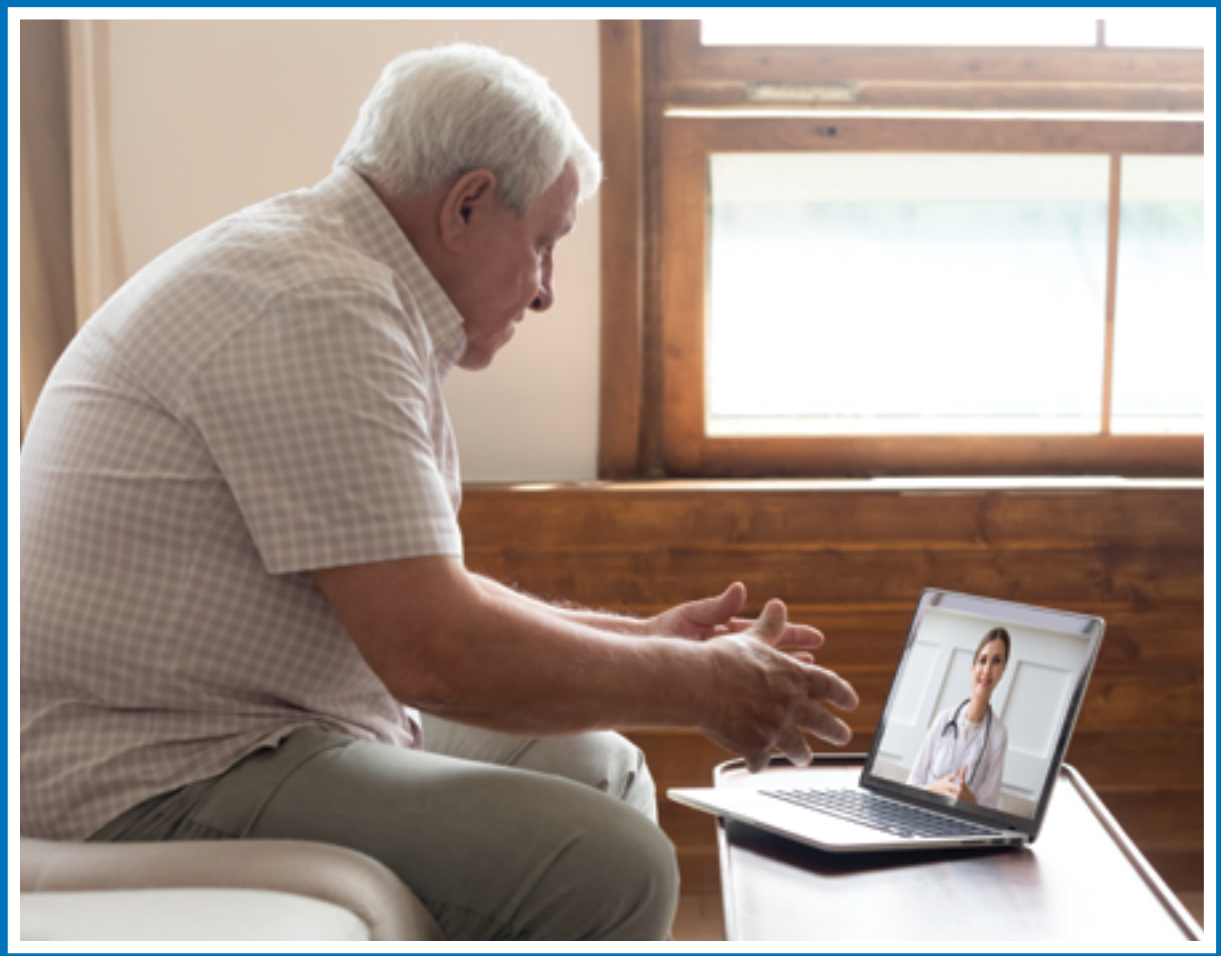
Emerging Technology to Improve Diabetes Care in Federal Medicine



U.S. Medicine
THE VOICE OF FEDERAL MEDICINE

Technology Helps Veterans Better Manage Diabetes During Pandemic

DURHAM, NC—Across the country, diabetes patients have faced extraordinary challenges throughout the pandemic.

