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Screening and Referral Program

Advocacy
Education
Leadership
Engagement
Outcomes

# Screen Today, Prevent DKA Tomorrow:
## Rewriting the Story of Type 1 Diabetes through Screening

May 14, 2026

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# Speaker Toolkit Acknowledgment

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I have considered the *Ohio AAP Speaker Toolkit* standards in preparing this presentation. It is my intent to foster respect, belonging, support and accountability with regard to the patients we serve.

If you have any concerns or comments, please contact Kelsey Logan, MD, MPH, FAAP at Kelsey.Logan@cchmc.org.

# CME Disclosure

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Nicole Sheanon, MD, MS has the following relationship to disclose:

| | |
|---|---|
| Enable | Site PI for 4 AAb kit testing |
| MannKind | Advisory Board - Afrezza |
| Sanofi | Advisory Board; Site PI for Freliximab and Beta Preserve |

The other planners, faculty and others in control of content (either individually or as a group) have no relevant financial relationships with ineligible companies.

# Objectives

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Describe the stages of early-stage Type 1 diabetes and recognize key clinical features associated with each stage.

Explain the importance of screening for T1D, including who should be screened and the evidence supporting early detection.

Identify available T1D screening options and outline the steps involved in the screening process.

Discuss how early identification of T1D can improve outcomes and guide timely referral or intervention.

# Case 1

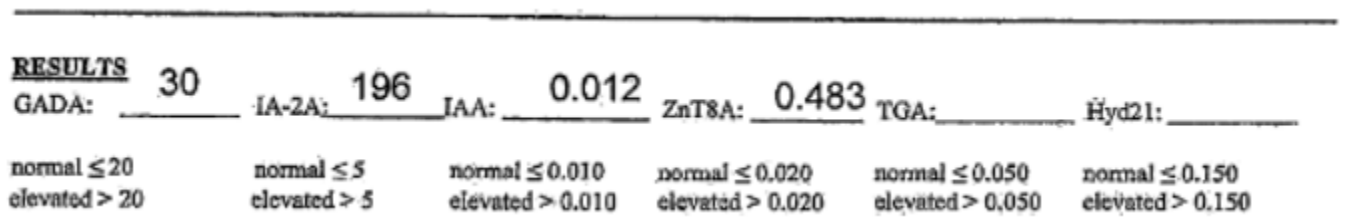
- 4 yo Female, previously healthy presented to the ED with 2 weeks of increased thirst and urination. She also had a 4 lb weight loss.
- Initial labs showed mild DKA with hyperglycemia and ketonuria. HbA1c 13.8%
- She was started on IV insulin and IV fluid resuscitation.
- She was admitted to hospital for monitoring and treatment and education. She was hospitalized for 4 days.

# Case 2

- 12 yo Male, previously healthy, presented to the ED with vomiting, abdominal pain and lethargy.
- He had significant weight loss and severe dehydration
- His labs showed severe DKA (pH 6.9, bicarb 5, glucose 467, anion gap 24). He was started on an insulin drip and IVF resuscitation
- He was initially admitted to the PICU due to pH and mental status changes. He was then transferred to floor and started on basal bolus injection therapy and received education.
- He was hospitalized for 4 days.
- HbA1c > 14%

# Case 2

- Islet Cell Autoantibody Screen: 4 positive antibodies



**RESULTS**

| GADA: | IA-2A: | IAA: | ZnT8A: | TGA: | Hyd21: |
|---|---|---|---|---|---|
| 30 | 196 | 0.012 | 0.483 | | |
| normal ≤ 20<br>elevated > 20 | normal ≤ 5<br>elevated > 5 | normal ≤ 0.010<br>elevated > 0.010 | normal ≤ 0.020<br>elevated > 0.020 | normal ≤ 0.050<br>elevated > 0.050 | normal ≤ 0.150<br>elevated > 0.150 |

- Also found to have new diagnosis of celiac disease
- Diagnosis complicated by insulin edema and he was readmitted 1 week after initial diagnosis

# Type 1 Diabetes Statistics

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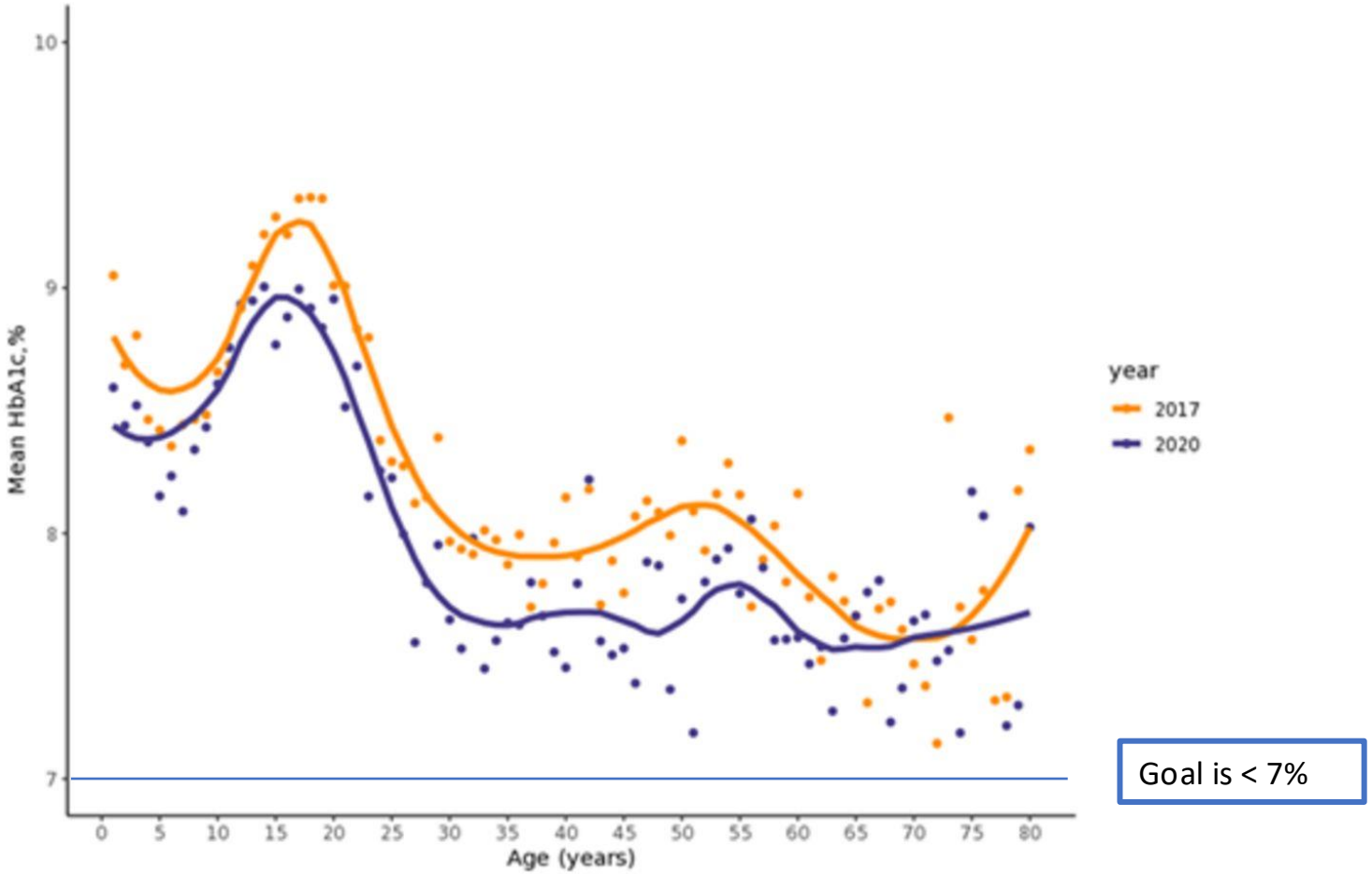
- **1.7 million** American adults live with type 1 diabetes
- **304,000 American children** and adolescents have T1D
- Approx 64,000 people are newly diagnosed with T1D each year
  - 27,000 Children (42%)
  - 37,000 Adults (58%)
- T1D affects all races and ethnicities

