************************************************************************************/
/* NEW LOCATION FOR EDIC SAS FILES */
libname newlib 'R:\05_Users\Norma\EDIC\Carotid Artery';

/* ORIGINAL LOCATION OF EDIC TRANSPORT FILES */
filename file1 'R:\03_Data_And_Tools\Studies\DCCT-EDIC\NEW-Studies\1-year-IMT-
data\edcimt1x.xpt';
filename file2 'R:\03_Data_And_Tools\Studies\DCCT-EDIC\NEW-Studies\1-year-IMT-
data\edicimt1.xpt';

/* CREATE THE DATASETS */
proc cimport library=newlib infile=file1; run;
proc cimport library=newlib infile=file2; run;
```

```
/*****************************************************************************************/
/*
/* Program: R:\05_Users\Norma\EDIC\Carotid Artery\verify_trt.sas
/* Author:  Norma Pugh
/* Date:    01 February 2008
/* Purpose: Verify that treatment assignment matches DCCT Baseline dataset.
/*****************************************************************************************/
/************************/
/* Libnames and formats */
/************************/
libname trt  'R:\03_Data_And_Tools\Studies\DCCT-EDIC\DCCT-
EDIC_FINAL\DCCT\Analyses\Baseline\SAS_DATA';
libname data 'R:\05_Users\Norma\EDIC\Carotid Artery';

%include 'R:\03_Data_And_Tools\Studies\DCCT-EDIC\NEW-Studies\1-year-IMT-data\fmt.sas';


/************************************************/
/* Get treatment assignment from DCCT baseline */
/************************************************/
data trt;
 set trt.baseline;
 keep mask_pat group;
 rename group=baseline_group;
run;

proc sort data=trt; by mask_pat; run;


/*******************************************************/
/* Get 1-year-IMT-data dataset treatment assignments */
/*******************************************************/
data temp1;
 set data.edicimt1;
 keep mask_pat group;
 rename group=temp1_group;
run;
proc sort data=temp1; by mask_pat; run;
proc freq data=temp1; tables temp1_group / missing; title'edicimt1'; run;


/************************************************/
/* Merge project data with treatment assignment */
/************************************************/
data table1; merge temp1(in=x1) trt(in=x2); by mask_pat; if x1 &
baseline_group^=temp1_group; run;
```

```
/*****************************************************************************************/
/*
/* Program: R:\05_Users\Norma\EDIC\Carotid Artery\table1.sas
/* Author:  Norma Pugh
/* Date:    01 February 2008
/* Purpose: Replicate Table 1 results from Diabetes article: Effect of Intensive Diabetes
/*           Treatment on Carotid Artery Wall Thickness in the Epidemiology of Diabetes
/*           Interventions and Complications (EDIC).
/*           (1999)
/*****************************************************************************************/
/************************/
/* Libnames and formats */
/************************/
libname data 'R:\05_Users\Norma\EDIC\Carotid Artery';

%include 'R:\03_Data_And_Tools\Studies\DCCT-EDIC\NEW-Studies\1-year-IMT-data\fmt.sas';


/*************************/
/* Get Table 1 variables */
/*************************/
data table1; set data.edicimt1; run;


/*********************************/
/* Table 1 Replication Analysis */
/*********************************/
title'Table 1: Baseline clinical characteristics of EDIC participants';
title2'by sex and original treatment group assignment during the DCCT';
title3'Categorical Counts/Percentages & p-values'; run;

proc freq data=table1;
 tables sex*group;
run;

proc freq data=table1;
 tables sex*group*bmi_27 / chisq;
 tables sex*group*ht / chisq;
 tables sex*group*aer_40 / chisq;
 tables sex*group*smoking / chisq;
run;


title2'Quantitative Means & Standard Deviations'; run;

proc sort data=table1; by sex group; run;
proc means data=table1 n mean std;
 by sex group;
 var att_age att_durn height bmi nwst_hip sbp dbp tchol hdl ldl trig aer gfr std_ins
hba1c avg_a1c fscore;
run;

proc sort data=table1; by group; run;
proc npar1way data=table1(where=(sex='F')) wilcoxon;
 class group;
 var att_age att_durn height bmi nwst_hip sbp dbp tchol hdl ldl trig aer gfr std_ins
hba1c avg_a1c fscore;
```