They disproportionately suffer from acute COVID-19 and experience higher rates of hospitalization and death. Shelter-at-home orders, job losses and distribution issues made finding adequate, nutritious and healthy food difficult for many. Closures of hospitals and clinics, deferral of nonessential care and social isolation reduced support from healthcare professionals and trained caregivers and led to poor disease management. Many healthcare systems struggled to create new options from scratch, leaving patients in the lurch for months.

But not the VA.

Veterans continued to receive care, kept regular appointments with their clinical team, provided updated glucose readings, monitored diabetic foot ulcers and eye complications, received automated medication refills, had access to yoga and cooking programs, and in some cases received necessary food deliveries thanks to the VA's long-standing commitment to the use of technology. The department couldn't make COVID-19 less virulent, but it could—and did—reduce the impact the coronavirus had on the lives of veterans with diabetes.

Benefits of Telehealth

The VA has been a national leader in telehealth for more than 20 years, in large part because 25% of veterans live in rural areas. The need to provide care to those who lived a significant distance from VA facilities prompted the department to develop ways to bring care closer. Increasingly, that's meant into the veteran's home.

As a consequence, when the pandemic closed many hospitals and clinics to non-COVID-19 care, the VA was well positioned to quickly offer care through alternative means—its robust telehealth services. It took the VA Connecticut Health Care System, for example, just three weeks to transition from seeing nearly all patients in person to conducting 97% of all primary care visits virtually, and at close to the same volume.[1]

Endocrinologists and other specialists rapidly adopted e-consults and e-referrals and video-to-home visits, particularly for high-risk patients. To maximize the value of those visits, the VA reallocated funds to expand its national loaned tablet program to patients with access issues and delivered other devices for remote patient monitoring, from smartphones to pulse oximeters to foot pads.[2]

The switch to telehealth put veterans in a better position than many of their neighbors. In a survey by the American Diabetes Association (ADA), 43% of diabetics reported delaying medical care during the pandemic, often because they feared contracting COVID-19. Veterans with diabetes had an option to stay home and receive care, allowing the vast majority to keep their appointments with their primary care teams, nutritionists and endocrinologists.

Some veterans who needed more structured care improved as a result of telehealth. "While telehealth has proven efficacious for diabetes in research settings, intensive telehealth interventions have rarely been implemented in standard care," said Elizabeth Kobe, MD candidate at Duke University Medical School. Kobe presented the results of an intensive telehealth intervention at the ADA's 80th Virtual Scientific Sessions in June 2020.

Using existing VA home telehealth infrastructure and staff, Kobe and her colleagues designed and implemented a six-month telehealth intervention that combined telemonitoring with a module-based self-management support and medication management program. Clinical staff called patients every two weeks for 30 minutes. Patients transmitted their blood glucose measurements daily via home telehealth-issued equipment.

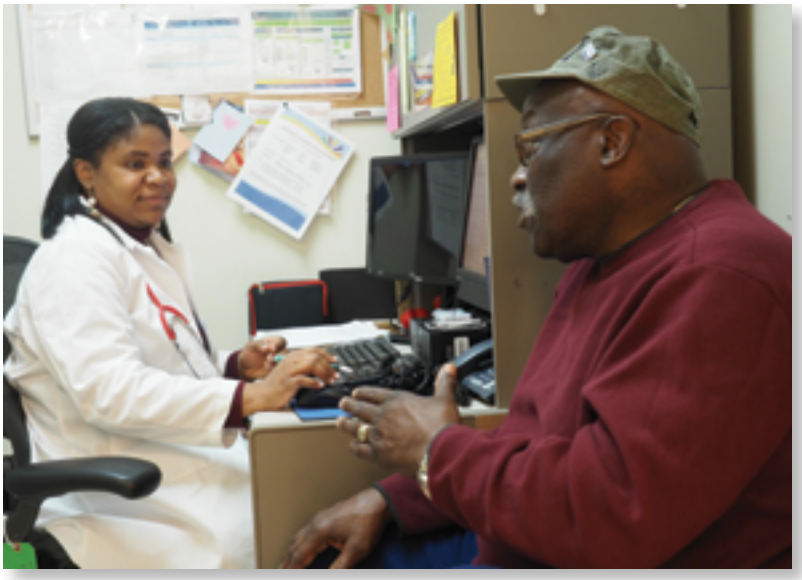
Her study found that participants in the Advanced Comprehensive Diabetes Care (ADCD) program improved their HbA1c by a mean of 1.36 points over six months, dropping to 7.89% and persisting for at least 18 months. While the study began before the pandemic, veterans continued to participate and benefit throughout

