

Online Appendix

Study Group Listing

Disclosures

Figure A-1

Figure A-2

Table A-1

Table A-2

Table A-3

The JDRF Continuous Glucose Monitoring Study Group

Clinical Centers: Listed in order of number of patients enrolled with clinical center name, city, and state. Personnel are listed as (PI) for Principal Investigator, (I) for co-Investigator and (C) for Coordinators:

Diabetes Care Center, University of Washington, Seattle, WA: Irl B. Hirsch, M.D. (PI); Lisa K. Gilliam, M.D., Ph.D. (I); Kathy Fitzpatrick, R.N., M.N., C.D.E. (C); Dori Khakpour, R.D., C.D., C.D.E. (C); *Department of Pediatrics, Yale University School of Medicine, New Haven, CT:* Stuart A. Weinzimer, M.D. (PI); William V. Tamborlane, M.D. (I); Brett Ives, M.S.N., A.P.R.N. (C); Joan Bosson-Heenan (C); *Adult Section, Joslin Diabetes Center, Boston, MA:* Howard Wolpert, M.D. (PI); Greeshma Shetty, M.D. (I); Astrid Atakov-Castillo (C); Judith Giusti, M.S., R.D., L.D.N., C.D.E. (C); Stacey O'Donnell, R.N., C.D.E. (C); Suzanne Ghiloni, R.N., C.D.E. (C); *Atlanta Diabetes Associates, Atlanta, GA:* Bruce W. Bode, M.D. (PI); Kelli O'Neil, C.D.E. (C); Lisa Tolbert, R.N., M.N., C.D.E. (C); *Nemours Children's Clinic, Jacksonville, FL:* Tim Wysocki, Ph.D. (co-PI); Larry A. Fox, M.D. (co-PI); Nelly Mauras, M.D. (I); Kimberly Englert, R.N. (C); Joe Permuy, M.S.N., A.R.N.P. (C); *Division of Pediatric Endocrinology and Diabetes, Stanford University, Stanford, CA:* Bruce Buckingham, M.D. (PI); Darrell M. Wilson, M.D. (I); Jennifer Block, R.N., C.D.E. (C); Kari Benassi, R.N., N.P. (C); *Department of Pediatrics, University of Iowa Carver College of Medicine, Iowa City, IA:* Eva Tsalikian, M.D. (PI); Michael Tansey, M.D. (I); Debra Kucera, A.R.N.P., C.P.N.P. (C); Julie Coffey, A.R.N.P., C.P.N.P. (C); Joanne Cabbage (C); *Pediatric Adolescent, and Young Adult Section, Joslin Diabetes Center, Boston, MA:* Lori Laffel, M.D., M.P.H., (PI), Kerry Milaszewski, R.N., C.D.E. (C); Katherine Pratt (C); Elise Bismuth, M.D., M.S., (C); Joyce Keady, M.S.N., C.P.N.P. (C); Margie Lawlor, M.S., C.D.E. (C); *Barbara Davis Center for Childhood Diabetes, University of Colorado, Denver, CO:* H. Peter Chase, M.D. (PI); Rosanna Fiallo-Scharer, M.D. (I); Paul Wadwa, M.D. (I); Laurel Messer, R.N., C.D.E. (C); Victoria Gage, R.N. (C); Patricia Burdick (C); *Departments of Pediatric Endocrinology and Research and Evaluation, Kaiser Permanente, San Diego and Pasadena, CA:* Jean M. Lawrence, Sc.D., M.P.H., M.S.S.A. (co-PI); Robert Clemons, M.D. (co-PI); Michelle Maeva, R.N., C.D.E. (C); Bonnie Sattler, M.S., R.D. (C); *Coordinating Center:* Jaeb Center for Health Research, Tampa, FL: Roy W. Beck, M.D., Ph.D.; Katrina J. Ruedy, M.S.P.H.; Craig Kollman, Ph.D.; Dongyuan Xing, M.P.H.; Judy Sibayan, M.P.H.; *University of Minnesota Central Laboratory:* Michael Steffes, M.D., Ph.D., Jean M. Bucksa, C.L.S., Maren L. Nowicki, C.L.S., Carol Van Hale, C.L.S., Vicky Makky, C.L.S. *Cost-effectiveness investigators: National Opinion Research Center, University of Chicago:* Michael O'Grady, Ph.D.; Elbert Huang, M.D., M.P.H.; Anirban Basu, Ph.D.; David O. Meltzer, M.D., Ph.D.; Lan Zhao, Ph.D. *University of Michigan:* Joyce Lee, M.D., M.P.H. *Juvenile Diabetes Research Foundation, Inc.:* Aaron J. Kowalski, Ph.D. *Operations Committee:* Lori Laffel, M.D., M.P.H. (co-chair), William V. Tamborlane, M.D. (co-chair), Roy W. Beck, M.D., Ph.D., Aaron J. Kowalski, Ph.D., Katrina J. Ruedy, M.S.P.H. *Data and Safety Monitoring Board:* Ruth S. Weinstock, M.D., Ph.D. (chair), Barbara J Anderson, Ph.D.; Davida Kruger, M.S.N., A.P.R.N.; Lisa LaVange, Ph.D.; Henry Rodriguez, M.D.