```
 title3'Women';
run;

proc npar1way data=table1(where=(sex='M')) wilcoxon;
 class group;
 var att_age att_durn height bmi nwst_hip sbp dbp tchol hdl ldl trig aer gfr std_ins
hba1c avg_a1c fscore;
 title3'Men';
run;
```

```
options mprint;
/*****************************************************************************************/
/*
/* Program: R:\05_Users\Norma\EDIC\Carotid Artery\table2.sas
/* Author:  Norma Pugh
/* Date:    01 February 2008
/* Purpose: Replicate Table 2 results from Diabetes article: Effect of Intensive Diabetes
/*           Treatment on Carotid Artery Wall Thickness in the Epidemiology of Diabetes
/*           Interventions and Complications (EDIC).
/*           (1999)
/*****************************************************************************************/
/************************/
/* Libnames and formats */
/************************/
libname data 'R:\05_Users\Norma\EDIC\Carotid Artery';

%include 'R:\03_Data_And_Tools\Studies\DCCT-EDIC\NEW-Studies\1-year-IMT-data\fmt.sas';


/****************************************/
/* Get Table 2 population and variables */
/****************************************/
/* Nondiabetics */
data nondiab;
 set data.edcimt1x;

 /* Flag dataset as nondiabetic (diab=0) */
 diab=0;
 label diab = 'Diabetic? (0=n,1=y)';

 /* Recode 'gender' to match 'sex' variable from diabetic dataset */
 if gender=1 then sex='M'; else if gender=2 then sex='F';

 keep diab sex decade common internal;       /* NOTE: mask_pat variable is empty on this
dataset */
run;

/* Type 1 diabetics */
data diab;
 set data.edicimt1(where=(decade in('20 - 29','30 - 39','40 - 49')));

 /* Flag dataset as diabetic (diab=1) */
 diab=1;
 label diab = 'Diabetic? (0=n,1=y)';

 keep mask_pat diab sex decade common internal;
run;

/* Merge data */
data table2; set nondiab diab;; run;


/********************************/
/* Table 2 Replication Analysis */
/********************************/
title'Table 2: Comparison of IMT in nondiabetic subjects with EDIC type 1 diabetes
cohort';
```

```
title2'Quantitative Means & Standard Deviations'; run;

proc sort data=table2; by sex diab decade; run;
proc means data=table2 n mean std;
 by sex diab decade;
 var common;
run;

proc means data=table2 n mean std;
 by sex diab decade;
 var internal;
run;

%macro pval(sex,age,var,title);
 proc sort data=table2; by diab; run;
 proc npar1way data=table2(where=(sex="&sex" & decade="&age")) wilcoxon;
  class diab;
  var &var;
  title3"&title";
 run;
%mend pval;

%pval(F,20 - 29,common,%str(Women, 20-29));
%pval(F,30 - 39,common,%str(Women, 30-39));
%pval(F,40 - 49,common,%str(Women, 40-49));

%pval(F,20 - 29,internal,%str(Women, 20-29));
%pval(F,30 - 39,internal,%str(Women, 30-39));
%pval(F,40 - 49,internal,%str(Women, 40-49));

%pval(M,20 - 29,common,%str(Men, 20-29));
%pval(M,30 - 39,common,%str(Men, 30-39));
%pval(M,40 - 49,common,%str(Men, 40-49));

%pval(M,20 - 29,internal,%str(Men, 20-29));
%pval(M,30 - 39,internal,%str(Men, 30-39));
%pval(M,40 - 49,internal,%str(Men, 40-49));
```