The Initiative to End Diabetic Limb Loss at VA (TIEDLLV), supplies at-risk, diabetic veterans with Podimetrics Mats, which can detect foot ulcers up to six weeks before they would be identified in an exam and from the comfort of their home.

2020. "Despite the drastic changes that COVID-19 has forced us to make, ACDC delivery has continued unabated," Kobe said.

Beyond being able to contact health-care providers, telehealth enables veterans to learn how to better manage their diabetes and participate in group sessions. In January 2021, the ADA awarded recognition status to the VA and DoD's Diabetic Self-Management Education (DSME), calling it one of the most engaging and true-to-life virtual medical experiences focused entirely on diabetes self-management.

Veterans access DSME through the VA's Virtual Medical Center (VMC). Using customizable avatars, veterans navigate the VMC, which looks much like most VA hospitals. Through the avatars, veterans attend any class in the virtual facility, ask diabetes educators questions and discuss issues with others in their classes.



Army Veteran William Baker, who has Type 2 diabetes, discusses his health with LaCresha Mitchum, a registered nurse and certified diabetes educator and diabetic coordination at the William Jennings Bryan Dorn VAMC in Columbia, SC. —Photo by Jennifer Scales, Dorn VAMC

"At first, the Virtual Medical Center was intimidating, but they have a lot of support staff," said Orville Bell, a 70-year-old Navy veteran. "I really like it because they keep me focused on how to eat, make good diet decisions. I also like listening to how other people remain disciplined. It's kind of like being in 'Diabetes Watchers' instead of Weight Watchers." With encouragement from the program, Bell has lost 30 pounds and dropped his HbA1c from 11 to 6.7.

Connected Devices

Diabetes can lead to foot ulcers, which account for 80% of nontraumatic amputations in veterans, and to diabetic retinopathy, the most common cause of blindness in American adults. The VA was determined to provide care to limit both of these frequent complications despite the pandemic. To do so, they enlisted the help of technology again.

The Initiative to End Diabetic Limb Loss at VA (TIEDLLV), supplies at-risk, diabetic veterans with Podimetrics Mats, which can detect foot ulcers up to six weeks before they would be identified in an exam, and from the comfort of their home. A veteran stands on the mat once a day, and in 20 seconds the device measures the temperature of the feet using thermal imaging and transmits the information Podimetrics' cloud-based artificial intelligence system. The AI analyzes the data and alerts the provider if there are signs of a developing diabetic foot ulcer.

Early results indicate that the Podimetrics system almost entirely eliminates severe ulcers and reduces ulcer-associated hospitalizations by 92%. "I saw countless Veterans lose their lives because of complications from diabetic foot ulcers," said Suzanne Shirley, VHA Innovation Ecosystem director of partnerships and community engagement. "I knew we had to tackle this problem and find a solution. Once we saw the results from the use of remote temperature monitoring, we worked to make sure that it became a part of VA's diabetic care."

The Tomah VAMC uses teleretinal imaging to detect changes in the eye for veteran with diabetes. A special camera captures images of the lining of the eye which medical staff sent to optometrists to evaluate. The reduction in the number of appointments and travel required for diagnosis and treatment has been particularly valuable with COVID-19 in circulation.

"Providing safe care to our veterans in locations convenient to them leads to regular use of technology and telehealth services," said Karen Long, Tomah VAMC's acting director. "We are proudly leveraging our virtual care tools to ensure our patients and staff are as safe as possible."

