American Pharmacists Association

January 30, 2024

Subject: Public comment: Digital Health Technologies for Detecting Prediabetes and Undiagnosed Type 2 Diabetes

Submitted electronically via www.regulations.gov to Docket No. FDA-2023-N-4853

Dear FDA Staff:

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) on Digital Health Technologies for Detecting Prediabetes and Undiagnosed Type 2 Diabetes (T2D). APhA appreciates FDA casting a broad net on input related to DHTs for prediabetes and undiagnosed T2D, as pharmacists are actively providing care to patients who would benefit from advances in these technologies.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

Pharmacists have played a significant role in diabetes prevention and management for decades. As clinically trained and knowledgeable healthcare providers, they deliver care in community, primary care, health system, and other settings. Roughly ninety percent of American's live within 5 miles of a community pharmacy.[1] In many parts of the country, particularly medically underserved and rural areas, the pharmacist may be the only health care provider that is accessible and available. Health screenings and detection services are often provided by pharmacists, who either provide care as appropriate, or refer the patient to their primary care provider.

[1] Berenbrok, Tang, Gabriel, Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis, J American Pharmacists Assn, July 12, 2022. https://doi.org/10.1016/j.japh.2022.07.003

APhA
American Pharmacists Association

APhA is pleased to provide the following information for select questions that were posed:

Community Engagement and Consortia Efforts

- **Which patient and community groups, health systems, pre-competitive consortia, or other organizations have prediabetes prevention, detection, or management programs?**

  Throughout the country, pharmacists are participating in the Center for Disease Control and Prevention's (CDC) National Diabetes Prevention Program (NDPP) focusing on lifestyle change interventions and APhA is actively engaged in the NDPP program. Under its umbrella hub organization designation with the CDC, the APhA Foundation partners with community pharmacy practice sites to deliver the NDPP. As part of this program, pharmacists screen patients for prediabetes or undiagnosed diabetes, using risk assessment and blood glucose tests, and refer the patient if they are at high risk or otherwise have high blood glucose. Additionally, trained lifestyle coaches have the ability to connect patients with preventive care services they otherwise may not have access to. Because of the high level of accessibility, community pharmacies offer a solution for the lack of availability of diabetes prevention, particularly for those living in rural areas or underserved communities.

  Additionally, APhA has resources, trainings, and other materials for pharmacists to use to screen for prediabetes and T2D. Pharmacists, also use the American Diabetes Association resources on predicting a patient's risk of diabetes and helping patients access these tools. In addition, employers, including the state, often offer prevention programs. Employers may also offer incentives for those who have their biometrics collected which can also lead to early prediction. For example, in the past, pharmacists in West Virginia were able to bill for a diabetes prevention program for state employees but this program was eliminated several years ago. This program was conducted in person. Many companies are now using virtual platforms for their employees to get coaching and education on healthy lifestyles. Patients can also find and pay for virtual diabetes management on their own as well, but this can be challenging because medication management by virtual providers can result in duplicate therapy or adverse effects if they are unaware of what the patient is currently taking. These virtual providers usually do not have a pharmacist or share electronic health records (EHR) with health systems, so they are unable to verify a patient's medications outside of what the patient reports. There are also various community programs here: https://www.cdc.gov/diabetes/prevention/find-a-program.html

- ***Are there any existing connected cohorts for people living with prediabetes? Connected cohorts are defined as groups of people with a common characteristic engaged longitudinally with digital technologies such as smartphones, apps, consumer wearables, or connected sensors for the purposes of health improvement or research. If so, how many people are members of the cohort and how are they "connected?"***

  Participants in the APhA NDPP are enrolled in a yearlong cohort. Over the course of a year, participants may have challenges with attending sessions in person. In these instances, some pharmacies may offer the opportunity for participants to join a group telehealth session via a distance learning option on their computer or smart phone. This allows for session delivery to continue despite barriers such as transportation or inclement weather. Many pharmacies, rather than discontinue services, chose to continue offering the diabetes prevention program through a distance learning modality during the recent public health emergency. While participating in group distance learning sessions, participants have the same opportunity to engage with their peers and meet program objectives. Certain program requirements such as obtaining weight values can be completed by use of Bluetooth connected scales. This example highlights not only the position of the community pharmacy to fill in a critical healthcare gap but leveraging digital health technology to do so.

