

New Late-Breaking Data At ADA Underscore Significant Benefits Of Abbott's FreeStyle Libre System For People Living With Diabetes

- Expanded Real-World Evidence from More than 250,000 individuals using FreeStyle Libre system Showed Higher Frequency Scanning is Associated with improved glucose control, decreased glucose variability and reduced incidence of both daytime and nocturnal hypoglycemia

- New meta-analysis showed for the first time that using the freestyle libre SYSTEM results in a significant decrease in HbA1c in a broad population

- Additional data demonstrate meaningful outcomes in teenagers and young adults and significant cost savings when compared to traditional blood glucose monitoring

ORLANDO, Fla., June 25, 2018 [/PRNewswire/](#) -- Abbott today announced results from multiple new clinical and real-world studies that provide a comprehensive look at the global use of the FreeStyle Libre system, the company's revolutionary continuous glucose monitor (CGM), and its impact on health outcomes across various patient populations and countries. These data were presented as part of multiple late-breaking abstracts at the American Diabetes Association (ADA) 78th Scientific Sessions in Orlando, Fla.

For the first time, a meta-analysis showed that using FreeStyle Libre system results in a meaningful decrease in HbA1c in a broad population of people with diabetes, including individuals with Type 1, Type 2 and of different ages¹. Several additional studies reaffirmed the ongoing health benefits that the FreeStyle Libre system provides^{2,3,5}. Also, a separate health economics analysis⁴ confirmed that use of the FreeStyle Libre system is associated with significant cost savings when compared to traditional blood glucose monitoring.

"These new data provide clear proof that the FreeStyle Libre system empowers people with diabetes to take control of their lives, make informed health decisions and live life fully without the burden of fingersticks," said Jared Watkin, senior vice president, Diabetes Care, Abbott. "The FreeStyle Libre system is living up to its full potential of truly being a life-changing technology for the millions of people living with diabetes globally."

Expanded Real-World Evidence from 250,000+ Individuals Show Decrease in Glucose Variability and Improved Glucose Control

In 2017, Abbott released results from its first real-world data analysis of 50,000 FreeStyle Libre users across Europe, which showed that higher frequency of glucose monitoring with the FreeStyle Libre system correlated with improved glucose control and estimated HbA1c for people with diabetes⁵. The new data, which included analyses generated from more than 250,000 individuals and more than 2.1 million sensors worldwide, further support those conclusions while also identifying additional positive outcomes, including:

- FreeStyle Libre system users scanned on average 13 times per day to check their glucose levels³. Higher frequency scanners' time in hypoglycemia was 37 percent less compared to lower frequency scanners. On average, higher frequency scanners spent significantly less time in hypoglycemia during the day compared to lower frequency scanners (15.2 vs. 24.2 minutes/day). There was a similar pattern overnight with 12.7 to 19.0 minutes/night when comparing high frequency to lower frequency scanners.
- More frequent use of FreeStyle Libre system is associated with lower glucose variability². Data showed for the first time that increased testing with the FreeStyle Libre system was associated with decreased glucose variability with 34.5 percent vs. 40.6 percent in higher frequency vs. lower frequency scanners, respectively. High variability is associated with both increased hyperglycemia and hypoglycemia.

The updated real-world findings were comprised of more than 2.2 billion glucose measurements and almost 300 million scans.

"Even with analyzing significantly more data and outcomes, the positive benefits previously demonstrated with FreeStyle Libre system remain consistent," said Mahmood Kazemi, M.D., divisional vice president, Global Medical and Scientific Affairs, Diabetes Care, Abbott. "Because of the simplicity and ease of use with the FreeStyle Libre system, people are testing their glucose more often, which is providing them with actionable information that allows them to make more informed and meaningful changes to the way they are managing their condition."

Additional Late-Breaking Abstracts

Further findings from the late-breaking abstracts at ADA demonstrated the following:

- **Significant Decrease in HbA1c Among a Broad Population:** A meta-analysis found that use of the FreeStyle Libre system resulted in a substantial decrease in HbA1c, a test that shows the average glucose level over a period of time, with an absolute change of -0.56 percent¹. This is a clinically-meaningful decrease in HbA1c that may be associated with lower rates of diabetes-related health complications.
- **FreeStyle Libre System = Significant Cost Savings:** Abbott also presented cost model data that showed significant

savings when using the FreeStyle Libre system in the U.S. compared with routine self-monitoring of blood glucose (SMBG)⁴. The data showed those testing their glucose six times per day with FreeStyle Libre system can save more than \$120 a month compared to the cost of six test strips per day. This has the potential to increase to \$290 a month for people testing 10 times per day. The ADA recommends testing blood glucose six to ten times per day for certain insulin-using populations.