[1] Spelman JF, Brienza R, Walsh RF, Drost P, Schwartz AR, Kravetz JD, Pitkin P, Ruser C. A Model for Rapid Transition to Virtual Care, VA Connecticut Primary Care Response to COVID-19. J Gen Intern Med. 2020 Oct;35(10):3073-3076. doi: 10.1007/s11606-020-06041-4. Epub 2020 Jul 23. PMID: 32705471; PMCID: PMC7377306.

[2] Heyworth L, Kirsh S, Zulman DM, Ferguson JM, Kizer KW. Expanding Access through Virtual Care: The VA's Early Experience with COVID-19. *NEJM Catalyst: innovations in care delivery*. 2020 Jul 1; https://catalyst.nejm.org/doi/full/10.1056/cat.20.0327.

[3] Kobe EA, et al. Implementation of an intensive telehealth intervention for rural patients with uncontrolled diabetes. Presented at: American Diabetes Association Scientific Sessions; June 12-16, 2020 (virtual meeting).

Pandemic Highlights Benefits of Continuous Glucose Monitors

Not Just for Type 1 Diabetes, CGM Now Aids Some Type 2 Patients

BALTIMORE, MD—For veterans with diabetes, managing their numbers has never been more important. While diabetes does not increase the risk of contracting COVID-19, it sharply increases the risk of severe disease and death.

Multiple studies have shown that Type 1 or Type 2 diabetes at least doubles and possibly quadruples the risk of death in individuals infected by SARS-CoV-2, the virus that causes COVID-19. Half of deaths in individuals younger than 65 have occurred in people with diabetes, according to the U.S. Centers for Disease Control and Prevention. Diabetics with poorly controlled serum glucose levels have the highest risk of more severe disease.

Those numbers translate into substantially greater risk for the 25% of veterans with diabetes. They also illuminate a way to improve outcomes for coronavirus infections and other infections in these veterans. It has long been known that people with diabetes have a harder time battling viral, bacterial, or fungal infections because they do not process glucose as well, they have a weaker immune response, and often have circulatory issues.

Because elevated blood sugar directly impairs immune system response, closely managing glucose levels has taken on greater importance during the pandemic for hospitalized patients with COVID-19 and people with diabetes who want to minimize their risk. As a result, the use of continuous glucose monitors (CGM) has risen markedly over the last year across all settings.

CGM Use in Hospitals

Hospitals quickly saw the advantages of CGM during the novel coronavirus outbreak. The need to reduce the risk faced by overtaxed nursing staff and preserve personal protective equipment made the pre-pandemic standard of testing for blood glucose levels untenable.

"Typically, glucose monitoring relies on point-of-care finger sticks which must happen frequently to prevent adverse events in patients with diabetes," said Thomas J. Hornyak, MD, PhD, associate chief of staff for Research and Development at the VA Maryland Health Care System (VAMHCS). For patients in intensive care who require insulin, standard procedures called for capillary testing of blood glucose levels every one to two hours, a requirement that became impossible to meet as hospitals converted other units, floors, and offices to intensive care units to treat COVID-19 patients, many of them diabetic. Other hospitalized patients also required frequent blood glucose testing.

Reducing or eliminating glucose monitoring wasn't a viable option. "Studies have indicated that insulin use in hospitalized patients with diabetes predisposes them to hypoglycemia, a condition that is associated with increased morbidity and mortality. Preventing hypoglycemia requires intensive glucose monitoring," explained Ilias Spanakis, a physician and researcher at VAMHCS and associate professor at the University of Maryland School of Medicine. Hyperglycemia has also emerged as an indicator of poor prognosis in COVID-19.

In light of the urgent need, the U.S. Food and Drug Administration issued guidance in April 2020 allowing the use of CGMs to monitor blood sugar levels in hospitalized patients during the pandemic. The American Diabetes Association (ADA), Insulin for Life and the Diabetes Disaster Response Coalition quickly partnered with Abbott to donate 25,000 CGM sensors to hospitals across the country.

