diaTribe

October 24, 2024

James Swink
Digital Health Advisory Committee
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 66
Silver Spring, MD 20993-0002

Submitted via Regulations.gov

RE: **Digital Health Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments [FDA-2024-N-3924]**

Dear Mr. Swink and Members of the Committee:

On behalf of The diaTribe Foundation, thank you for the opportunity to provide written comments in advance of the Digital Health Advisory Committee's (DHAC) inaugural meeting on November 20-21. We appreciate DHAC's consideration of "Total Product Lifecycle Considerations for Generative Artificial Intelligence-Enabled Medical Devices." We believe artificial intelligence (AI) can enhance – and be used in conjunction with – existing technologies and metrics to better manage diseases like diabetes.

The diaTribe Foundation

As you know, over thirty-eight million Americans are affected by diabetes.[1] The mission of The diaTribe Foundation is to help people with diabetes and prediabetes and to advocate for action. Our goal is to ensure that people have the resources and education needed to thrive with diabetes. The diaTribe Foundation is dedicated to bringing people with diabetes to the conversation on regulatory issues, connecting the field and the diabetes community, and changing the narrative around diabetes. Through our publication, *Learn*, which reaches more than six million people each year, we offer deep insights into the patient experience and closely cover the latest research, treatments, and initiatives in diabetes.

In addition, because everyone with diabetes deserves to have the tools, therapies, and technologies to live their best life, we established the *Time in Range Coalition (TIRC)*, a multi-stakeholder group of foundations, non-profit organizations, researchers, people with diabetes, clinicians, and industry with the goal of establishing time in range (TIR) as an essential part of diabetes care and making TIR accessible to all people with diabetes and their care teams. Using TIR in daily diabetes management can positively change lives[2,3]—we are spearheading the work to make that a reality for everyone living with diabetes.

The diaTribe Foundation also aims to reduce the impact of diabetes on society and improve the lives of people with diabetes by fostering an understanding of the disease and eliminating misplaced blame through the work of our program, *dStigmatize*.

The Critical Role of Continuous Glucose Monitors (CGMs) and AI in Diabetes Management

Reflecting TIR data's importance to the quality of life and health outcomes for people with diabetes, a central goal of The diaTribe Foundation has been the use of data derived from CGMs in regulatory decision-making. CGMs provide real-time data on glucose levels and are a vital tool for individuals seeking to manage diabetes, including through the use of TIR. People with type 1 or type 2 diabetes can use the data and alarms powered by CGMs to avoid dangerous glucose levels and to help make real-time adjustments to anti-diabetic treatments, doses, food intake, exercise, and more. TIR is real-world data; each day tens of millions of individuals utilize CGMs to gain insights into their glucose levels and how changes in their diet and activities impact their TIR. We encourage DHAC to recognize that TIR is an at-the-ready real-world dataset available to help inform research, practice, and care.

The use of AI to enhance or supplement CGMs is a logical next step technologically. In fact, AI-enabled CGMs are already a reality.[4] As the subject of your meeting acknowledges, this advancement requires risk management and robust pre- and post-market performance monitoring. AI-enabled CGMs have the potential to make CGMs even more useful with personalized recommendations and longer lead prediction times. As it stands, non-AI-enabled CGMs have been shown to improve diabetes outcomes.[5–9] Further, the FDA acknowledged the value of CGM and CGM-based metrics in the development and regulatory assessment of new therapies in its May 2023 draft guidance, which notes the agency "recognizes that CGM systems have certain advantages over self-monitoring blood glucose (SMBG) test systems."[10] AI systems that can build on already-effective CGM data to predict needed adjustments ahead of time would be immensely beneficial for people with diabetes.

Health Equity & Discrimination Concerns Vis-à-vis AI

While the potential of AI, especially coupled with CGMs, is highly promising, The diaTribe Foundation recognizes that AI presents potential problems in terms of health equity, bias, and discrimination. AI is ultimately designed by humans and as such can entrench human biases.

Ensuring the use of AI in diabetes management does not introduce or exacerbate biases is even more important given that diabetes has a disproportionate impact on low-income, rural, and racially minoritized communities in America. Among adults, prevalence of diabetes is highest among American Indians and Alaska Natives (13.6%), followed by non-Hispanic Black adults (12.1%), those of Hispanic origin (11.7%), and non-Hispanic Asian individuals (9.1%), with lowest prevalence among non-Hispanic white adults (6.9%).[1] Differences are also observed by education level, an indicator of socioeconomic status: 13.1% of adults with less than a high school education have diagnosed diabetes compared to 9.1% of those with a high school education, and 6.9% of individuals with more than a high school education.[1] Finally, diabetes is more prevalent in rural areas.[1]

The disproportionate impact of diabetes extends to diabetes-related health complications, as well. Black and Hispanic adults with diabetes disproportionately experience microvascular complications compared to white adults and Black and Mexican Americans are less likely to meet targets for cardiovascular risk reduction.[11] Compared with residents of cities, Americans living in small towns have greater risk of hyperglycemia, end-stage kidney disease, myocardial infarction, heart failure, amputation, and other lower-extremity complications.[12] Additionally, rural counties experience persistently higher overall diabetes mortality rates than more urban areas.[13]

The data input into AI diabetes technology via machine learning must reflect these disparities and account for them. While continuous glucose monitoring metrics such as TIR are unbiased data, a growing body of evidence demonstrates that Hemoglobin A1C (A1C) does not reflect the same average glucose in all individuals, as red blood cell glycation rates vary greatly across individuals.[14–22] Importantly, A1C has been shown to consistently overestimate glycemia in Black people with diabetes,[23–27] with studies also demonstrating A1C inconsistencies in association with commonly co-occurring conditions,[28–33] medication use,[34,35] age,[37] and other factors.

In considering the potential risks of bias in AI, The diaTribe Foundation encourages DHAC to look to President Biden's "Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence" issued on October 30, 2023.[36] That order emphasized the need for guardrails in the development of AI, including addressing "unlawful discrimination and other harms that may be exacerbated by AI." It pointed to disaggregated data, representative population sets, and continuous monitoring of algorithmic performance for bias as key steps to take to minimize AI-enabled discrimination. With proper guardrails in place, AI has great potential to enhance diabetes management and improve outcomes for individuals living with diabetes.

Conclusion

The diaTribe Foundation is committed to ensuring that people with diabetes can access the therapies they need and to eliminating cost-prohibitive barriers to life-sustaining medication. This commitment extends to therapies assisted by technology like CGMs, real-world data like TIR, and, going forward, AI. We believe that with the proper planning and precautions the benefits of the use of AI in diabetes management can be maximized, while minimizing biases, resulting in better outcomes for individuals with diabetes. We urge DHAC to shape its AI discussion around achieving that public health goal.

Thank you for considering our comments. If we can be of any assistance to you as you consider AI in management of diabetes, please do not hesitate to contact us.

Sincerely,

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