

July 22, 2024

Re: The diaTribe Foundation Comments to Docket No. FDA-2024-N-2780

Home as a Health Care Hub – Stakeholder Listening Session

To Whom it May Concern:

On behalf of The diaTribe Foundation, thank you for the opportunity to provide input on the direction of the FDA’s new Home as a Health Care Hub initiative. We believe there is great opportunity for the delivery of health care and the generation of clinical evidence in the home environment using digital health technologies. With the economic cost of diabetes nearing \$413 billion in the United States, we appreciate FDA’s novel approach to improving care and outcomes for this complex and growing population.¹ While the innovation supported through this initiative holds great potential to improve lives, we urge the agency not to overlook that additional work is needed to expand access to existing, effective, evidence-supported technologies—including continuous glucose monitoring and its metrics—to support home-based care. It is critical that this initiative reflect the reality of daily disease management and implement the latest science on the value of technologies for improving health and quality of life without increasing burden on patients.

The diaTribe Foundation

The mission of The diaTribe Foundation (diaTribe) is to help people with diabetes 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) with 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. Research shows that using time in range in daily diabetes management can positively change lives—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*.

Health equity concerns in diabetes

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In launching this new initiative, diaTribe is grateful for FDA’s focus on the disproportionate impact diabetes has 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%).² 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.² Finally, diabetes is more prevalent in rural areas.²

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.³ 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.⁴ Additionally, rural counties experience persistently higher overall diabetes mortality rates than more urban areas.⁵

Need for digital health technologies to improve access to care

Last month, we had the privilege of hearing Commissioner Califf speak at the American Diabetes Association Scientific Sessions. Dr. Califf raised several important issues about the value of technology for addressing the epidemic of diabetes in this country that are relevant to this initiative, including the current shortage of endocrinologists⁶ to care for the 38 million Americans with diabetes.² We agree with his assessment that addressing this care gap will require both integrating other types of healthcare providers *and* developing and deploying evidence-based digital tools for everyone who needs them.

Proven benefits of continuous glucose monitoring

Continuous glucose monitors (CGMs) are front and center among technologies with proven benefits for people with all types of diabetes. High quality evidence continues to confirm that CGM is superior to self-monitoring of blood glucose (SMBG) in helping people with diabetes monitor and improve their glycemic control, specifically in improving their time in range, reducing glucose variability, and lowering their risk of hypoglycemia.⁷⁻²² Further, emerging evidence directly ties CGM use to lower risk of developing diabetic retinopathy.²³ Unlike SMBG, which requires people with diabetes to collect many fingersticks a day to monitor their glucose, continuous glucose monitoring automatically measures glucose levels every one to five minutes. Data shows people with diabetes using SMBG do not test as regularly as advised, further reducing the data points available to guide management adjustments without CGM.²⁴

Individuals living with diabetes and their care providers can use CGMs to guide health care decision-making. CGM data are actionable, empowering, impactful, and, thanks to continued advances in technology, highly accurate.^{25,26} There is clear clinical consensus on the value of

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CGMs and time in range for diabetes management.²⁷ In fact, the American Diabetes Association’s 2024 Standards of Care clearly state that diabetes technologies should be offered to all people with diabetes and further emphasize that CGM, specifically, should be offered to all individuals using insulin.²⁸ It is our hope that steps FDA is taking to incorporate CGM metrics into drug labels will further encourage use of this essential digital tool.

In addition to value for individual patient care, there are well-established benefits and protocols for the use of CGMs in generating clinical evidence.²⁹ CGMs provide consistently accurate data across participant sub-groups, while there are many confounding factors known to undermine the accuracy of another commonly used glycemic indicator: HbA1c (A1C).^{30,31} Specific races, health conditions, and medications have been correlated to inaccurate A1c values.³²⁻⁴³ These biases may lead to inaccurate health information and over- or undertreatment, worsening the very disparities this initiative seeks to disrupt. CGMs can additionally support representative research by reducing the frequency of in-person appointments necessary for data collection, making study participation far more accessible—an essential element of the Home as a Health Care Hub objective. FDA has acknowledged some of these benefits, noting CGMs provide a more comprehensive assessment of hypoglycemia than SMBG by limiting bias as the devices do not rely on participant effort to measure glucose but rather record all hypoglycemic events—even those that occur while patients are sleeping or in patients with hypoglycemia unawareness.⁴⁴ Further, CGM data can provide researchers with rich data on duration of hypo- and hyperglycemic events, glycemic variability, and correlations to exercise and other data in a way not possible with SMBG or A1C-based glycemic monitoring.