Like many hospitals around the country, VAMHCS turned to continuous glucose monitoring systems, which check glucose levels every five minutes and send the results to a centralized monitoring device at the nurses station. Spanakis and his colleagues compared CGM results to standard care in a study published in *Diabetes Care.*

"Dr. Spanakis' study demonstrates that glucose levels can be monitored more frequently and efficiently," Hornyak added. "Also, in the face of the COVID-19 pandemic, use of the continuous glucose monitoring systems proved to be prescient, showing a decrease in hypoglycemia while also safeguarding health care providers caring for virus-positive patients with diabetes."[1] Several small trials indicated CGMs offer similar benefits in ICUs and other wards.[2]

An international panel of experts in diabetes technology, including VA researchers, issued a strong recommendation for the use of CGMs to reduce nurse contact and use of PPE for frequent glucose testing in hospitalized patients isolated with "highly contagious infectious diseases (e.g., COVID)" in September 2020.[3]

That recommendation followed implementation recommendations by a U.S. panel that included Spanakis and Francisco Pasquel, MD, MPH, of the Atlanta VAMC. They concluded that "CGM may be on the threshold of becoming a widely accepted form of continuous automated physiologic monitoring in the hospital setting."

The pandemic provided opportunities for greater use an analysis of CGMs outside the hospital, too. Restricted

access to clinics and in-person appointments drove the adoption of telehealth on a broad scale, a trend likely to continue after the pandemic recedes.

"Based on the experience that we have obtained with the current crisis, I predict that several things may change in the near future, affecting drastically how we manage patients with diabetes," Spanakis observed in an editorial. "With so many telemedicine platforms available even now, the vast majority of the outpatient visits will be transformed to telehealth appointments."[4]

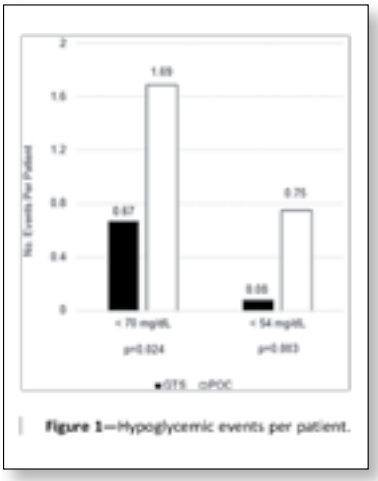


Figure 1—Hypoglycemic events per patient.

Source: Diabetes Care *2020;43:2736–2743 / https://doi.org/10.2337/dc20-0840*

Because diabetes management relies on tracking numbers, the data-sharing capability of continuous glucose monitors and insulin pumps facilitates better management during virtual visits. "The abundance of data provided by CGM offers opportunities to analyze patient data more granularly than was previously possible, providing additional information to aid in achieving glycemic targets," according to the ADA's *Standards of Medical Care in Diabetes*-2021. The ADA recommends that CGM devices should be considered for all patients prescribed insulin.[5]

The data from CGMs help patients take more control of their diabetes between visits, too. "You can look at trend analysis and a whole bunch of different things that are derived from that technology. The data allows you to make some pretty good decisions and see what's going on with your body," Army veteran Jason Syr told 12WBOY. Syr's dedicated use of a CGM allowed him to stay in the Army for six more years after his diagnosis of Type 1 diabetes.

The DoD and VA have covered CGMs for Type 1 diabetes for years. Just in time for the pandemic, the DoD expanded authorization to include CGM for servicemembers with uncontrolled Type 2 diabetes, as well. In 2019, VA began authorizing CGMs for veterans who use insulin and require frequent blood glucose testing to manage their Type 2 diabetes.

CGMs have been shown to help manage diabetes in this group. A previous study conducted at the Malcom Randall VAMC in Gainesville, FL, found that veterans with diabetes who either required insulin or had A1c levels above 7% who received a CGM had significantly improved glycemic control and expressed 100% satisfaction with the device.[6]

Last November, VA relaxed its restrictions on who could use the devices to "permit COVID-19 patients to more closely monitor their glucose levels given that they are at risk for unpredictable impacts of the infection on their glucose levels and health," said Kameron Leigh Matthews, MD.

