



Inequity in Racial-Ethnic Representation in Randomized Controlled Trials of Diabetes Technologies in Type 1 Diabetes: Critical Need for New Standards

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Racial/ethnic inequity exists in all aspects of health care and does not exclude the field of advanced diabetes technology. Despite the recent increase in technological therapeutic options for diabetes management and mounting evidence of positive effects on glycemic outcomes, emerging reports have highlighted that insulin pump and continuous glucose monitor use remain significantly lower in Black and Hispanic compared with White populations (1,2). Critical needs remain to bridge gaps in technology use. An important issue that we in the scientific and research communities can modify is the inclusion of minorities in clinical trials of diabetes devices. The population prevalence estimates of type 1 diabetes in the U.S. were as follows: non-Hispanic White, 72%; Hispanic, 15.7%; non-Hispanic Black, 9.3%; and Asian, 2.4% (3). Adequate racial/ethnic representation in parallel with the prevalence of type 1 diabetes is needed not only to evaluate widespread efficacy and acceptability of diabetes technology but also to create better dissemination and marketing plans that increase use among underrepresented groups.

To evaluate the current state, we investigated racial/ethnic enrollment of participants in published clinical trials

of type 1 diabetes technology to estimate whether trial enrollment had adequate representation of racial/ethnic minority groups. We used Medline, Embase, and Cochrane Central databases to systematically search for randomized controlled trials (RCTs) of currently U.S. Food and Drug Administration (FDA)-approved hybrid closed-loop and continuous glucose monitoring devices in the U.S. We included only U.S. studies, as race/ethnicity categorization is defined differently in other countries. Studies had to be at least 3 months in duration with predefined glycemic outcomes and include children and adults with type 1 diabetes. We included trials published between 1 January 2015 and 22 October 2020 to reflect currently available FDA-approved technologies.

In total, 1,118 abstracts were reviewed, and 67 met criteria for detailed review. Out of 67 studies, nine met inclusion criteria. One of the nine studies did not report any race/ethnicity, so it was excluded. In the remaining eight RCTs, out of a total of 1,354 enrolled participants with type 1 diabetes, the great majority were non-Hispanic White (84.5%, $n = 1,144$). For racial/ethnic minorities, 6% were Hispanic ($n = 82$), 2.2% were non-Hispanic Black ($n = 30$), 1% were Asian ($n = 14$), and 2% were

categorized as “other” racial/ethnic group (Table 1). Approximately 4% of all participants ($n = 56$) had no race/ethnicity reported. None of the trials reported prespecified enrollment targets by race/ethnicity criteria.

Our results highlight large disparities in racial/ethnic representation among RCTs of diabetes technologies for type 1 diabetes, including pivotal trials used to gain FDA approval for currently available commercial devices. Moreover, percent enrollment of racial/ethnic minority groups was significantly lower than the current population prevalence estimates of underrepresented groups with type 1 diabetes. Even more concerning is the fact that none of the trials reported a specified recruitment target for different racial/ethnic minority groups, despite recent FDA recommendations for the inclusion of racial and ethnic minorities in clinical trials (4) and given that rates of type 1 diabetes are increasing in underrepresented groups (5). These disheartening findings, coupled with the fact that Black populations with type 1 diabetes, in particular, suffer from the worst medical outcomes in the U.S. (5), demonstrate an urgent need for more inclusive recruitment in clinical

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Table 1—Racial/ethnic distribution of participants with type 1 diabetes in RCTs of diabetes technologies

Ref. no.	First author, year	Diabetes technology	Total population, <i>N</i>	Race/ethnicity distribution, <i>N</i> (% of total population)				
				Non-Hispanic White	Hispanic or Latino	Non-Hispanic Black	Asian	Other
6	Breton, 2020	Control-IQ	101	82 (81.1)	8 (7.9)	0	NR	11 (12)
7	Brown, 2019+	Control-IQ	168	147 (87.5)	18 (10.7)	NR	NR	NR
8	Aleppo, 2017+	Dexcom G4	226	207 (91.5)	9 (4)	5 (2.2)	4 (1.7)	NR
9	Beck, 2017*+	Dexcom G4	75	65 (86.6)	2 (2.6)	5 (6.6)	NR	NR
10	Feig, 2017##+	Medtronic Guardian	325	279 (85.8)	NR	NR	NR	NR
11	Pratley, 2020+	Dexcom G5	203	187 (92)	5 (2.4)	6 (3)	1 (0.5)	2 (1)
12	Forlenza, 2018	Basal-IQ and Dexcom G5	103	82 (79.6)	7 (6.8)	2 (1.9)	3 (2.9)	9 (8.8)
13	Laffel, 2020+	Dexcom G5	153	95 (62)	33 (21.5)	12 (7.8)	6 (3.9)	6 (3.9)
14	Kovatchev, 2020##	Control-IQ	80##	NR	NR	NR	NR	NR
Total of participant race reported+			1,354	1,144 (84.5)	82 (6)	30 (2.2)	14 (1)	28 (2)

NR, not reported. *The main study ($n = 158$) did not report racial distribution (15); therefore, we included this substudy. +Some studies have missing data on race/ethnicity. #This is a multinational study including U.S. sites. ##This study was not included in the final analysis, as they did not report race/ethnicity.

trials of future diabetes technological treatments.

The inclusion of underrepresented groups in clinical trials should at least match population prevalence estimates. Apart from being more equitable in representation, there are other benefits of including underrepresented groups with type 1 diabetes in clinical trials. Through enrollment and trial participation, lived experience and cultural attitudes of these populations can be gleaned and further incorporated into the development, marketing, and dissemination of devices.

Inclusion should enhance the acceptability of devices by historically excluded populations and result in improved uptake upon commercial release. More importantly, inclusion may start the process of decreasing disparities in short- and long-term outcomes.

According to the FDA guidance on enhancing the diversity of clinical trial populations published in 2020, clinical trial site selection in certain geographic locations may limit the ability to enroll a diverse trial population (4). In addition, participants may be less likely to enroll in research where recruitment staff do not share similar cultural and racial backgrounds with participants. The FDA suggested that clinical trial sites include geographic locations with a higher

concentration of racial/ethnic minority groups and indigenous populations as well as specifically selecting locations within neighborhoods where these populations receive their health care. Furthermore, the FDA suggested using more diverse health care provider panels and study coordinators to assist with clinical trial recruitment (4). While FDA guidance was a noble first step in alerting researchers of the importance of inclusion of racial/ethnic minorities, without the implementation and enforcement of specific enrollment criteria, the status quo has continued.

We believe that accountability for inclusion and diversity has to be taken by all parties along the diabetes technology pipeline. The FDA should set benchmarks for racial/ethnic minority inclusion in clinical trials of diabetes devices such that device companies have to comply. Device companies will need to create solutions to recruit adequate numbers of racial/ethnic minority populations by convening advisory boards involved in the development and recruitment processes of clinical trials, educating research staff on best practices for minority recruitment, and diversifying workforces to reflect the desired participant population. To mirror this requirement and as a way of enforcement, scientific journals should require

reporting of race/ethnicity for publication of clinical trial results. Race/ethnicity reporting will inform readers on the generalizability of study findings and relevance to local type 1 diabetes patient panels.

Health care providers need to translate research to practice swiftly by recognizing their role as gateways to diabetes technologies and overcoming possible implicit biases. Overall, the first step to reducing racial/ethnic disparities in diabetes technology use among Black and Hispanic people with type 1 diabetes is to create systems of regulations and reporting that promote inclusion and diversity in type 1 diabetes technology clinical trials and align public health, research, medical, and regulatory bodies to enable easier adoption.

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