# Mean A1c by Age, T1 Exchange Data






Goal is < 7%

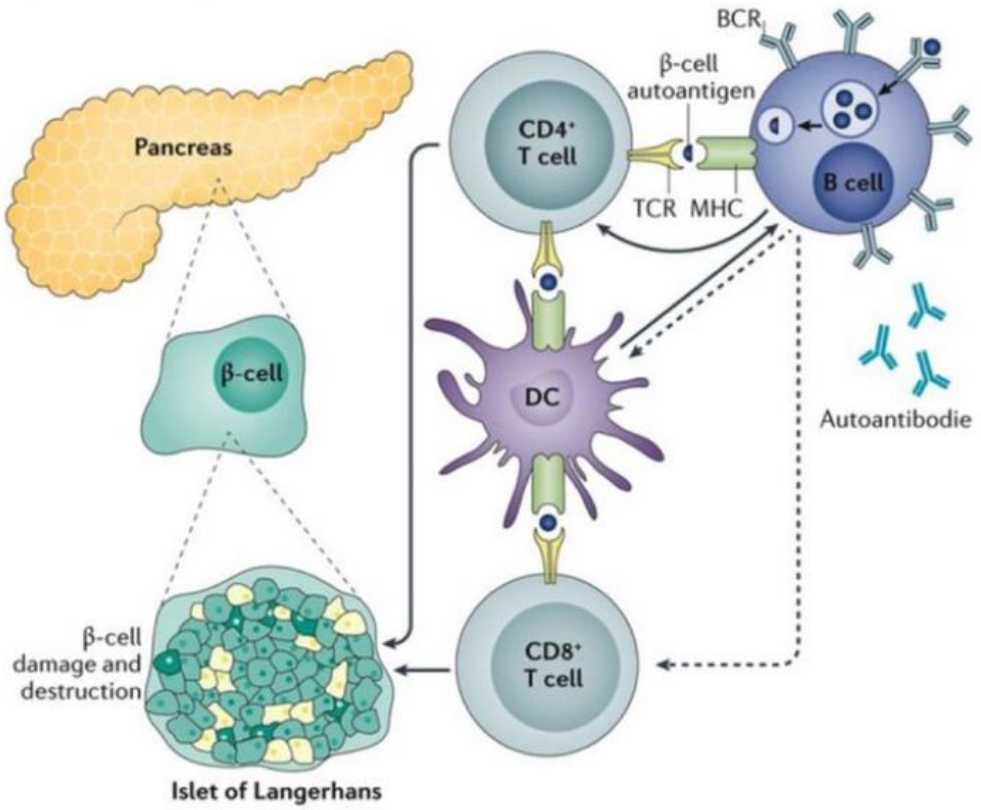
Diabetes. 2021;70(Supplement_1). doi:10.2337/db21-833-P

# Burden of T1D

- **180 extra decisions made each day**
- Wake up, check CGM. It is expiring in 4 hours. Change it before leave the house
- Give insulin bolus for breakfast. Shower and get dressed
- Eat breakfast. Ate less than bloused for because ran out of time. Grab a juice on the way out the door to bus/car
- Get to school/work. Pump alarm to charge the pump, 15% battery remaining. Find a place to plug in
- Pump alarm for high glucose. Give a correction
- Pump alarm for set change reminder. Ignore
- Time for lunch. Count carbs. Give insulin. Low insulin alert. Fill reservoir. Each lunch.
- Go on a walk/recess after lunch. Forgot to turn on activity mode before. Decide to suspend pump for 30 minutes. Have a nice walk/play gaga. Pockets are full of meter and low supplies just in case/all supplies in classroom or with school nurse
- CGM alert high. Forgot to resume insulin delivery after walk/recess. Resume insulin. Give a correction.
- IT's ONLY 2 PM

# Immunology of Type 1 Diabetes



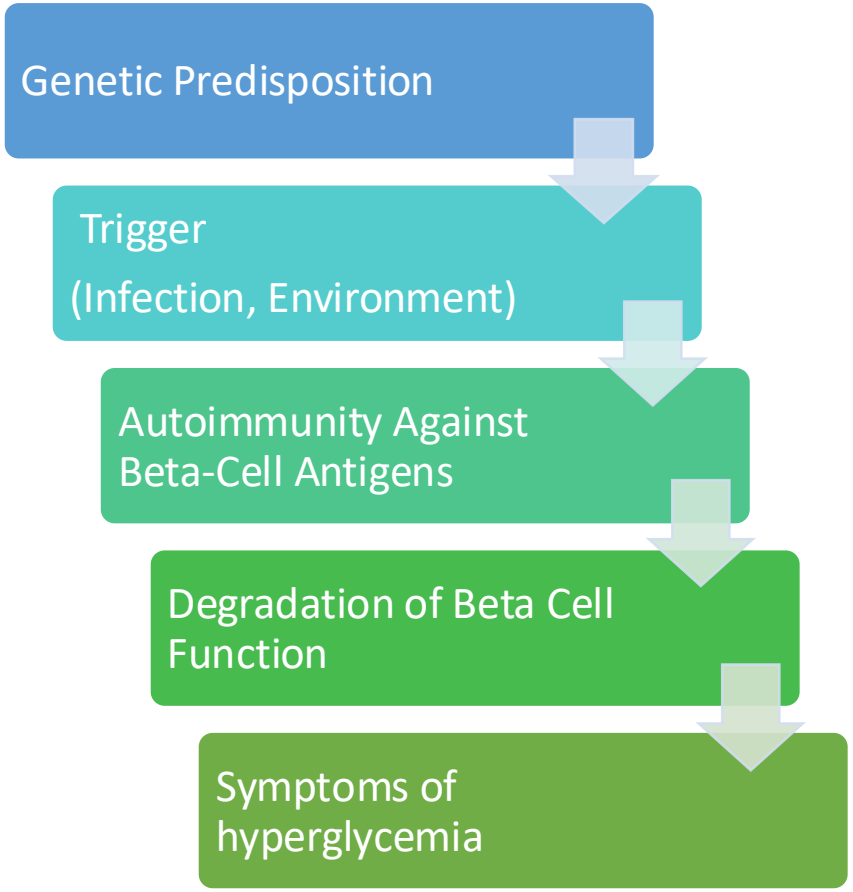



- Antigen presenting cells present beta cell antigens to T cells. Normal T cells recognize these as "self" and ignore them
- Genetic and environmental factors contribute to tolerance loss of some T cells
- T cells that have lost tolerance to beta cell antigens attack beta cells
- Autoantibodies to beta cell antigens are released into the bloodstream.

Katsarou et al. Pathogenesis of T1D. 2017. Nat Rev

# What Causes Type 1 Diabetes?





# Diagnostic Criteria for Diabetes

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- Pre-diabetes
  - Fasting plasma glucose 100-125
  - 2 hour post glucose load 140-199 on OGTT
  - HbA1c 5.7-6.4%

- Diabetes
  - Symptoms of diabetes plus random glucose > 200 mg/dL
  - Fasting plasma glucose > 126
  - 2 hour post glucose load $\geq$ 200 on OGTT
  - HbA1c $\geq$ 6.5%

*ADA Diabetes Standards of Care. 2026. Diabetes Care*

# Poll Break #1

- Are you screening for T1D risk factors (e.g., first-degree relative, autoimmune conditions, etc.) today?
- Are you screening for T1D autoantibodies today?
- Are you comfortable explaining antibodies associated with T1D and the stages of T1D?

# Islet Autoantibodies in T1D



| Auto-Antibody | Islet Specificity | Characteristics |
|---|---|---|
| IAA | Insulin | One of first seen in younger children |
| GADA | GAD | Most common first detected up to age 15 yo, slower progression, Often single AA in adults |
| IA2A | Tyrosine Phosphatase antigen 2 | More advanced autoimmunity and faster progression |
| ZnT8 | Zinc Transporter Type 8 | Improved risk stratification |