Further, Matthews noted in a memo to VISN directors, "the use of therapeutic continuous glucose monitors may allow patients to proactively treat their diabetes and prevent the need for hospital-based diabetic care. Practitioners will also have greater flexibility to allow more of their diabetic patients to better monitor their glucose and adjust insulin doses from home by using a therapeutic continuous glucose monitor" during the pandemic.

Further expansion is likely to occur in the future. Michael Bergman, MD, section chief of endocrinology at the VA NY Harbor Healthcare System and director of NYU Langone's Diabetes Prevention Program is studying the use of the Abbott FreeStyle Libre CGM as a screening tool for high-risk individuals in the outpatient setting. The study team also is testing the device to identify blood glucose abnormalities in veterans admitted to the Manhattan campus of the VA NYHHS with acute coronary syndrome. Picking up glucose abnormalities early, before a patient reaches prediabetic levels or has diabetes, can head off development of the disease altogether.

"So far, the data look very compelling, and if the results remain consistent, the use of the CGM would be a much simpler and practical approach to screening for glucose disorders than asking patients to undergo the [oral glucose tolerance test] in a clinical laboratory," Bergman said. "I think it would promote more reliable screening than what is done currently."

[1] Singh LG, Satyarengga M, Marcano I, Scott WH, et. al. Reducing Inpatient Hypoglycemia in the General Wards Using Real-time Continuous Glucose Monitoring: The Glucose Telemetry System, a Randomized Clinical Trial. *Diabetes Care.* 2020 Nov;43(11):2736-2743. doi: 10.2337/dc20-0840. Epub 2020 Aug 5. PMID: 32759361; PMCID: PMC7576426.

[2] Galindo RJ, Aleppo G, Klonoff DC, Spanakis EK, et. al. Implementation of Continuous Glucose Monitoring in the Hospital: Emergent Considerations for Remote Glucose Monitoring During the COVID-19 Pandemic. *J Diabetes Sci Technol.* 2020 Jul;14(4):822-832. doi: 10.1177/1932296820932903. Epub 2020 Jun 14. PMID: 32536205; PMCID: PMC7673156.

[3] Galindo RJ, Umpierrez GE, Rushakoff RJ, Continuous Glucose Monitors and Automated Insulin Dosing Systems in the Hospital Consensus Guideline. *J Diabetes Sci Technol.* 2020 Nov;14(6):1035-1064. doi: 10.1177/1932296820954163. Epub 2020 Sep 28. PMID: 32985262; PMCID: PMC7645140.

[4] Spanakis E. Diabetes and Technology in the Covid-19 Pandemic Crisis. *J Diabetes Sci Technol.* 2020 May; doi. org/10.1177/1932296820929385.

[5] American Diabetes Association. 7. Diabetes Technology: *Standards of Medical Care in Diabetes-2021*. Diabetes Care. 2021 Jan;44(Suppl 1):S85-S99. doi: 10.2337/dc21-S007. PMID: 33298418.

[6] Barsamyan G, Da Silva A, Whyte L, Amole M, Ghayee H, Leey JA. 855-P: Utilization of Continuous Glucose Monitoring (CGM) and Its Impact on the Care of Veterans. *Diabetes.* Jun 2020, 69 (S1) 855-P; DOI: 10.2337/db20-855-P.

Apps, Wearable Devices Increasingly Help Veterans Improve Diabetes Management

TAMPA, FL—Like Americans everywhere, veterans have integrated smartphones and wearable devices into many aspects of their lives. For veterans with diabetes, those devices, healthcare and wellness apps are increasingly transforming care and improving outcomes.

"VA's Office of Connected Care has made significant strides in telehealth and mobile health technologies and the future looks even more promising as we continue to lead from the cutting edge by expanding our capabilities through these efforts and others," said Kathleen Frisbee, executive director, Connected Health at the VA in a recent editorial. "Most importantly, our use of patient-generated data to influence major improvements in our veterans' health care cannot be overemphasized."

