

American Diabetes Association Showcases Innovations and Guidance for Early Risk Monitoring of Type 1 Diabetes

International Consensus Offers Guidance for Monitoring Autoantibody Positive Individuals in Early-Stage Type 1 Diabetes

Data Shows Continuous Glucose Monitoring Helps Classify Patient Risk of Type 1 Diabetes

ORLANDO, FL. (JUNE 24, 2024) – New developments for early risk monitoring of Type 1 Diabetes (T1D) were presented as part of the American Diabetes Association's® (ADA) 84th Scientific Sessions in Orlando, FL. An international consensus provided insights into how health care professionals can improve patient care for individuals with autoantibodies in early stage type 1 diabetes and new research highlighted the benefits of continuous glucose monitoring (CGM) metrics in predicting disease progression and risk.

This comes at a time when more than <u>2 million Americans</u> live with type 1 diabetes, including about 304,000 children and adolescents. Type 1 diabetes can frequently present with <u>preventable life-threatening complications such as diabetic ketoacidosis</u>. Despite <u>recommendations from the ADA</u> for screening of all types of diabetes every three years for adults 35 years and older and adults with overweight under 35 years with an additional risk factor, <u>22.8% US adults</u> have undiagnosed diabetes, including type 1 and type 2 diabetes.

"Early screening and risk monitoring has become critical in the care and delay of type 1 diabetes, to reduce the risk of complications with the disease such as diabetic ketoacidosis," said Robert Gabbay,_MD, PhD, ADA's chief scientific and medical officer. "The studies and guidance statement presented at this year's annual meeting will help pave the way for a new era of treatment for individuals with type 1 diabetes."

Monitoring Guidance Provides Clear, Actionable Advice for Healthcare Professionals

Presented as a symposium, researchers from Schneider Children's Medical Center of Israel and Riley Children's Health at Indiana University Health presented a new consensus statement for monitoring autoantibody positive individuals in early stage type 1 diabetes. The guidance provides clear, actionable advice for healthcare professionals in primary and specialty care on how to follow up during the early, preclinical stages of



type 1 diabetes. Development of the consensus guidance was led by Breakthrough T1D (formerly JDRF) and is endorsed by the ADA and the European Association for the Study of Diabetes. It was simultaneously published in *Diabetes Care* and *Diabetologia*.

The consensus provides specific advice to care for children, adolescents, and adults, and includes educational and psychosocial advice. The consensus emphasizes the benefits of early detection of type 1 diabetes, including reduced risk of diabetic ketoacidosis at diagnosis, increased planning and preparation time, and the opportunity to consider research aimed at delaying and preventing type 1 diabetes.

"We are experiencing a paradigm shift in type 1 diabetes care, and we can now identify people in the earlier, presymptomatic stages of type 1 diabetes, before insulin is required, and intervene," said Anastasia Albanese-O'Neill, PhD, APRN, CDCES, Breakthrough T1D, (formerly JDRF), New York, NY, and co-chair of the symposium. "Until now, there was no consensus on how to care for these individuals in the clinical setting and provide appropriate education and psychological support. This new guidance should be used widely by healthcare providers to inform and guide the care of individuals in early stage T1D."

The authors of this consensus cite the next critical steps as the diffusion of knowledge and clinical implementation to ensure the benefits are realized by individuals in early stage type 1 diabetes and their families. Intensive communication and education on how to operationalize this paradigm shift in the treatment of type 1 diabetes will be essential.

CGM Metrics Identify Risk of Imminent Type 1 Diabetes Development

Results show that a CGM model developed from metrics collected from participants with one or more of the markers used to predict the risk and progression of type 1 diabetes (positive islet autoantibody (IAb) typeS), demonstrated CGM metrics can help predict type 1 diabetes progression and classify the participants' risk of impending type 1 diabetes diagnosis.

The study combined baseline CGM data from five studies including the Autoimmunity Screening for Kids (ASK), Belgian Diabetes Registry (BDR), Diabetes Autoimmunity Study in the Young (DAISY), Type 1 Diabetes Prediction and Prevention (DIPP), and TrialNet Pathway to Prevention (TrialNet) with a median follow-up time of 2.6 years. A CGM and baseline factor model and a baseline-only model were compared. The CGM model classified participants as low, medium, or high risk of stage 3 type 1 diabetes based on less than 10%, 10% through less than 30%, and greater than or equal to 30% probability by year two.



The results of the study showed the probability of developing type 1 diabetes by two years was 4%, 17%, and 51% in the low, medium, and high risk groups. Notably, compared to low-risk participants, high-risk participants had higher % time >140 mg/dL (TA140) – which is associated with a high risk of progression to clinical diabetes, higher total increase in glucose over a period of time or area under the curve 140 mg/dL (AUC140), and higher spread in glucose readings around the average or glucose standard deviation.

"Over the years, our understanding of the relationship between CGM metrics and T1D progression has improved. This data is exciting because now we can say using CGM metrics to classify risk of imminent stage 3 T1D diagnosis is effective," said Peter Calhoun, PhD, Jaeb Center for Health Research, Tampa, FL, and lead investigator. "CGM monitoring can help assist in identifying high risk patients, who would most benefit from early intervention."

The authors hope future drug trials will use CGM metrics as an eligibility requirement to identify those at the highest risk of progression and patients with one or more positive islet autoantibodies will consider utilizing CGMs temporarily to better understand their own risk of developing stage 3 type 1 diabetes.

Research presentation details:

Dr. Calhoun will present the findings at the following oral presentation session:

 Oral Presentations - New Technology—What's New? (Presidents' Select Abstract)

CGM Metrics from Five Studies Identify Participants at High Risk of Imminent Type 1 Diabetes (T1D) DevelopmentT1D

• Presented on Friday, June 21, 2024 at 2:00 PM EDT

Dr. Albanese-O'Neill will present the findings at the following symposium:

- Symposium Consensus Monitoring Guidance in Early Stage Type 1 Diabetes
- Presented on Monday, June 24, 2024 at 8:00 AM EDT

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About the ADA's Scientific Sessions

The ADA's 84th Scientific Sessions, the world's largest scientific meeting focused on diabetes research, prevention, and care, will be held in Orlando, FL on June 21-24. More than 11,000 leading physicians, scientists, and health care professionals from around the world are expected to convene both in person and virtually to unveil cutting-



edge research, treatment recommendations, and advances toward a cure for diabetes. Attendees will receive exclusive access to thousands of original research presentations and take part in provocative and engaging exchanges with leading diabetes experts. Join the Scientific Sessions conversation on social media using #ADAScientificSessions.

About the American Diabetes Association

The American Diabetes Association (ADA) is the nation's leading voluntary health organization fighting to bend the curve on the diabetes epidemic and help people living with diabetes thrive. For 83 years, the ADA has driven discovery and research to treat, manage, and prevent diabetes while working relentlessly for a cure. Through advocacy, program development, and education we aim to improve the quality of life for the over 136 million Americans living with diabetes or prediabetes. Diabetes has brought us together. What we do next will make us Connected for Life®. To learn more or to get involved, visit us at diabetes.org or call 1-800-DIABETES (1-800-342-2383). Join the fight with us on Facebook (American Diabetes Association), Spanish Facebook (Asociación Americana de la Diabetes), LinkedIn (American Diabetes Association), Twitter (@AmDiabetesAssn), and Instagram (@AmDiabetesAssn).