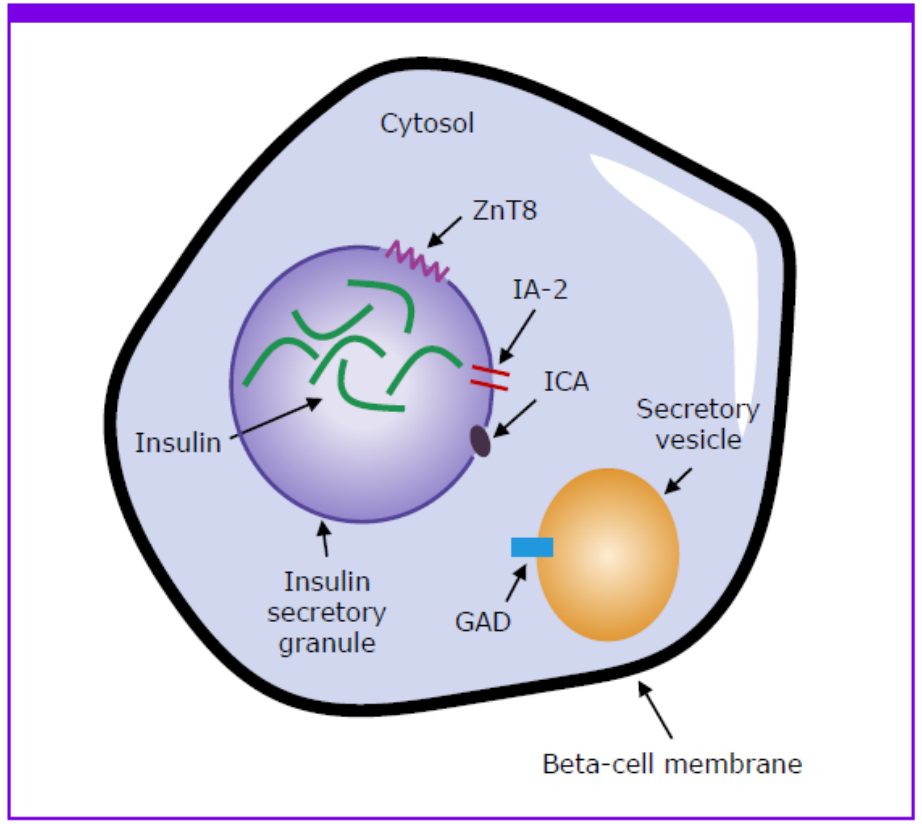
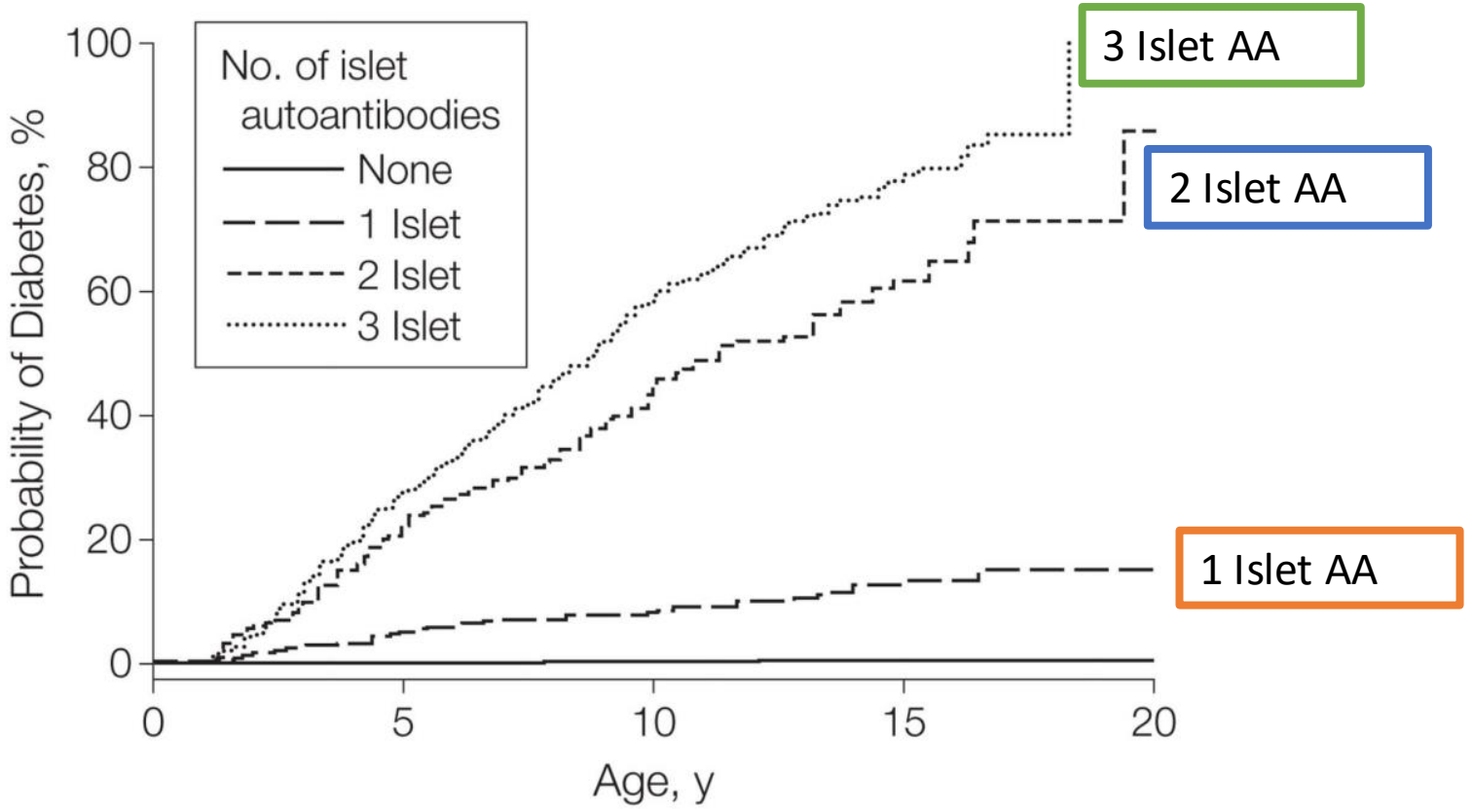



Figure adapted from Misra S. *Pract Diabetes.* 2017;34(6):221-223.[3]

# T1D: Predictable by Measuring Autoantibodies (AA)






*Zeigler AG et al. JAMA 2013. Risk of Progression to Diabetes in Children*

# Population Screening Studies



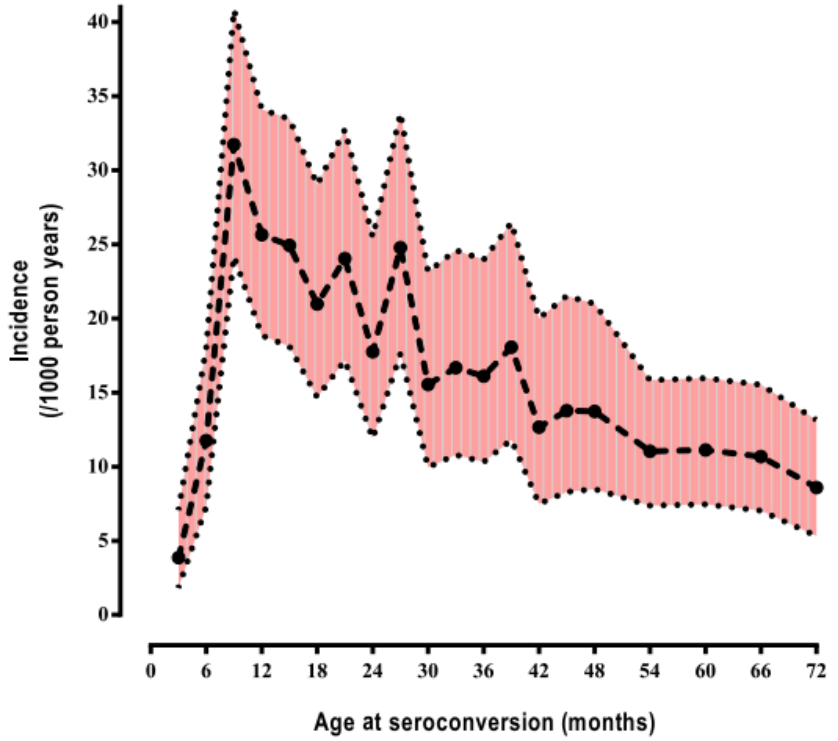



**Figure 1**—Incidence of antibodies among 0- to 6-year-old children in TEDDY by age of seroconversion (incidence and 95% piecewise confidence bands). Autoantibodies appeared in 589 of 8,503 children.

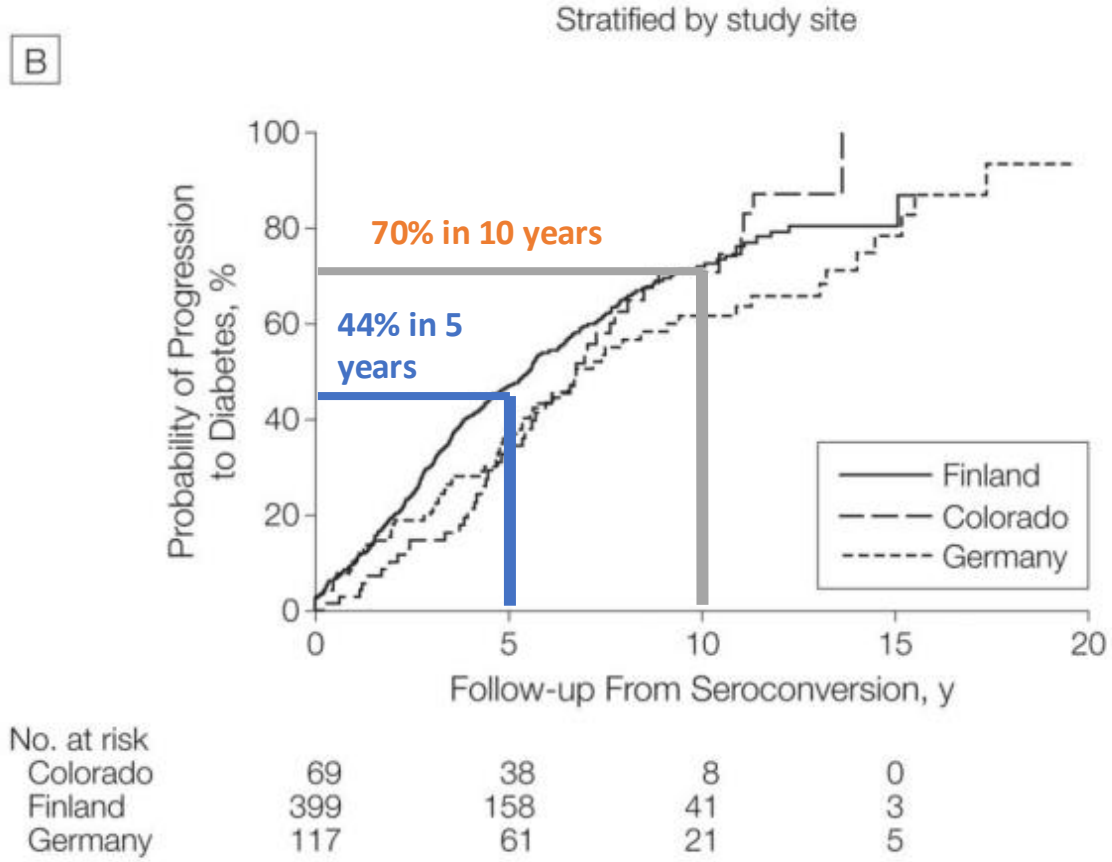
***Krischer. Diabetes Care 2017. Genetic and Environmental***