Mobile health technologies address many common issues for veterans with diabetes. At the James A. Haley Veterans' Hospital in Tampa, FL, the VA has launched a program that combines telehealth technology with health data from Apple Watches to monitor heart health, a common concern for diabetic patients. Veterans use the VA-provided watches to perform an electrocardiogram (EKG) and then upload the results to the Health app on their iOS device. The data can be shared with their care team during a VA Video Connect appointment or through the VA's online patient portal, My HealtheVet.

The VA has developed a mobile app, Sync-My-Health-Data (SMHD), that transfers data from Fitbits or glucometers.

The VA has also developed a mobile app, Sync-My-Health-Data (SMHD), that transfers data from Fitbits or glucometers via a paired device to the VA's Patient Generated Database for analysis. The Office of Connected Care is currently analyzing this data plus data from the VA's electronic health record and socioeconomic data for patients with diabetes.

At the South Texas Veterans Health Care System in San Antonio, Texas, researchers have used Fitbit to support behavioral lifestyle interventions in overweight or obese Type 2 diabetics during the pandemic. The study used the Look AHEAD and Diabetes Prevention Program Group Lifestyle Balance, delivered over 10 sessions. Participants received a Fitbit and the accompanying Fitbit app to record their food and activity. Only two veterans left the study before its conclusion at six months.[1]

"[A}lthough one might expect reduced interest in the program due to disruptive stressors related to the pandemic, participant responses reflected a high degree of acceptability for the behavioral intervention while dealing with new challenges," the authors wrote. "Overall program acceptability was observed in the participant descriptions of mindfully tracking their diet and physical activity through the Fitbit application, as well as enthusiasm in their plans to continue to track behavior using program strategies."

Notably, the study showed that older adults (average age of participants was 72) could successfully use mobile health technology to support behavioral modification, with many commenting that they enjoyed using the Fitbits for self-monitoring and to gain greater confidence in their decisions around self-care and diabetes management.

More Diabetes Apps

The Annie app helps veterans take care of themselves through text messages. Annie is named for Lt. Annie G. Fox, Army Nurse Corps, the chief nurse at Hickam Field during the attack on Pearl Harbor on Dec. 7, 1941, and the first woman to receive the Purple Heart for combat. The app can be programmed to reflect the needs of each veteran. For diabetics, Annie could text a reminder to a patient to take their medications, check their blood glucose levels, have a snack, or move, and reinforce the importance of taking the nudged step as part of reaching the veteran's health goals.

Annie also provides COVID-19 specific information on staying healthy, identifying symptoms, managing stress and receiving vaccinations, and more.

"VA providers should be wholeheartedly enthusiastic about using Annie. It allows us to reach our patients in ways we couldn't previously and ultimately improve health outcomes," said Lynn Kataria, MD, chief of

Neurology Education at the Washington, DC, VAMC.

Another app, MobileKidney, helps diabetic veterans with kidney disease track their personal information, such as blood pressure, weight, and blood glucose levels. The app reminds users to log their health information and allows veterans to share that data with their health-care provider. It also sends reminders from the care team and provides information about kidney health.

The MOVE! Coach app helps veterans manage their weight with a 16-week program that builds awareness of the components of a healthy diet while encouraging regular physical activity. The app provides a daily weight, activity, and diet diary and tools to measure exercise intensity, calories burned and activity-to-step conversions.

Apps also simplify scheduling VA appointments online, requesting medication refills and using Video Connect for medical visits with the care team.

Beyond Apps

In addition to a wide range of apps, the VA delivers other tools via technology for veterans with diabetes to better manage their health. At least two groups provide live online yoga sessions. At the Coatesville VAMC in Pennsylvania, Ompractice offers 16 weeks of free access to their online classes to veterans participating in self-management programs for diabetes, weight loss, and some other conditions. The Coatesville classes are led by a veteran who attributes his own recovery from combat injuries that resulted in double amputations to yoga. The small classes allow the instructor to connect with and encourage new students. The Veterans Yoga Project offers three hours of free, live practices on Zoom and Facebook.