- **Teenagers and Young Adult Populations Improved Time in Range:** Additional analysis of two previously reported clinical studies in Europe--IMPACT⁶ (2016) and SELFY⁷ (2017) --evaluated the FreeStyle Libre system as a replacement for SMBG and examined outcomes in patients aged 13-24 years old⁸. Both studies demonstrated improvements in glycemic control in the teenager and young adult age groups -- two groups that are known to have significant challenges with glycemic control during this transitional period. Teenagers in the SELFY study significantly improved time in range by 1.2±2.5 hours/day and significantly improved their HbA1c. This is one of the first studies to demonstrate the benefits of continuous glucose monitoring in these age groups.

The FreeStyle Libre system is now being used by more than 650,000 people across more than 42 countries⁹. Abbott has secured partial or full reimbursement for the FreeStyle Libre system in 28 countries, including France, Ireland, Japan, the United Kingdom, and the U.S. For more information, please visit: www.freestylelibre.us.

For the U.S. version of FreeStyle Libre system, the Indications and Important Safety Information is below.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

The FreeStyle Libre Flash Glucose Monitoring system is a continuous glucose monitoring (CGM) device indicated for replacing blood glucose testing and detecting trends and tracking patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments in persons (age 18 and older) with diabetes. The system is intended for single patient use and requires a prescription.

CONTRAINDICATIONS: Remove the sensor before MRI, CT scan, X-ray, or diathermy treatment.

WARNINGS/LIMITATIONS: Do not ignore symptoms that may be due to low or high blood glucose, hypoglycemic unawareness, or dehydration. Check sensor glucose readings with a blood glucose meter when Check Blood Glucose symbol appears, when symptoms do not match system readings, or when readings are suspected to be inaccurate. The FreeStyle Libre system does not have alarms unless the sensor is scanned, and the system contains small parts that may be dangerous if swallowed. The FreeStyle Libre system is not approved for pregnant women, persons on dialysis, or critically-ill population. Sensor placement is not approved for sites other than the back of the arm and standard precautions for transmission of blood borne pathogens should be taken. The built-in blood glucose meter is not for use on dehydrated, hypotensive, in shock, hyperglycemic-hyperosmolar state, with or without ketosis, neonates, critically-ill patients, or for diagnosis or screening of diabetes. Review all product information before use or contact Abbott Toll Free (855-632-8658) or visit www.freestylelibre.us for detailed indications for use and safety information.

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¹ Seibold, Alexander et al. A Meta-Analysis of Real World Observational Studies on The Impact of Flash Glucose Monitoring on Glycemic Control as Measured by HbA1c. Presented at the American Diabetes Association 78th Scientific Sessions. https://plan.core-apps.com/tristar_ada18/abstract/5188446740e191fd289345d56a78c104

² Jangam, Sujit et al. Glucose Variability and Flash Glucose Monitoring in the Real World. Presented at the American Diabetes Association 78th Scientific Sessions. https://plan.core-apps.com/tristar_ada18/abstract/5188446740e191fd289345d56a7a6d8e

³ Pryor, Heather et al. Real-world Patterns of Daytime and Nocturnal Hypoglycemia during Flash Continuous Glucose Monitoring. Presented at the American Diabetes Association 78th Scientific Sessions. https://plan.core-apps.com/tristar_ada18/abstract/5188446740e191fd289345d56a7d4359

⁴ Hellmund, Richard. Cost Calculation and Adherence to ADA Recommendations based on a Flash Continuous Glucose Monitoring System. Presented at the American Diabetes Association 78th Scientific Sessions. https://plan.core-apps.com/tristar_ada18/abstract/5188446740e191fd289345d56a78cdc8

⁵ Data on file. Dunn T, Xu Y, Hayter G; Evidence of a Strong Association Between Frequency of Flash Glucose Monitoring and Glucose Control Measures During Real-World Usage

⁶ Bolinder, Jan, et al. Novel glucose-sensing technology and hypoglycemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. The Lancet 388.10057 (2016): 2254-2263

⁷ Data on file, Abbott Diabetes Care, Inc., Evaluation of the Accuracy of the Abbott Sensor Based Glucose Monitoring System- Paediatric Label Extension Study (CE) (2015)

⁸ Campebell, Fiona et al FreeStyle Libre Use for Self-Management of Diabetes in Teenagers and Young Adults. Presented at the American Diabetes Association 78th Scientific Sessions. https://plan.core-apps.com/tristar_ada18/abstract/5188446740e191fd289345d56a7bbf18.

⁹ Data on file, Abbott Diabetes Care

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