***Interactions Modify Risk***

- Antibodies can be detected as early as 6 months of age
- Most children will develop antibodies in the first 5 years of life
- Even children with genetic predisposition may NOT develop antibodies
  - Environmental Triggers of Autoimmunity

# Progression to T1D with multiple AA






Progression occurs more quickly in those with younger age, multiple positive antibodies, or IA-2A present

*Zeigler 2013, JAMA, Seroconversion to multiple IAA and risk of progression to DM in children*

# Type 1 Diabetes Disease Progression

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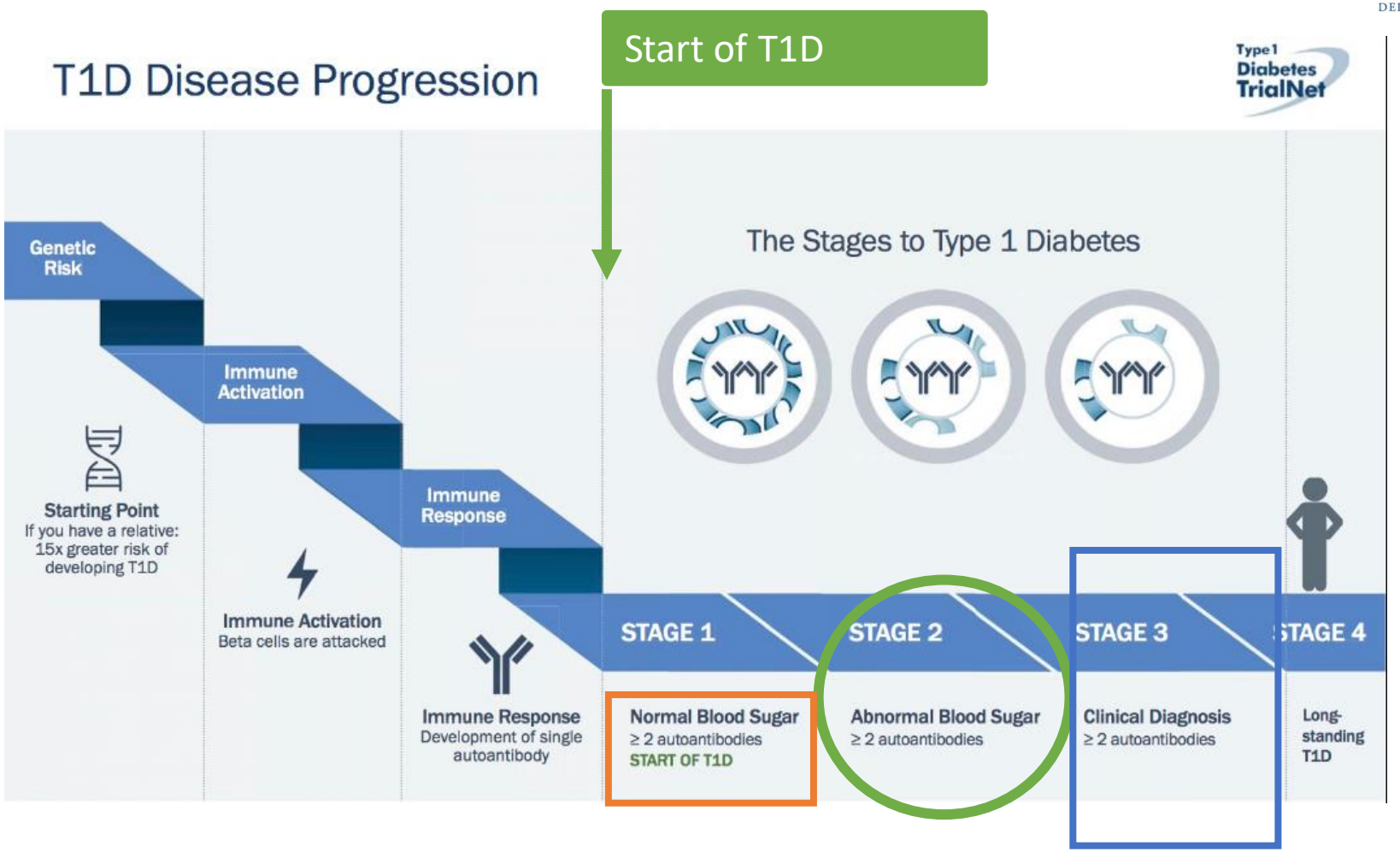

# Stages of Type 1 Diabetes

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## Stage 1, T1D

- 2 or more islet autoantibodies
- Normal glucose levels
- No symptoms

## Stage 2, T1D

- 2 or more islet autoantibodies
- Dysglycemia
  - Fasting 100-125, PP 140-199, A1c 5.7-6.4%
- No symptoms

## Stage 3, T1D

- Autoantibodies may become absent
- Hyperglycemia
  - Fasting > 126, PP > 200, A1c > 6.5%
- Symptoms
  - Polyuria, polydipsia, weight loss

*ADA. Diabetes Care 2024;47 (suppl 1):S20-S42.*

# WHY Should We Screen?

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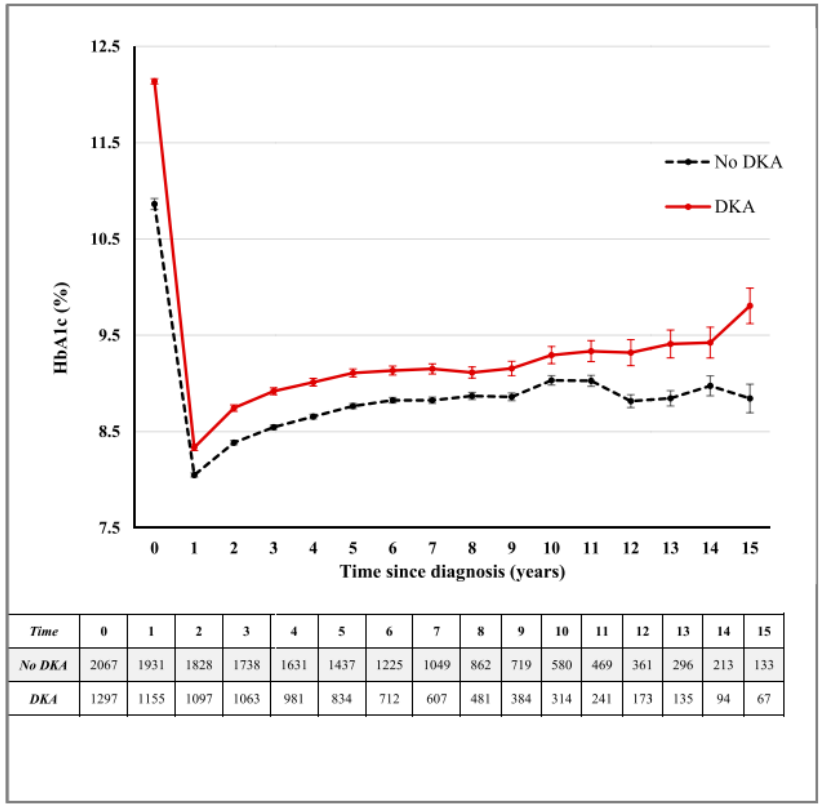
- **Prevent DKA at onset of T1D and minimize hospitalization**
- More time to adapt to diagnosis and receive education
- T1D symptoms can be slow in onset and can masquerade as common childhood illnesses.
- Identify individuals who may benefit from therapeutic interventions
- To avoid misdiagnosis and delayed initiation of insulin

# What Do We Know About DKA at Diagnosis?



- Patients Acutely:
  - Increased mortality
  - Longer hospitalization
  - Higher insulin requirements
  - Shorter honeymoon period
  - Less residual c-peptide

- Patients Long Term:
  - Worse glucose control independent of social determinants of health and demographics




| Time | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| No DKA | 2067 | 1931 | 1828 | 1738 | 1631 | 1437 | 1225 | 1049 | 862 | 719 | 580 | 469 | 361 | 296 | 213 | 133 |
| DKA | 1297 | 1155 | 1097 | 1063 | 981 | 834 | 712 | 607 | 481 | 384 | 314 | 241 | 173 | 135 | 94 | 67 |

**Figure 1**—DKA at diagnosis of children with type 1 diabetes and long-term glycemic control. The numbers reported below the figure represent the number of participants contributing the overall $HbA_{1c}$ level during that point in time. Data presented are mean ± SE from unadjusted linear mixed model.