Veteran Orville Bell, who receives care at the VA Louis Stokes Cleveland VAMC, accesses diabetic self-management education via VA's Virtual Medical Center. —Photo from Jan. 23, 2021 VAntage Point Blog

The West Texas VA Healthcare System engages veterans with diabetes through a fun and easy cooking class, which will be available in a monthly video series as of 2021. The program promotes healthy eating and a positive approach to making lifestyle changes to prevent or manage diabetes. "We want everyone participating to ask questions, to find ways to improve their situation," said Marcia Merrell, chief of Nutrition and Food Services at the West Texas VA. "For me, cooking classes are all about inspiration. It's really about inspiring you to do more research and inspiring you to ask questions."

Marine Corp Veteran Tim Foley teaches yoga for Ompractice, which entered into a partnership with the Coatesville, PA, VAMC, offering 16 weeks of free access for veterans participating in self-management programs for chronic pain, diabetes, weight loss and evidence-based treatment for mental health. —Photo from May 28, 2020, VAntage Point blog

[1] Jiwani R, Dennis B, Bess C, Monk S, Meyer K, Wang J, Espinoza S. Assessing acceptability and patient experience of a behavioral lifestyle intervention using Fitbit technology in older adults to manage Type 2 diabetes amid COVID-19 pandemic: A focus group study. *Geriatr Nurs.* 2020 Nov 19;42(1):57-64. doi: 10.1016/j.gerinurse.2020.11.007. Epub ahead of print. PMID: 33248357.

All articles were written by Annette M. Boyle, chief medical writer.

The FreeStyle Libre 2 system

Glucose monitoring without fingersticks,* now with optional alarms†

MORE PATIENTS CAN DO IT WITHOUT FINGERSTICKS*

SIMPLE | Easiest iCGM to apply,‡ with no in-person patient training required[1]

ACCURATE | Unsurpassed 14 day accuracy[2] for adults and children with diabetes (ages 4 and older)

AFFORDABLE | More affordable CGM§ at one-third the cost of other CGMs‖

Discover the **#1 CGM worldwide**¶ by contacting your Government Team at **1-844-324-5807** or visit **Provider.FreeStyleLibre.us**

FreeStyle Libre 2
FLASH GLUCOSE MONITORING SYSTEM

life. to the fullest.®

Abbott

*Fingersticks are required if your glucose alarms and readings do not match symptoms or when you see Check Blood Glucose symbol during the first 12 hours. †Notifications will only be received when alarms are turned on and the sensor is within 20 feet of the reading device. ‡Based on a comparison to Dexcom G6. §Based on a comparison of list prices of the FreeStyle Libre 14 day system versus competitors' CGM systems. The FreeStyle Libre 2 system will be list priced the same rate as the FreeStyle Libre 14 day system. The actual cost to patients may or may not be lower than other CGM systems, depending on the amount covered by insurance, if any. ‖Based on a comparison of list prices of the FreeStyle Libre 14 day system versus competitors' CGM systems. The FreeStyle Libre 2 system will be list priced the same rate as the FreeStyle Libre 14 day system, assuming annual use of one receiver (or equivalent hardware) and quantity of transmitters and/or sensors according to use life. ¶Data based on the number of users worldwide for FreeStyle Libre family of personal CGMs compared to the number of users for other leading personal CGM brands and based on CGM sales dollars compared to other leading personal CGM brands.

References: 1. Data on file. Abbott Diabetes Care. **2.** FreeStyle Libre 2 User's Manual.

Indications and Important Safety Information

The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older.** **WARNINGS/LIMITATIONS**:** The System must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems. Remove the sensor before MRI, CT scan, X-ray, or diathermy treatment. Do not take high doses of vitamin C (more than 500 mg per day), as this may falsely raise your Sensor readings. Failure to use the System according to the instructions for use may result in missing a severe low blood glucose or high blood glucose event and/or making a treatment decision that may result in injury. If glucose alarms and readings from the System do not match symptoms or expectations, use a fingerstick blood glucose value to make diabetes treatment decisions. Seek medical attention when appropriate and contact Abbott toll-free 855-632-8658 or visit ** www.FreeStyleLibre.us for detailed indications for use and safety information.

**Please refer to www.FreeStyleLibre.us for the indications and important safety information.