Disclosure

Financial support: Study funding was provided by the Juvenile Diabetes Research Foundation, Inc. (grant numbers 22-2006-1107, 22-2006-1117, 22-2006-1112, 22-2006-1123, and 01-2006-8031).

Continuous glucose monitors and sensors were purchased at a bulk discount price from DexCom, Inc. (San Diego, CA), Medtronic MiniMed, Inc. (Northridge, CA), and Abbott Diabetes Care, Inc. (Alameda, CA.). Home glucose meters and test strips were provided to the study by LifeScan, Inc. and Abbott Diabetes Care, Inc. The companies had no involvement in the design, conduct, or analysis of the trial or the manuscript preparation.

Below is a listing of relationships of the investigators with companies that make products relevant to the manuscript between July 1, 2006 and October 26, 2009. Research funds were listed below were provided to the legal entity that employs the individual and not directly to the individual.

Jennifer M. Block, RN, CDE reports having received honoraria from Abbott Diabetes Care, Inc. and Medtronic MiniMed, Inc., and serving on a medical advisory board for Tandem Diabetes and Arkal Medical; Dr. Bode reports having received consulting fees, honoraria, travel reimbursement, and research funds from Abbott Diabetes Care, Inc., and Medtronic MiniMed, Inc., and grant support from DexCom, Inc.; Dr. Buckingham reports having received a speaker honorarium and research funding from Abbott Diabetes Care, Inc., a fee for serving on a medical advisory board for Lifescan, Inc., a speaker honorarium, consulting fees, and research funding from Medtronic MiniMed, Inc., and a consulting fee from Novo Nordisk, Inc.; Dr. Chase reports having received a speaker honorarium from Abbott Diabetes Care, Inc. and Sanofi-Aventis, and grant support from Symlin; Dr. Fiallo-Scharerer reports having received supplies for research from Abbott Diabetes Care, Inc. and Medtronic MiniMed, Inc.; Dr. Fox reports having received supplies for research from Abbott Diabetes Care, Inc. and Smiths Medical; Dr. Hirsch reports having received consulting fees and travel reimbursement from Abbott Diabetes Care, Inc., and grant support from Medtronic MiniMed, Inc.; Dr. Kollman reports having received consulting fees from Medtronic MiniMed, Inc.; Kerry Milaszewski, RN, CDE reports having received consulting fees from Medtronic MiniMed, Inc.; Dr. Laffel reports having received consulting fees from Lifescan, Inc., consulting fees and a speaker honorarium from Abbott Diabetes Care, Inc., consulting fees and research funding from Medtronic MiniMed, Inc., and consulting and speaker fees from Roche; Dr. Mauras reports having received grant support from Medtronic MiniMed, Inc.; Dr. Tamborlane reports having received consulting fees from Abbott Diabetes Care, Inc. and Lifescan, Inc. and consulting fees, a speaker honorarium, and research funding from Medtronic MiniMed, Inc.; Dr. Weinzimer reports having received research support and a speaker honorarium from Medtronic MiniMed, Inc.; Dr. Wolpert reports having received consulting fees from Abbott Diabetes Care, Inc. and research funding from Medtronic MiniMed, Inc.