*Duca et al. 2017. Diabetes Care. DKA at diagnosis of T1D Predicts Poor long term glycemic control*

# A Word About C-peptide…

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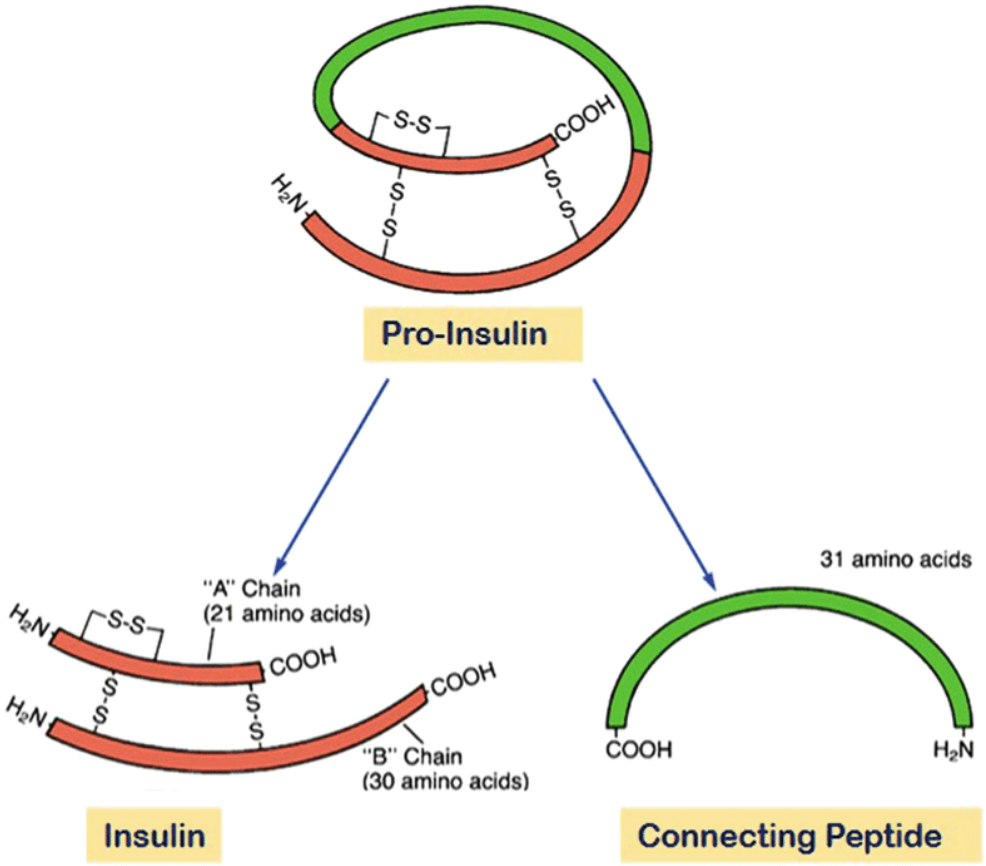


- Patients with residual c-peptide
  - Have less complications from diabetes (retinopathy and nephropathy)
  - Have lower frequency of severe hypoglycemia
  - Lower A1c and less glycemic variability
  - Lower daily insulin requirement

Asimul. (2020). Management of Insulin Through Co-Solute Engineering: A Therapeutic Approach.

# Back To My 2 Cases…

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- Each were admitted to the hospital for 4 days
- Both were in DKA
- Both had A1c > 14%
- Both had a family history of T1D
  - The 4 year old had a parent with T1D
  - The 12 year old had an aunt and 2 cousins with T1D

**DKA CAN BE PREVENTED WITH SCREENING**

# 40-60% of children diagnosed with type 1 diabetes present in DKA at new onset here in the US.

# Screening Reduces Rate of DKA at Diagnosis and Improves Diabetes Control

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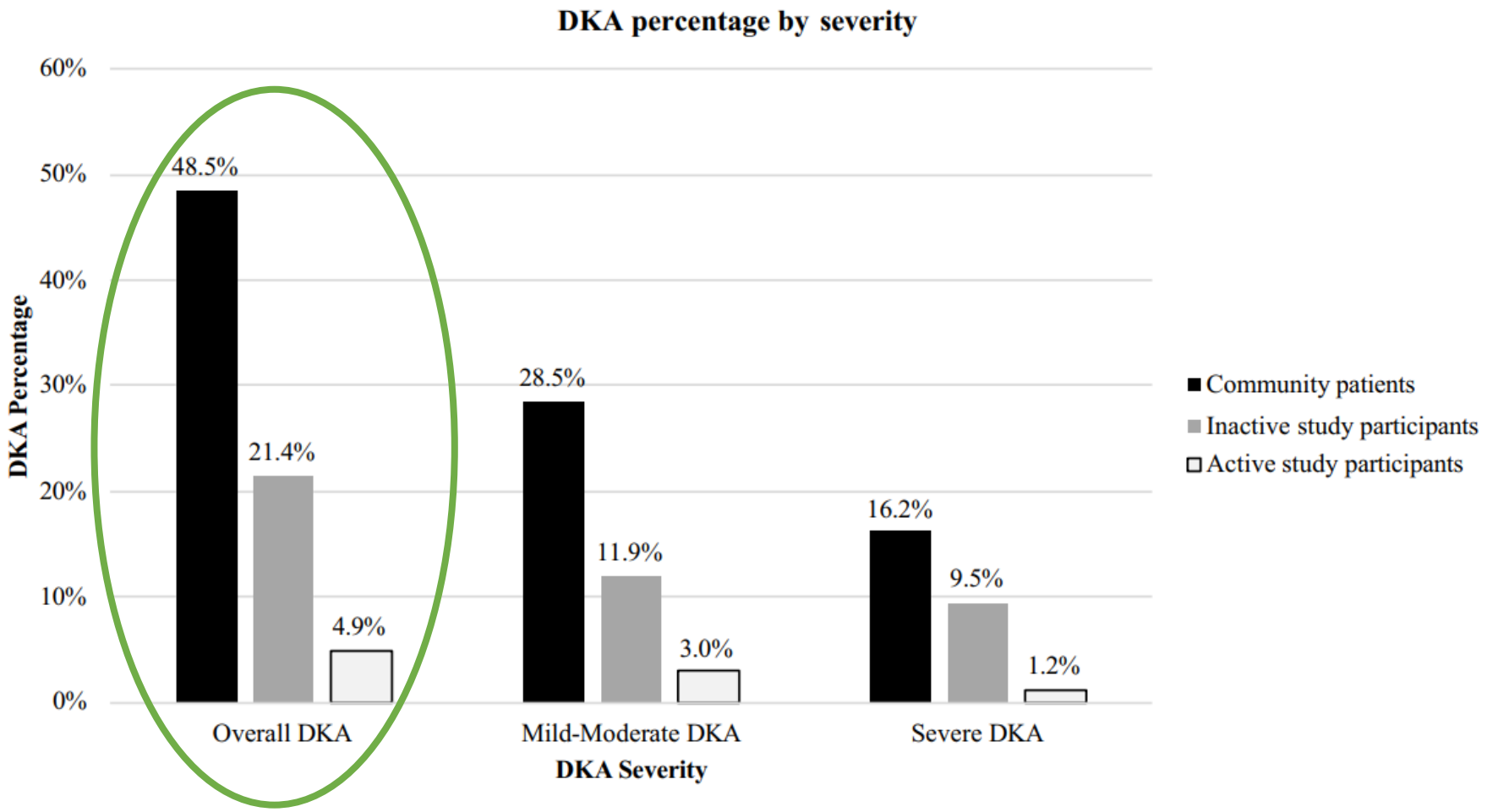


**Figure 2.** Percentage of children with DKA by severity and study status.

*Sooy et al. Lower Prevalence of Diabetic Ketoacidosis at Diagnosis in Research Participants Monitored for Hyperglycemia, JCEM, 2024*

