May 22, 2024

Dr. William Cefalu
Executive Secretary
Diabetes Mellitus Interagency Coordinating Committee
National Institute of Diabetes and Digestive and Kidney Diseases
6707 Democracy Boulevard
Democracy 2, Room 6037
Bethesda, MD 20892

Submitted via dmicc@mail.nih.gov

RE: **Diabetes Mellitus Interagency Coordinating Committee Meeting – "Artificial Intelligence in Diabetes Precision Medicine: Real world data, real world opportunities and challenges" [FR Doc. 2024-09591]**

Dear Dr. Cefalu:

On behalf of The diaTribe Foundation, thank you for the opportunity to provide written comments in advance of the virtual Diabetes Mellitus Interagency Coordinating Committee (DMICC) meeting on May 30. We appreciate DMICC's consideration of "Artificial Intelligence in Diabetes Precision Medicine: Real world data, real world opportunities and challenges." We believe artificial intelligence (AI) can enhance and be used in conjunction with existing technologies and metrics to better manage diabetes.

The diaTribe Foundation

As you know, thirty-seven 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 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 CGMs and AI in Diabetes Management

Reflecting TIR data's importance to the quality of life and health outcomes for these individuals, a central goal of The diaTribe Foundation has been the use of data derived from continuous glucose monitors (CGMs) in regulatory decision-making. CGMs provide real-time data on blood 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 blood glucose levels and to help make real-time adjustments to anti-diabetic treatments, doses, food intake, exercise, and more. TIR is real-world data; every day tens of millions of individuals utilize CGMs to gain insights into their blood glucose and how changes in their diet and activities impact their TIR. We encourage the DMICC 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 title of your meeting acknowledges, this advance presents both opportunities and challenges. 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 has 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 have biases is even more important given that minority communities bear a disproportionate burden of diabetes. Black (17.4%), Asian (16.7%), and Hispanic (15.5%) adults have higher prevalence rates than whites (13.6%) and Indigenous Peoples are twice as likely as whites to have diabetes.[1] The data input into AI diabetes technology via machine learning must reflect these disparities and account for them. For instance, A1c levels can be falsely elevated in Black people with diabetes,[11–13] while a TIR-based approach using CGMs does not vary across race and ethnicities.

In considering the potential risks of bias in AI, The diaTribe Foundation encourages DMICC 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.[14] 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 DMICC to shape its AI discussion around achieving that 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 me at julie.heverly@diaTribe.org.

Sincerely,

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