Supplemental Figures and Tables.

Figure A-1. Mean glucose by age group (error bars represent one standard deviation). There was a slight association of lower age and higher mean glucose level ($P=0.009$) which was seen both during the day ($P=0.04$) and overnight ($P<0.001$).

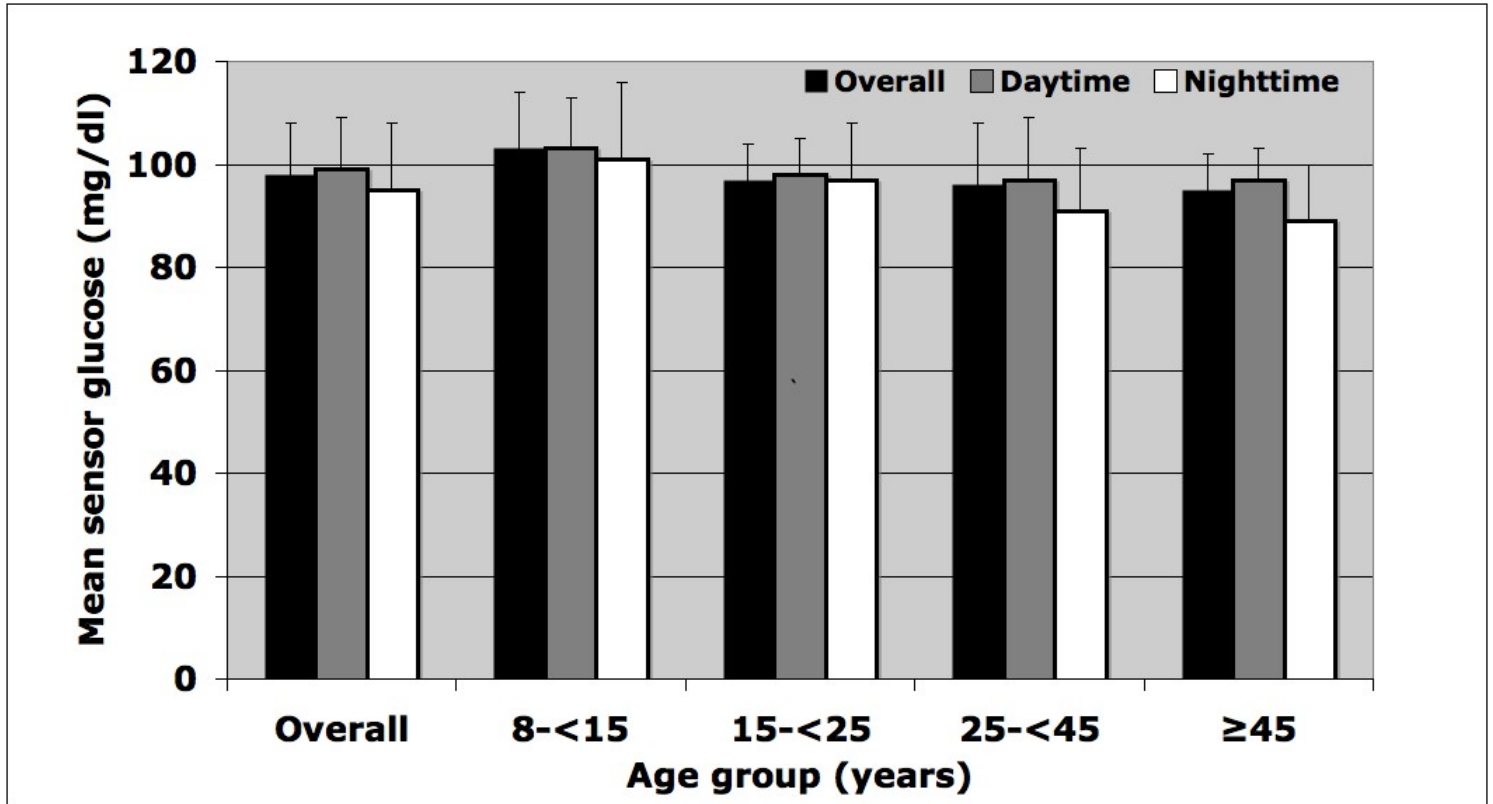


Figure A-2. Mean glucose values by time of day for entire study population and by age group. Shaded area represents nighttime values (midnight – 6 a.m.). P=0.009 for the association of overall mean glucose with age; P=0.04 for the association of mean glucose with age during the daytime; P<0.001 for the association of mean glucose with age overnight. All P values are after adjusting for device type.