# DKA at Diagnosis of T1D

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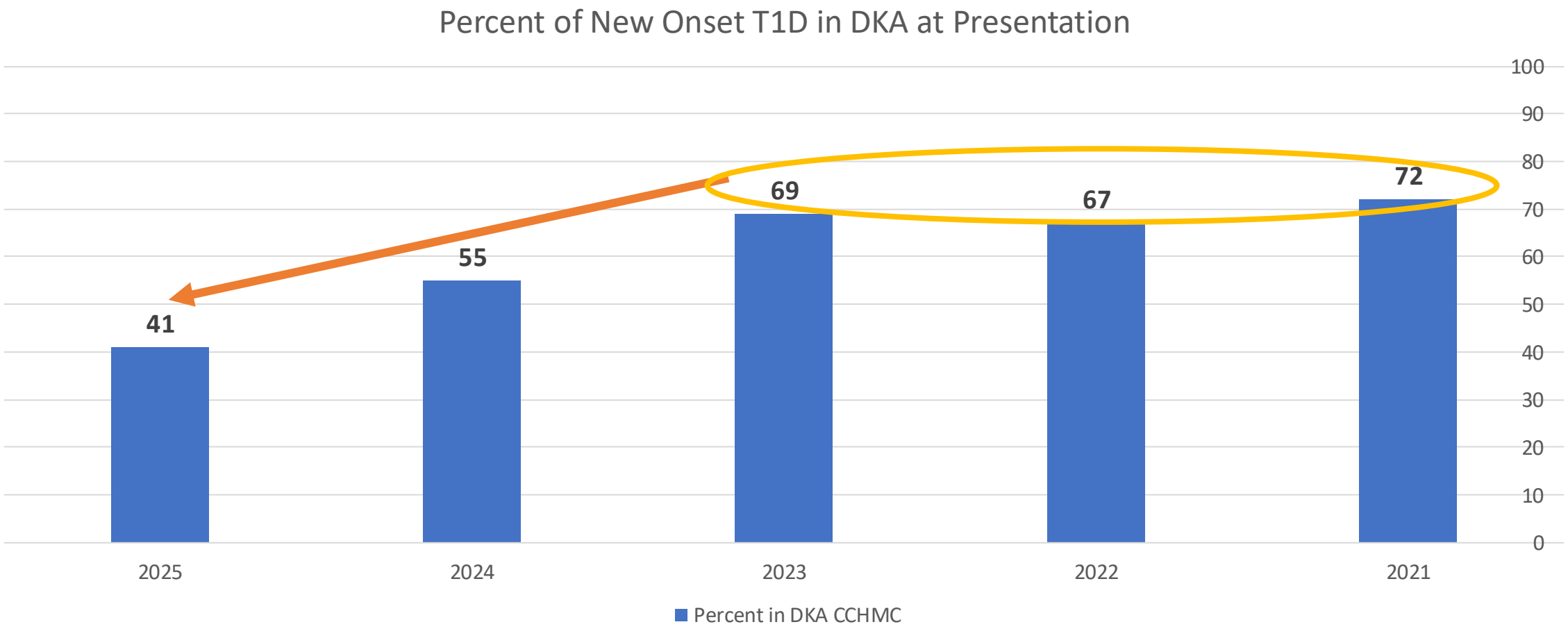
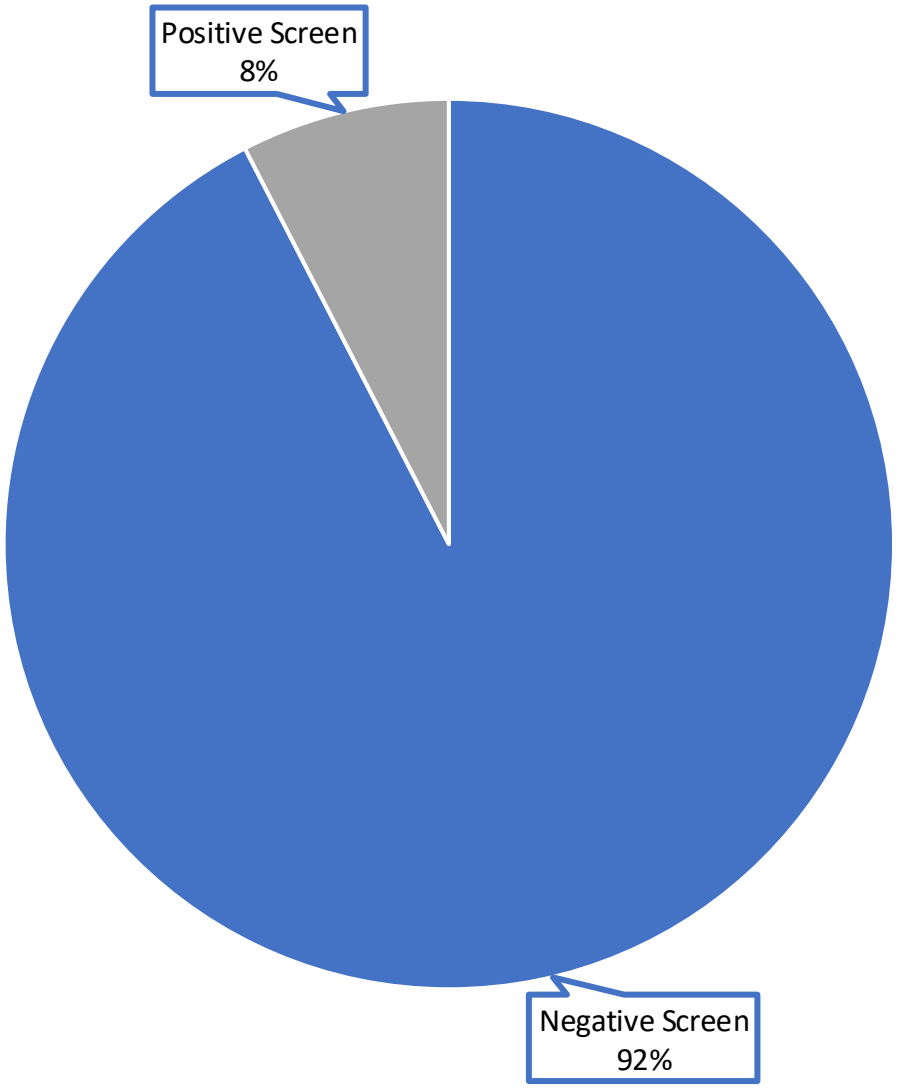
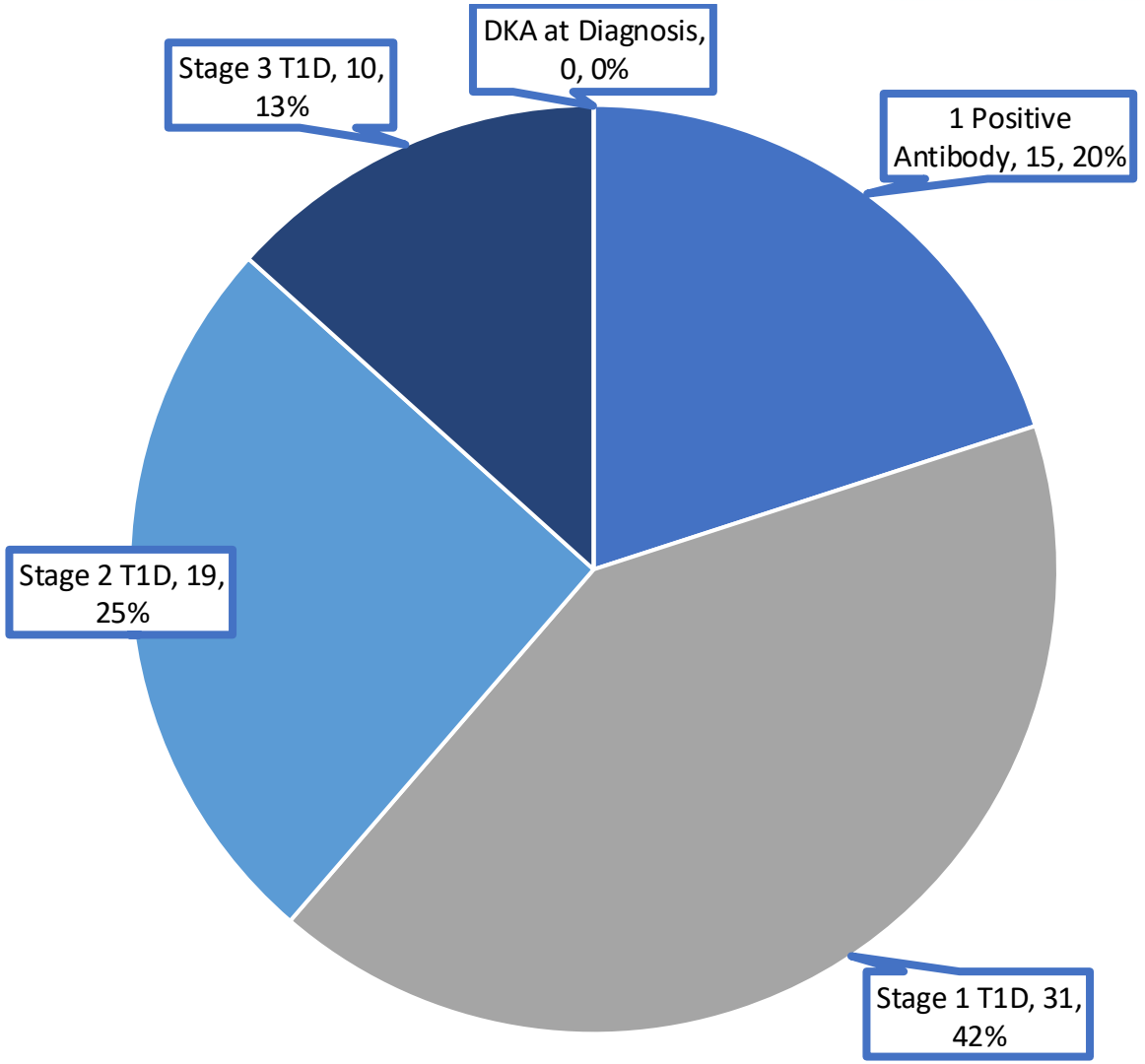


# Screening Program





# How Diagnosis of T1D Looks Different with Screening…

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- 11 yo female, screened when her brother was diagnosed
- 4 positive antibodies
- Intermittent monitoring over the next year
- Glucose started to trend up
- Day hospital to start insulin at convenience of family
- 1 week after starting insulin transitioned to an automated insulin delivery system (pump)
- A1c has been < 7% since diagnosis (3 years)

# Poll Break #2

- Approximately how many patients have you screened for T1D within the last year?
  - 0
  - 1-5
  - 6-10
  - >10

# **WHO** is at Risk?



## Family History Risk

Children who have a family member with T1D have a **15x increased risk** of developing T1D.
Siblings 6-7% lifetime risk
Offspring of mothers have a 4-6% risk
Offspring of fathers have a 6-9% risk
Identical twins have a 50% risk

90% of children diagnosed with type 1 diabetes **DO NOT** have a family history of T1D.