- **What existing research consortia are developing risk prediction models for pre-disease states including prediabetes?**

  The CDC and American Diabetes Association developed a prediabetes risk test (https://www.cdc.gov/diabetes/prevention/pdf/Prediabetes-Risk-Test-Final.pdf). These are commonly used at community health screenings to detect risk factors for diabetes.

Science/Innovation

- **What DHTs, including those enabled by AI/ML algorithms, are currently being used outside the clinic to prevent, detect, treat, or reverse prediabetes?**

  For the most part, a simple survey can be used to predict a patient's risk for diabetes. In addition, patients can wear continuous glucose monitors or use traditional blood glucose monitors to observe blood glucose trends and determine if these fall into a category of concern. Traditional monitors can be purchased over the counter and have standard values associated with prediabetes. Continuous glucose monitors are prescription only. APhA is not aware of currently published data predicting prediabetes using these devices. However, this would be a good area for future research as it is minimally invasive for patients and the results can be easily shared electronically with their pharmacist who can then refer for further intervention if needed.

- **Who are key subpopulations of interest that might benefit the most from remote screening and diagnostic tools? Please include clinical and non-clinical considerations.**

  Patients who are unemployed would benefit from DHT for prediabetes and undiagnosed T2D because screening is often driven by employee health programs, which is not available for unemployed persons. Rural and underserved patients would benefit from DHT devices such as continuous glucose monitors because they use Bluetooth- not wifi, so glucose can be measured anywhere and readily shared with their local pharmacist rather than waiting for their yearly primary care visit. Similarly, DHT would be helpful for rural, underserved, and home-bound patients with transportation issues. Women who are pregnant or planning for pregnancy would benefit from DHT to focus on changing habits that increase the risk of gestational diabetes. With a device such as a continuous glucose monitor, they could learn what causes glucose to spike and prevent it from occurring again, with guidance from a professional.

- **What are high-prevalence and high-impact risk factors for prediabetes and undiagnosed type 2 diabetes that are or could be captured by DHTs?**

  Continuous glucose monitors have seen a significant increase in patient utilization over the past several years, due to their accuracy and usefulness in tracking blood glucose values. Although most patients use the device secondary to their diabetes diagnosis, it is worth nothing that this DHT could also be prescribed for patients with prediabetes. Through the APhA Foundation's Project IMPACT: CGM Access, enrolled patients are able to connect with their pharmacist to learn more about the proper wear and use of these devices. This pharmacist-provided service allows the patient to better understand the data obtained by the device, and ultimately how to improve their health by attempting to keep their blood glucose in normal range. Some other commonly worn pseudo-DHTs such as the Apple Watch or FitBit could also be very valuable in capturing physical activity, which is a high-impact risk factor for prediabetes. Oftentimes, these multi-purpose devices may be the only DHT that a person has access to. These devices typically capture details on one's activity such as length of time, type of exercise, etc, which is valuable information when it comes to prediabetes risk factors.

ADA guidelines table 2.4 also lists other considerations for pre-diabetes screening:

Table 2.4 [2] *Criteria for screening for diabetes or prediabetes in asymptomatic adults*

1. Testing should be considered in adults with overweight or obesity (BMI ≥25 kg/m^2 or ≥23 kg/m^2 in Asian American individuals) who have one or more of the following risk factors:
• First-degree relative with diabetes
• High-risk race and ethnicity (e.g., African American, Latino, Native American, Asian American, Pacific Islander)
• History of cardiovascular disease
• Hypertension (≥130/80 mmHg or on therapy for hypertension)
• HDL cholesterol level <35 mg/dL (<0.9 mmol/L) and/or a triglyceride level >250 mg/dL (>2.8 mmol/L)
• Individuals with polycystic ovary syndrome
• Physical inactivity
• Other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans)
2. People with prediabetes (A1C ≥5.7% [≥39 mmol/mol], IGT, or IFG) should be tested yearly.
3. People who were diagnosed with GDM should have lifelong testing at least every 3 years.
4. For all other people, testing should begin at age 35 years.
5. If results are normal, testing should be repeated at a minimum of 3-year intervals, with consideration of more frequent testing depending on initial results and risk status.
6. People with HIV, exposure to high-risk medicines, history of pancreatitis