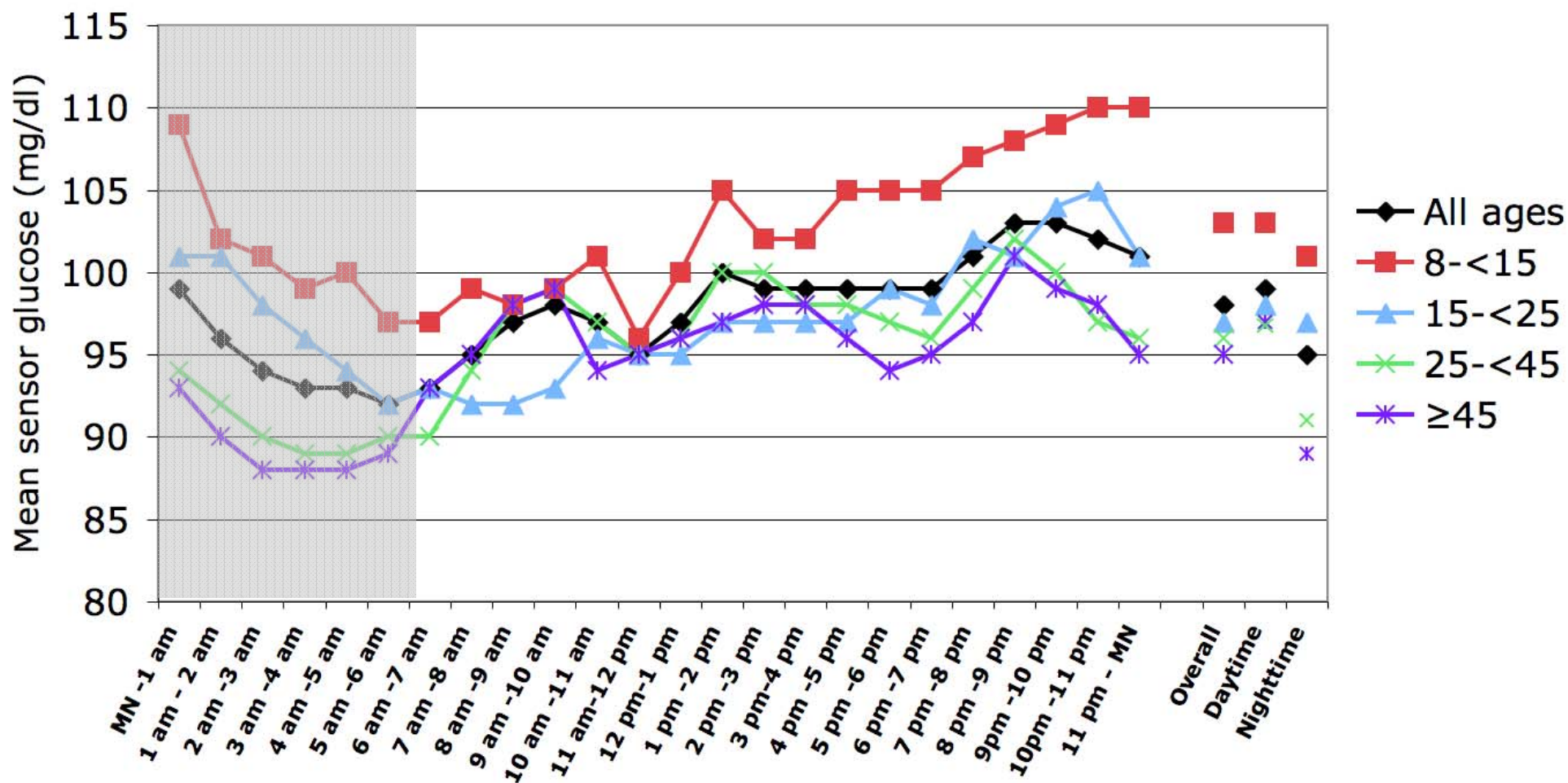


Table A-1. Sensor Glucose Values and Glucose Variability by Device Type

	DexCom	Guardian	Navigator
	N=35	N=38	N=36
HbA1c (%) (mean±SD)	5.3±0.3	5.3±0.2	5.3±0.3
Mean sensor glucose (mean±SD)			
Overall	101±11	98±9	98±11
Daytime (6 a.m.-12 a.m.)	101±11	98±10	100±10
Nighttime (12 a.m.-6 a.m.)	98±17	96±11	93±16
Mean peak sensor glucose (mean±SDmedian) †			
Daytime (6 a.m.-12 a.m.)	163	129	133
Nighttime (12 a.m.-6 a.m.)	128	110	106
Mean nadir sensor glucose (mean±SDmedian) †			
Daytime (6 a.m.-12 a.m.)	67	72	75
Nighttime (12 a.m.-6 a.m.)	72	83	79
Distribution of sensor glucose levels (median)			
71-120 mg/dL	65.9%	88.5%	92.0%
≤70 mg/dL	7.2%	2.8%	0.9%
≤60 mg/dL	1.3%	0.1%	0.2%
>120 mg/dL	17.0%	5.7%	5.4%
>140 mg/dL	7.8%	0.4%	0.6%
Overall glucose variability (median)			
Standard deviation (mg/dL)	26.7	14.6	12.7
Absolute rate of change (mg/dL/minute)	0.73	0.31	0.36
Coefficient of variation (%)‡	27	15	13
Mean amplitude of glycemic excursions (mg/dL)	47.1	28.3	27.1

† The calculation of peak and nadir glucose was restricted to days with ≥12 hours and nights with ≥4 hours of glucose data.

‡SD divided by mean glucose, expressed as a percentage.

Table A-2 Distribution of Glycemic Indices by Age Group for Various Glucose Levels