# WHO Should be Screened?

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- Relatives of a person with Type 1 Diabetes
- Anyone with an autoimmune condition
  - Thyroid Disease
  - Celiac Disease
  - Addison's Disease
- Relatives of a person with an autoimmune condition
- Other considerations:
  - Hypoglycemia
  - Steroid induced diabetes
  - Pre-diabetes or Type 2 diabetes

**General population?**

**Proposal to screen at 2, 4-6, 9-12, and 15-18**

# Poll Break #3

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- What are your biggest barriers to T1D screening?

# How Do You Talk About Screening with Families?

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- Screening is recommended
- What is involved
- Can I share some facts about why screening is important

# How Do You Screen?

- Clinical Testing Options:
  - Islet Cell Autoantibody Screen
    - Tests for 4 antibodies: GAD, IAA, IA2A, and ZnT8
    - Send out to Barbara Davis Center in Colorado, takes 4-7 days
  - Clinical Lab Panel (Quest, LabCorp, ARUP, Mayo)
  - Enable Kit
    - Tests for 3 antibodies, finger poke with blood spots
- Research
  - ASKtheExperts.org
    - Screen for celiac and T1D ages 1-17 and 18-70, mail kit
  - TrialNet.org
    - Screen for T1D in first and second degree relatives age 2-45 yo, mail or in person

# Language for Documentation

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- Child's Name is a(n) Age year old **with a first degree relative with type 1 diabetes**. Analysis of birth cohorts have shown that peak rates of autoantibody seroconversion occur around 1.5 years in those who progress to clinical type 1 diabetes, and most individuals seroconvert by 2–3 years of age (1,2). If two tests can be done, straddling the 3- to 4-year age-group (i.e., at 2 and 5–7 years of age) has been suggested (2,3). Most genetically high-risk young children who convert from single to multiple autoantibody positivity do so within 2 years after initial seroconversion, suggesting that a single autoantibody-positive individual should be rescreened after this interval (2).
- There is evidence that screening for type 1 diabetes antibodies reduces risk of DKA at onset of diabetes. In addition, there is now an FDA approved treatment called Teplizumab that delays the onset of type 1 diabetes**. For these reasons, screening is recommended in first degree relatives of those with type 1 diabetes and also other autoimmune conditions (5).**


- Parikka V, Näntö-Salonen K, Saarinen M, et al. Early seroconversion and rapidly increasing autoantibody concentrations predict prepubertal manifestation of type 1 diabetes in children at genetic risk. Diabetologia 2012;55:1926–1936
- Chmiel R, Giannopoulou EZ, Winkler C, Achenbach P, Ziegler AG, Bonifacio E. Progression from single to multiple islet autoantibodies often occurs soon after seroconversion: implications for early screening. Diabetologia 2015;58:411–413
- Bonifacio E, Weiß A, Winkler C, et al.; TEDDY Study Group. An age-related exponential decline in the risk of multiple islet autoantibody seroconversion during childhood. Diabetes Care 2021;44:2260–2268
- Ziegler AG, Kick K, Bonifacio E, et al.; Fr1da Study Group. Yield of a public health screening of children for islet autoantibodies in Bavaria, Germany. JAMA 2020;323:339–351
- ADA Standards of Care 2026. Diabetes Care.

# Reimbursement: CPT and ICD Codes

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| CPT CODE | DESCRIPTION | REIMBURSEMENT |
|---|---|---|
| 99385 | Preventative visit, new pt | Low if billed alone |
| 99213 | Problem focused | High if billed with ICD for Fam Hx |
| 83036 | HbA1c | High |
| 86341 | GAD antibody, ZnT8 | High if billed with ICD for Fam Hx |
| 86231 | IA-2A antibody | High if billed with ICD for Fam Hx |
| 86337 | IAA antibody | High if billed with ICD for Fam Hx |

| ICD-10 CODE | DESCRIPTION | REIMBURSEMENT |
|---|---|---|
| Z83.3 | Family history of T1D | High |
| E06.3 | Hypothyroidism | High |
| K90.0 | Celiac Disease | High |
| Z13.1 | Encounter for Screening for diabetes | Often denied if not combined with a reason (Fam Hx) |
| Z83.49 | Family history of endocrine disorders | Can help but higher denial rates |

# Best Reimbursement Outcomes



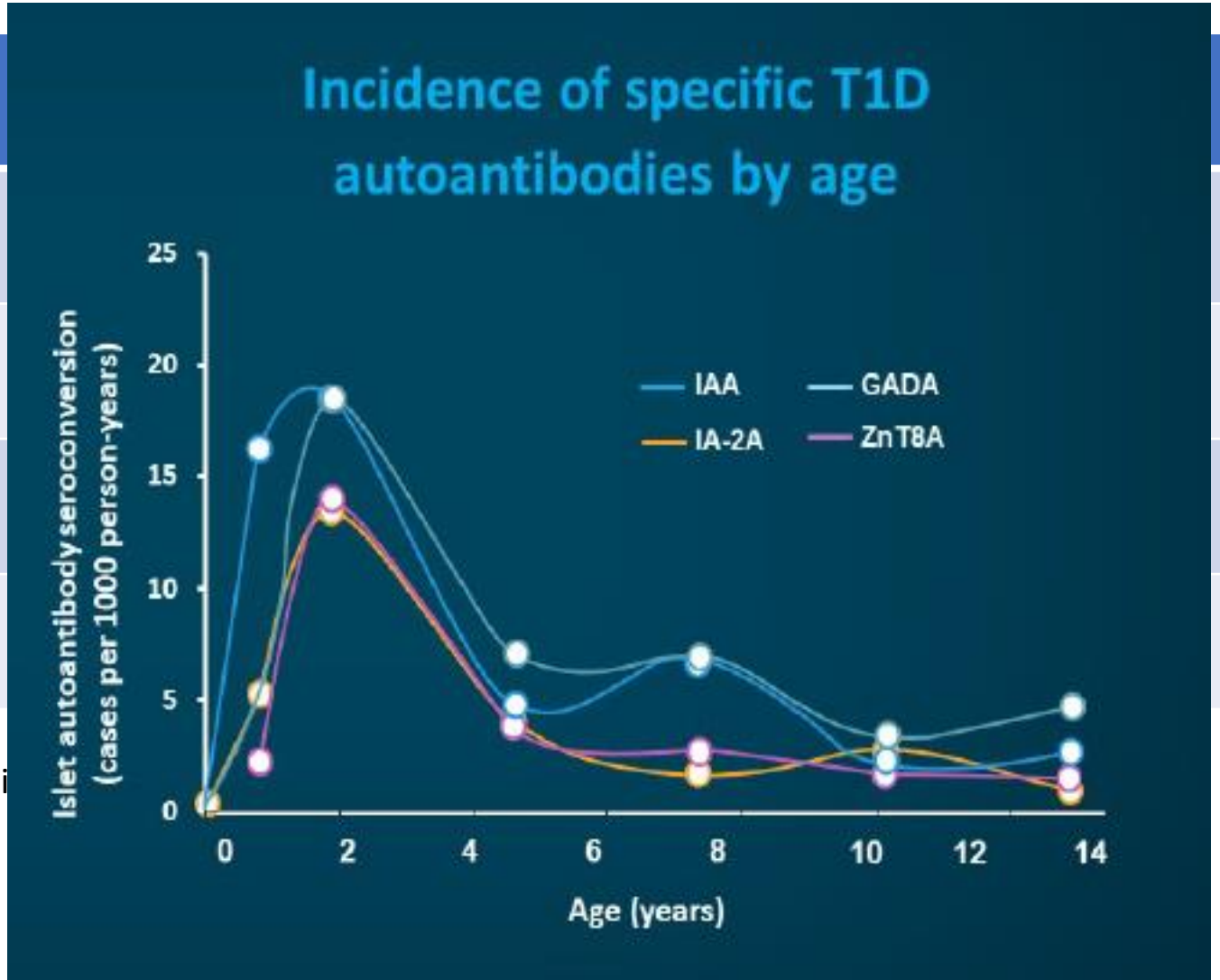
- Screening with family hx of T1D
  - "Screening Encounter for Diabetes" AND "Family history of Diabetes"
  - Z13.1 AND Z83.3

- Screening with personal autoimmune disease
  - "Screening Encounter for DM" AND "Autoimmune Hypothyroidism"
  - Z13.1 AND E06.3

# How Often Should Screening for T1D be Done in Those that are Negative?



Screeni



Diabetes Care
American Diabetes Association

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# Consensus Guidance for Monitoring Individuals With Islet Autoantibody–Positive Pre-Stage 3 Type 1 Diabetes

## Who should be monitored?

Any child, adolescent, or adult who has tested positive for islet autoantibodies in early-stage type 1 diabetes (T1D)

**Nearly 100% of individuals** in early-stage T1D with two or more persistent islet autoantibodies will progress to a stage 3 (clinical) diagnosis

