

Measures derived from patient generated health data provide insights on glycemic control beyond A1C for people with type 2 diabetes

Mansur Shomali, MD, CM

WellDoc, Inc., Columbia, MD and MedStar Union Memorial Hospital, Baltimore, MD

Background: Measures beyond A1C are needed to identify clinical glycemic control issues such as wide BG variations and very high and very low BGs. Such metrics may correlate with quality of life (QOL) and risk of significant adverse health outcomes. For people with type 1 diabetes using continuous glucose monitors, parameters that reflect glycemic variability and percent time in range have been proposed.

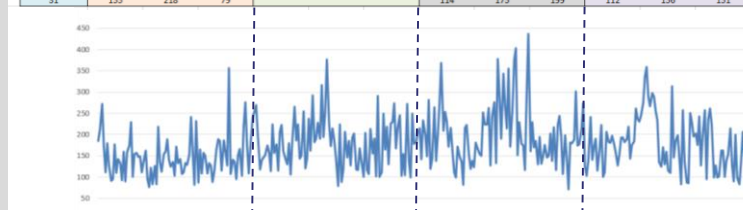
Type 1 diabetes	Type 2 diabetes
Dense BG data	Sparse BG data
CGM, frequent SMBG	Infrequent SMBG
Insulin therapy only	Insulin and non-insulin therapies

Methods: We constructed the following measures that are more suitable for people with type 2 diabetes who generally have sparse data. We evaluated how useful these metrics would be for real de-identified patient data coming from a user of a digital health tool (BlueStar, WellDoc, Inc., Columbia, MD).

- SDF.....standard deviation fasting
- SDNF.....standard deviation non-fasting
- NLD.....# days per month that a hypo (BG <70) is recorded
- NHD.....# days per month that a very high (BG>300) is recorded
- NLHD.....#days per month that a hypo or a very high is recorded
- PDIR.....% of days per month in which all BGs are in the target range
- PDNE.....% of days per month without BG extremes

Example of Log Book Data of a Person with T2 Diabetes

Day	October			November			December			January		
	B	L	D	B	L	D	B	L	D	B	L	D
1	104	134	177	55	166	206	76	187	183	85	65	92
2	112	154	169	94	204	157	99	166	159	78	140	
3	186	47	101	136	158	138	143	117	114	106	153	189
4	94	146	119	99		129	132	187	90	89	73	118
5	83	154	264	124	195	174	242	260	157	119	140	176
6	99		130	187	168	197		200	233	89	70	81
7	131	147	149	86	109	192	207	170	257	182		100
8	119	141	141	106	168	244	88	211	216	133	95	195
9	144	92		91	82	151	123	224	198	83		157
10	148	185	215	137	147	174	122	173	126	99	131	180
11	108	132		88		209	151	131	296	96	296	185
12	190	281	196	96	115	188	127	129	199	71	180	136
13	119	293	253	155	171	173	110	73	225	81	217	148
14	76	147	115	239	168		97	126	177	86	199	124
15	123	247		123	145	201	106	174	222	164	125	155
16	153	247	305	107	82	208	157	130	73	129	167	
17	123	119	289	113	190	201	106	264	168	209	143	190
18	160		348	123	164		93	186	121	103	189	208
19	111	133	81	89	203	119	126	81	182	107	147	182
20	101	134	151	131	177	112	173	93	165	92	107	215
21	145	145	161	79	170	128		85	149	75	179	135
22	92	197	160	94	105	158	107	105	178	77	164	119
23	139	131	202	105	156	197	83	157	98	146	219	185
24	138	130	96	119	152	276	131	122	141	141	232	339
25	144	170	162	112	92	231	101	252	211	179	132	191
26	63	72	103	70	139	241	88	110	121	164	193	247
27	107	149	243	60	246	171	92	281	188	174	172	116
28	72	120	134	107	189		77	136	85	94	107	123
29	101	169		125	150	272	172	153	253	208	156	203
30	284	282	167	111	148	164	169	131	176	79	263	214
31	155	218	79				114	175	199	112	156	151



Results: In the table, measures were calculated from a patient who was checking 3 BGs per day. The average BG and projected A1C appear constant. The average fasting BG and SDF did not change monthly, but changes occurred in the SDNF, suggesting issues with the consistency of breakfast and lunch meals. Despite stability of A1C and average BG, the PDIR worsened from 52% in month 1 to 33, 39, and 23% in months 2, 3, and 4, respectively. This reflects changes that can be appreciated via visual inspection of the logbook..

Proposed Measures Applied to Log Book Data

Measure	Month 1	Month 2	Month 3	Month 4
Mean BG (mg/dL)	153	150	153	147
Projected A1C (%)	7.0	6.9	7.0	6.9
Mean fasting BG, SDF	127, 43	112, 37	125, 40	118, 41
Mean pre-lunch BG, SDNF	163, 60	154, 39	161, 56	159, 55
Mean pre-dinner BG, SDNF	174, 71	185, 43	173, 54	167, 53
NLD	2	2	0	1
NHD	1	0	0	0
NLHD	3	2	0	1
PDIR	0.52	0.33	0.39	0.23
PDNE	0.90	0.93	1.00	0.94

Conclusion: These proposed metrics provide insight to user BG data that go beyond measures of average. Digital health tools are capable of calculating these metrics and making them available for provider clinical decision support. Future studies will examine if these measures correlate with QOL or health outcomes.