Additionally, though concerns remain about the accessibility of patient costs for CGMs, the devices have been found to be cost-effective.⁴⁵⁻⁴⁸ While this has been long-established for type 1 diabetes,^{49,50} recent evidence suggests use of CGM may reduce diabetes-related medical costs in people with type 2 diabetes by reducing hospital admissions, duration of hospital stays, and therefore inpatient costs.⁴⁷ A recent large analysis of data from patients with type 1 and type 2 diabetes in the Veterans Health Administration found that CGM led to reductions in A1C, hyperglycemia, and all-cause hospitalizations, indicating the promise this tool holds for combatting both the complications and costs described above.⁵¹

Improving CGM accessibility and integration

The clinical utility and benefits of CGMs and their metrics are now undisputed, and access is gradually expanding. However, as Dr. Califf noted in his speech, more work needs to be done for this technology to reach the majority of people who need them.

While we understand the Home as a Health Care Hub initiative is focused on “shifting the care model from systems to people,” making these interventions truly supportive of health equity will require a 360-degree approach to innovation. We urge the agency not to overlook payer and health system-level changes that would broadly expand access. For example, working with health systems and electronic health record companies to better integrate data from

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devices like CGMs and with payers to ensure adequate reimbursement of devices and reduced barriers to remote care would enable more effective and equitable use of this proven technology within the Home as a Health Care model.

A key barrier to the home becoming a health care hub is the lack of coverage and burdensome cost-sharing that puts essential digital health technology out of reach. We know that policies that extend coverage substantively improve access, uptake, and outcomes. When a regional Medicaid program fully subsidized CGM, glycemic control improved and device uptake increased in individuals with both type 1 and type 2 diabetes, with no significant differences across racial/ethnic groups observed.⁵² Similarly, expansion of Medicare coverage for CGMs in 2023 was estimated to provide access to 1.5 million beneficiaries in the Medicare population, where disparate effects of diabetes are particularly notable.^{53,54} We urge FDA to work closely with the Centers for Medicare and Medicaid Services to ensure that technologies deemed safe and effective continue to become more accessible and affordable for all beneficiaries, particularly minoritized communities and individuals living in rural areas.

Finally, reducing barriers to telehealth care has clear health benefits, and CGM is key in facilitating high-quality remote diabetes care. Temporary measures to broaden telehealth access during the COVID-19 public health emergency demonstrated increased access and improved continuity of care, particularly among Black patients.^{55,56} In fact, diabetes-specific telehealth interventions have also been shown to improve outcomes, with particular benefit among racially-minoritized groups.⁵⁷⁻⁶¹ CGM can be initiated remotely,⁶¹ and plays a primary role in the efficacy of continued remote diabetes care by enabling clinical review of glycemic patterns, shared-decision making in regard to treatment adjustments, self-management skill troubleshooting, and more.^{60,62-65} In order to better facilitate health care in the home, patients must have affordable coverage of remote care, including with a broad range of practitioners, as 62% of rural counties in the United States do not have diabetes self-management education and support.⁶⁶

Conclusion

diaTribe appreciates FDA's ongoing dedication to improving health equity and effort to center individual patient needs through the development of the Home as a Health Care Hub initiative. We look forward to engaging with the innovative ideas that this project will foster, and thank you for the opportunity to share what those of us in the diabetes patient and professional community believe to be significant opportunities and important considerations as the agency considers the future direction of this project. If we can address any questions about these comments or be of assistance to this initiative, please do not hesitate to contact us at julie.heverly@diaTribe.org.

Sincerely,



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