- **Are there any existing tools, datasets, or devices used for prediabetes detection? Are there any that are particularly indicated for individuals of a particular race, ethnicity, gender, language, and/or comorbid disability?**

  Participants of the APhA Foundation's NDPP (IMPACT Diabetes) are screened through the CDC's prediabetes screening tool: https://www.cdc.gov/prediabetes/takethetest/

  Generally, formal detection of prediabetes or undiagnosed T2D is typically done with lab work or personal blood glucose monitoring. Increasing access to screening and testing is crucial and should be expanded by technologies that enable more point of care A1c testing, such as in pharmacies, that are properly calibrated to identify prediabetes. More patients would be able to access this care if pharmacists were reimbursed for this service and their time taken to administer the test and/or to review patient's personal blood glucose monitoring, as well as patient counseling.

Outcomes

- **What patient and community-centered outcomes could be measured for prediabetes and undiagnosed type 2 diabetes (e.g., symptoms, activities of daily living, co-morbidities, hospitalizations, costs, psychosocial factors, etc.)?**

  A1c at diagnosis would be a good predictor of whether the patient was appropriately screened, as it should be low at diagnosis as it is progressive.

[2] Standards in Care in Diabetes – 2023 Abridged for primary care providers. Clin Diabetes 2023; 41:4-31. https://doi.org/10.2337/cd23-as01

Clinical Integration and Implementation

- **How can digitally derived measures of biomarkers be integrated into clinical decision support systems or electronic health records to identify undiagnosed type 2 diabetes or prediabetes? What are some of the barriers and proposed solutions to implementation?**

  It is very important that all health care providers, including pharmacists, have access to a patient's digitally derived biomarkers. As the most accessible healthcare provider, a pharmacist is often the one who has the first opportunity to help a patient understand that he/she may be at risk for prediabetes. Barriers to implementation are interoperable EHR platforms and direct sharing of health data.

  Also, more emphasis on routine screening of A1c would be helpful. Often, blood glucose is checked randomly on a basic metabolic panel and if it is not abnormal, providers will not investigate further. Relying on this random glucose should be minimized to prevent missing a diagnosis. Additionally, most EHRs are not designed to collect and consider information on sedentary lifestyle, so adding this as a data point would be helpful.

  Persistently elevated glucose levels or A1c via laboratory results without a diagnosis of diabetes assigned to the patient can generate a flag for providers to update information and/or conduct confirmatory testing. A barrier to effectiveness of this would be alert fatigue.

- **Are there effective ongoing early screening and prevention efforts for prediabetes and undiagnosed type 2 diabetes that utilize DHTs? If yes, please describe. If no, please describe what a solution would look like to enable such an effort.**

  Patients need more access to monitoring of blood sugar whether this is at point of care A1c testing at the pharmacy, traditional blood glucose monitors, or continuous glucose monitors. This data can be easily shared with clinicians via integration into the EHR. Currently, individual companies who produce blood glucose monitors have data from patients and ways to share it with clinicians, however using different platforms puts a large burden on clinicians. Having a streamlined way to get blood glucose data from home into the EHR is critical for pharmacists and others to review the key information that determines if someone has prediabetes or T2D.

APhA
American Pharmacists Association

Conclusion

APhA appreciates the opportunity to provide feedback on FDA's request for information on DHTs for detecting prediabetes and undiagnosed T2D. As you can see, pharmacists currently play a key role on the health care team in providing patient care in this area. As FDA develops guidance, standards, and best practices, please keep pharmacists and pharmacies in mind as patient partners in delivering care using DHTs for diabetes prevention and disease and therapeutic management. If you have any questions or need any additional information, please contact me at ibernstein@aphanet.org.

Thank you for your consideration.

Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice & Government Affairs