	All N=74	Age Group			
		8-<15 N=20	15-<25 N=17	25-<45 N=20	≥45 N=17
Below 70 mg/dL					
Median	1.7%	1.8%	0.6%	2.9%	1.6%
0%	21 (28%)	6 (30%)	5 (29%)	5 (25%)	5 (29%)
>0 to <1%	13 (18%)	2 (10%)	5 (29%)	4 (20%)	2 (12%)
1% to <5%	17 (23%)	7 (35%)	2 (12%)	4 (20%)	4 (24%)
5% to <10%	11 (15%)	4 (20%)	1 (6%)	3 (15%)	3 (18%)
10% to <15%	6 (8%)	1 (5%)	2 (12%)	1 (5%)	2 (12%)
≥15%	6 (8%)	0 0	2 (12%)	3 (15%)	1 (6%)
Below 60 mg/dL					
Median	0.2%	0.2%	0.0%	0.2%	0.1%
0%	33 (45%)	8 (40%)	9 (53%)	8 (40%)	8 (47%)
>0 to <1%	18 (24%)	6 (30%)	3 (18%)	5 (25%)	4 (24%)
1% to <5%	14 (19%)	5 (25%)	2 (12%)	4 (20%)	3 (18%)
5% to <10%	5 (7%)	1 (5%)	1 (6%)	1 (5%)	2 (12%)
10% to <15%	3 (4%)	0 0	2 (12%)	1 (5%)	0 0
≥15%	1 (1%)	0 0	0 0	1 (5%)	0 0
Below 50 mg/dL					
Median	0.0%	0.0%	0.0%	0.0%	0.0%
0%	49 (66%)	14 (70%)	11 (65%)	14 (70%)	10 (59%)
>0 to <1%	11 (15%)	2 (10%)	2 (12%)	2 (10%)	5 (29%)
1% to <5%	12 (16%)	4 (20%)	4 (24%)	2 (10%)	2 (12%)
5% to <10%	2 (3%)	0 0	0 0	2 (10%)	0 0
Within 71-120 mg/dL					
Median	91.0%	85.1%	87.9%	91.4%	93.7%
95-<100%	14 (19%)	2 (10%)	5 (29%)	2 (10%)	5 (29%)
90-<95%	24 (32%)	5 (25%)	3 (18%)	9 (45%)	7 (41%)
80%-<90%	16 (22%)	8 (40%)	3 (18%)	3 (15%)	2 (12%)
70-<80%	11 (15%)	2 (10%)	4 (24%)	3 (15%)	2 (12%)
<70%	9 (12%)	3 (15%)	2 (12%)	3 (15%)	1 (6%)

Above 120 mg/dL					
Median	5.6%	8.2%	8.3%	4.2%	4.4%
0%	1 (1%)	0 0	0 0	1 (5%)	0 0
>0 to <1%	9 (12%)	0 0	4 (24%)	2 (10%)	3 (18%)
1% to <5%	22 (30%)	4 (20%)	3 (18%)	8 (40%)	7 (41%)
5% to <10%	24 (32%)	7 (35%)	5 (29%)	6 (30%)	6 (35%)
10% to <15%	7 (9%)	3 (15%)	3 (18%)	0 0	1 (6%)
≥15%	11 (15%)	6 (30%)	2 (12%)	3 (15%)	0 0
Above 140 mg/dL					
Median	0.4%	1.3%	0.3%	0.3%	0.0%
0	29 (39%)	4 (20%)	8 (47%)	8 (40%)	9 (53%)
>0 to <1%	15 (20%)	5 (25%)	2 (12%)	5 (25%)	3 (18%)
1% to <5%	20 (27%)	7 (35%)	4 (24%)	5 (25%)	4 (24%)
5% to <10%	4 (5%)	1 (5%)	1 (6%)	1 (5%)	1 (6%)
10% to <15%	3 (4%)	2 (10%)	1 (6%)	0 0	0 0
≥15%	3 (4%)	1 (5%)	1 (6%)	1 (5%)	0 0
Above 160 mg/dL					
Median	0.0%	0.0%	0.0%	0.0%	0.0%
0	53 (72%)	12 (60%)	14 (82%)	15 (75%)	12 (71%)
>0 to <1%	11 (15%)	5 (25%)	1 (6%)	2 (10%)	3 (18%)
1% to <5%	8 (11%)	2 (10%)	2 (12%)	2 (10%)	2 (12%)
5% to <10%	1 (1%)	0 0	0 0	1 (5%)	0 0
10% to <15%	1 (1%)	1 (5%)	0 0	0 0	0 0
Above 180 mg/dL					
Median	0.0%	0.0%	0.0%	0.0%	0.0%
0	64 (86%)	17 (85%)	14 (82%)	18 (90%)	15 (88%)
>0 to <1%	4 (5%)	1 (5%)	2 (12%)	1 (5%)	0 0
1% to <5%	5 (7%)	1 (5%)	1 (6%)	1 (5%)	2 (12%)
5% to <10%	1 (1%)	1 (5%)	0 0	0 0	0 0

Table A-3. Distribution of Glycemic Indices for Various Glucose Levels by Daytime vs. Nighttime (midnight-6 a.m.)