```
/*****************************************************************************************/
/*
/* Program: R:\05_Users\Norma\EDIC\Carotid Artery\table3.sas
/* Author:  Norma Pugh
/* Date:    01 February 2008
/* Purpose: Replicate Table 3 results from Diabetes article: Effect of Intensive Diabetes
/*           Treatment on Carotid Artery Wall Thickness in the Epidemiology of Diabetes
/*           Interventions and Complications (EDIC).
/*           (1999)
/*****************************************************************************************/
/************************/
/* Libnames and formats */
/************************/
libname data 'R:\05_Users\Norma\EDIC\Carotid Artery';

%include 'R:\03_Data_And_Tools\Studies\DCCT-EDIC\NEW-Studies\1-year-IMT-data\fmt.sas';


/*************************/
/* Get Table 3 variables */
/*************************/
data table3; set data.edicimt1; run;


/*********************************/
/* Table 3 Replication Analysis */
/*********************************/
title'Table 3: Spearman correlation coefficients of clinical';
title2'characteristics with average maximum IMT';
title3'Common & Internal Carotid Artery Results by Gender'; run;

proc sort data=table3; by sex; run;
proc corr data=table3 spearman;
 by sex;
 var att_age att_durn height bmi nwst_hip sbp dbp tchol hdl ldl trig cum_smok std_ins
hba1c avg_a1c fscore aer gfr;
 with common internal;
run;
```

```
/*****************************************************************************************/
/*
/* Program: R:\05_Users\Norma\EDIC\Carotid Artery\table4.sas
/* Author:  Norma Pugh
/* Date:    01 February 2008
/* Purpose: Replicate Table 4 results from Diabetes article: Effect of Intensive Diabetes
/*           Treatment on Carotid Artery Wall Thickness in the Epidemiology of Diabetes
/*           Interventions and Complications (EDIC).
/*           (1999)
/*****************************************************************************************/
/************************/
/* Libnames and formats */
/************************/
libname data 'R:\05_Users\Norma\EDIC\Carotid Artery';

%include 'R:\03_Data_And_Tools\Studies\DCCT-EDIC\NEW-Studies\1-year-IMT-data\fmt.sas';


/****************************************/
/* Get Table 4 population and variables */
/****************************************/
data table4; set data.edicimt1;
 if group='EXPERIMENTAL' then intense=1; else intense=0;
run;


/*********************************/
/* Table 4 Replication Analysis */
/*********************************/
title'Table 4: Summary of multiple linear regression models for common carotid IMT and
internal carotid IMT';

proc reg data=table4(where=(sex='F'));
 title'Women';
 model common = att_age att_durn height cum_smok bmi sbp ldl gfr avg_a1c intense;
run;

proc reg data=table4(where=(sex='M'));
 title'Men';
 model common = att_age att_durn height cum_smok bmi sbp ldl gfr avg_a1c intense;
run;
```

```
/*****************************************************************************************/
/*
/* Program: R:\05_Users\Norma\EDIC\Carotid Artery\table5.sas
/* Author:  Norma Pugh
/* Date:    01 February 2008
/* Purpose: Replicate Table 5 results from Diabetes article: Effect of Intensive Diabetes
/*           Treatment on Carotid Artery Wall Thickness in the Epidemiology of Diabetes
/*           Interventions and Complications (EDIC).
/*           (1999)
/*****************************************************************************************/
/************************/
/* Libnames and formats */
/************************/
libname data 'R:\05_Users\Norma\EDIC\Carotid Artery';

%include 'R:\03_Data_And_Tools\Studies\DCCT-EDIC\NEW-Studies\1-year-IMT-data\fmt.sas';


/****************************************/
/* Get Table 5 population and variables */
/****************************************/
data table5;
 set data.edicimt1(where=(decade in('20 - 29','30 - 39','40 - 49')));
run;


/*********************************/
/* Table 5 Replication Analysis */
/*********************************/
title'Table 5: Average maximum IMTs by age and randomized treatment assignment';

proc sort data=table5; by sex decade group; run;
proc means data=table5 n mean std;
 by sex decade group;
 var common;
run;

proc means data=table5 n mean std;
 by sex decade group;
 var internal;
run;
```