	Time of Day		
	Overall N=74	Daytime N=74	Nighttime N=74
Below 70mg/dL			
Median	1.7%	1.1%	2.2%
A)0	21 (28%)	26 (35%)	32 (43%)
B)>0 to <1%	13 (18%)	10 (14%)	2 (3%)
C)1% to <5%	17 (23%)	19 (26%)	15 (20%)
D)5% to <10%	11 (15%)	8 (11%)	4 (5%)
E)10% to <15%	6 (8%)	3 (4%)	9 (12%)
F)≥15%	6 (8%)	8 (11%)	12 (16%)
Below 60mg/dL			
Median	0.2%	0.0%	0.0%
A)0	33 (45%)	40 (54%)	47 (64%)
B)>0 to <1%	18 (24%)	15 (20%)	4 (5%)
C)1% to <5%	14 (19%)	15 (20%)	11 (15%)
D)5% to <10%	5 (7%)	1 (1%)	2 (3%)
E)10% to <15%	3 (4%)	3 (4%)	6 (8%)
F)≥15%	1 (1%)	0 0	4 (5%)
Below 50mg/dL			
Median	0.0%	0.0%	0.0%
A)0	49 (66%)	57 (77%)	58 (78%)
B)>0 to <1%	11 (15%)	6 (8%)	6 (8%)
C)1% to <5%	12 (16%)	9 (12%)	3 (4%)
D)5% to <10%	2 (3%)	2 (3%)	5 (7%)
E)10% to <15%	0 0	0 0	2 (3%)
Within 71-120 mg/dL			
Median	91.0%	90.4%	90.3%
A)100%	0 0	0 0	10 (14%)
B)95-<100%	14 (19%)	17 (23%)	22 (30%)
C)90-<95%	24 (32%)	21 (28%)	6 (8%)
D)80%-<90%	16 (22%)	18 (24%)	12 (16%)
E)70-<80%	11 (15%)	10 (14%)	10 (14%)
F)<70%	9 (12%)	8 (11%)	14 (19%)
Above 120mg/dL			
Median	5.6%	5.9%	1.1%
A)0	1 (1%)	2 (3%)	32 (43%)
B)>0 to <1%	9 (12%)	8 (11%)	5 (7%)
C)1% to <5%	22 (30%)	20 (27%)	11 (15%)
D)5% to <10%	24 (32%)	24 (32%)	7 (9%)
E)10% to <15%	7 (9%)	8 (11%)	5 (7%)
F)≥15%	11 (15%)	12 (16%)	14 (19%)
Above 140mg/dL			
Median	0.4%	0.5%	0.0%
A)0	29 (39%)	31 (42%)	58 (78%)
B)>0 to <1%	15 (20%)	13 (18%)	2 (3%)
C)1% to <5%	20 (27%)	19 (26%)	7 (9%)
D)5% to <10%	4 (5%)	6 (8%)	2 (3%)

	Time of Day		
	Overall N=74	Daytime N=74	Nighttime N=74
E)10% to <15%	3 (4%)	2 (3%)	1 (1%)
F)≥15%	3 (4%)	3 (4%)	4 (5%)
Above 160mg/dL			
Median	0.0%	0.0%	0.0%
A)0	53 (72%)	54 (73%)	68 (92%)
B)>0 to <1%	11 (15%)	9 (12%)	0 0
C)1% to <5%	8 (11%)	9 (12%)	5 (7%)
D)5% to <10%	1 (1%)	1 (1%)	0 0
E)10% to <15%	1 (1%)	1 (1%)	0 0
F)≥15%	0 0	0 0	1 (1%)
Above 180mg/dL			
Median	0.0%	0.0%	0.0%
A)0	64 (86%)	67 (91%)	70 (95%)
B)>0 to <1%	4 (5%)	1 (1%)	1 (1%)
C)1% to <5%	5 (7%)	6 (8%)	2 (3%)
D)5% to <10%	1 (1%)	0 0	0 0
F)≥15%	0 0	0 0	1 (1%)