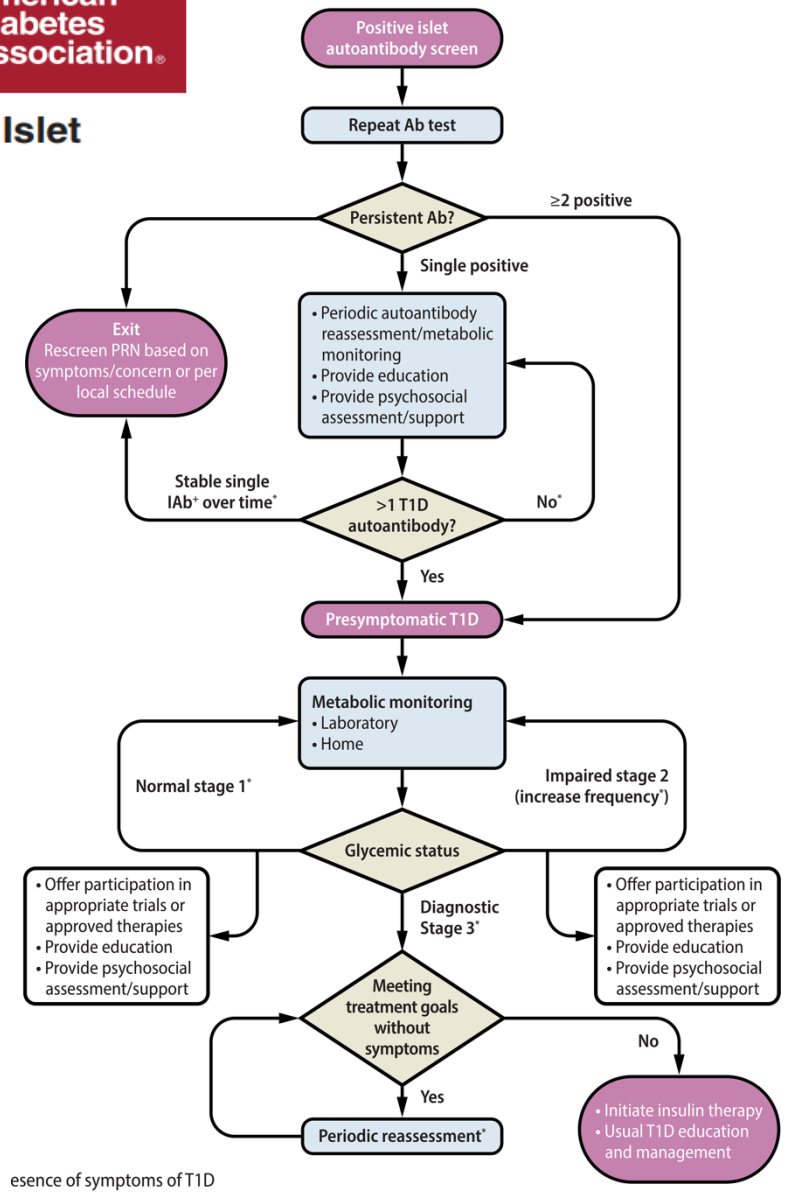
## What is the purpose of monitoring in early-stage T1D?

**Primary purpose is to prevent DKA and minimize the risk of emergency care or hospital admission**

- Identification of individuals eligible to receive therapeutic intervention(s) to delay onset of stage 3 T1D and prolong β-cell function
- To provide advice for the start of insulin in stage 3 T1D, when glucose is elevated and before symptoms develop, to mitigate the consequences of long-term hyperglycemia
- To avoid misdiagnosis of T2D and delayed start of insulin therapy
- Referral for participation in research studies

## Who is involved in monitoring in early-stage T1D?

- Primary care health care professionals
- Pediatric and adult endocrinologists
- Diabetologists
- Diabetes behavioral health professionals
- General pediatricians
- Diabetes education specialists
- Allied health care professionals
- Individuals with early-stage T1D and families




esence of symptoms of T1D

Diabetes Care. 2024;47(8):1276-1298. doi:10.2337/dci24-0042

# Monitoring Patients with Positive AA

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- First step:
  - Obtain random glucose and A1c
  - If A1c > 6.5 or glucose > 200 **urgent** referral to Peds Endo
- Next steps:
  - Refer to Peds Endo/Prevention Clinic
  - Establish stage of diabetes, confirm antibodies
  - Provide Education
  - Metabolic monitoring
    - Oral glucose tolerance test
    - A1c
    - Home glucose monitoring
    - Continuous glucose monitoring

| Age | Stage 1 T1D | Stage 2 T1D |
|---|---|---|
| < 4 years | Every 3 months | Every 3 months |
| 4-5 years | Every 4-6 months | Every 3 months |
| ≥ 6 years | Every 6 months | Every 3 months |

# Immune Modulating Therapy for T1D

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- Teplizumab is the first and only FDA approved drug to delay the onset of stage 3, type 1 diabetes
- FDA approval in November 2022

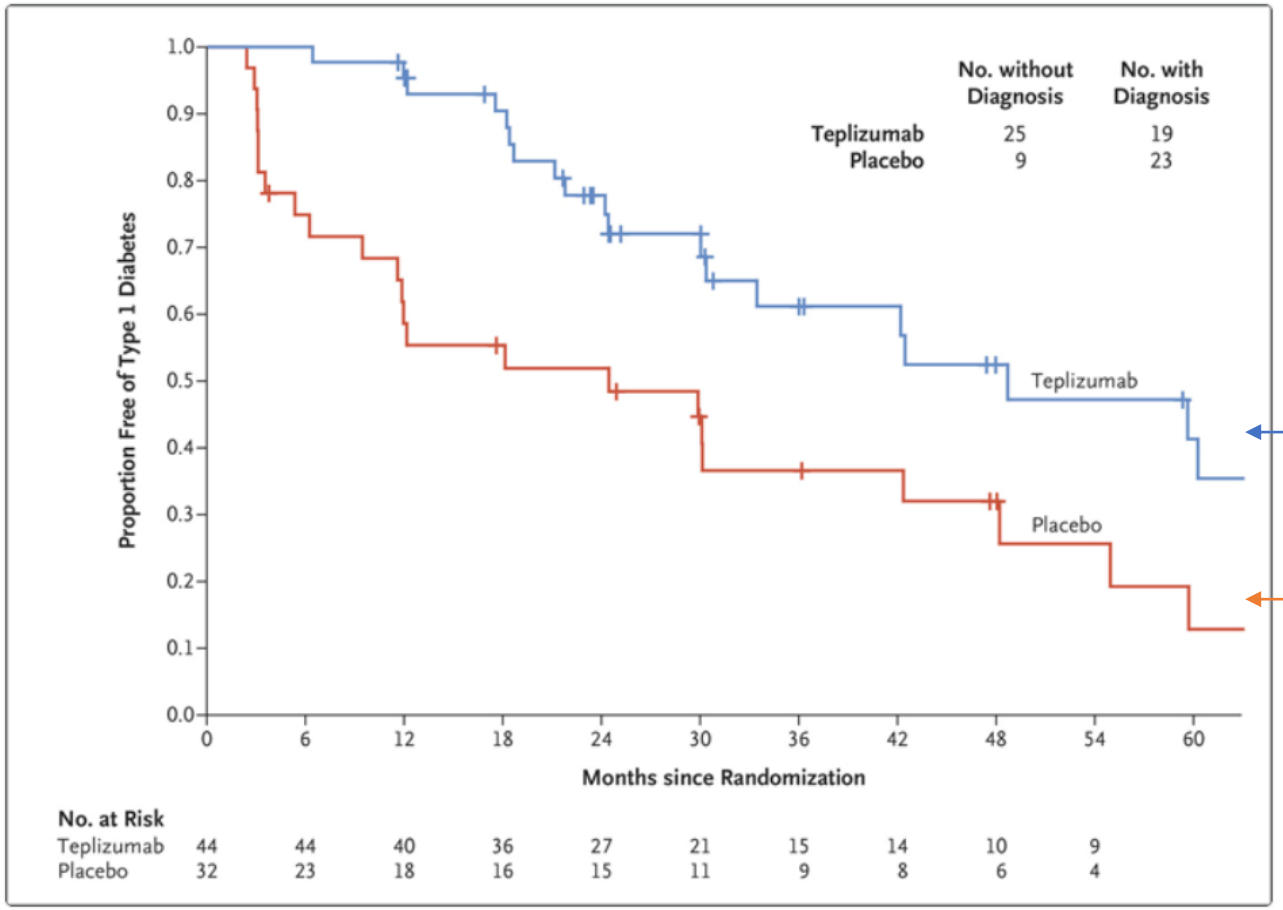
TZIELD is a CD3-directed monoclonal antibody that binds to CD3 antigens presented on the surface of T cells.[1]

The mechanism of action may involve the partial agonistic signaling and deactivation of pancreatic beta cell autoreactive T cells.[1]

TZIELD can potentially delay the onset of Stage 3 T1D in your patients with Stage 2 T1D.[1]

# Kaplan Meier Curve-Proportion without T1D






Median Time to Diagnosis of T1D: 54 months

Median Time to Diagnosis of T1D: 24 months

Herold KC et al. Type 1 Diabetes TrialNet Study Group. An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes. N Engl J Med. 2019 Aug

# Who is it for?

- 1 years of age or older
- Stage 2, type 1 diabetes
- No evidence of type 2 diabetes

- Challenges:
  - Cost
  - 14 day infusion
  - Finding patients in stage 2 that are eligible

- Contra-indications:
  - Pregnancy
  - Active infection

# Safety

- An excellent safety record. Has been studied for 30 years.

- Most Common Side Effects:
  - Cytokine Release Syndrome (fever, rash, headache)
  - Lymphopenia
- Rare, but Possible Side Effects:
  - Hypersensitivity Reaction
  - Serious Infection (Reactivation of EBV)

# Where is the Research Now?

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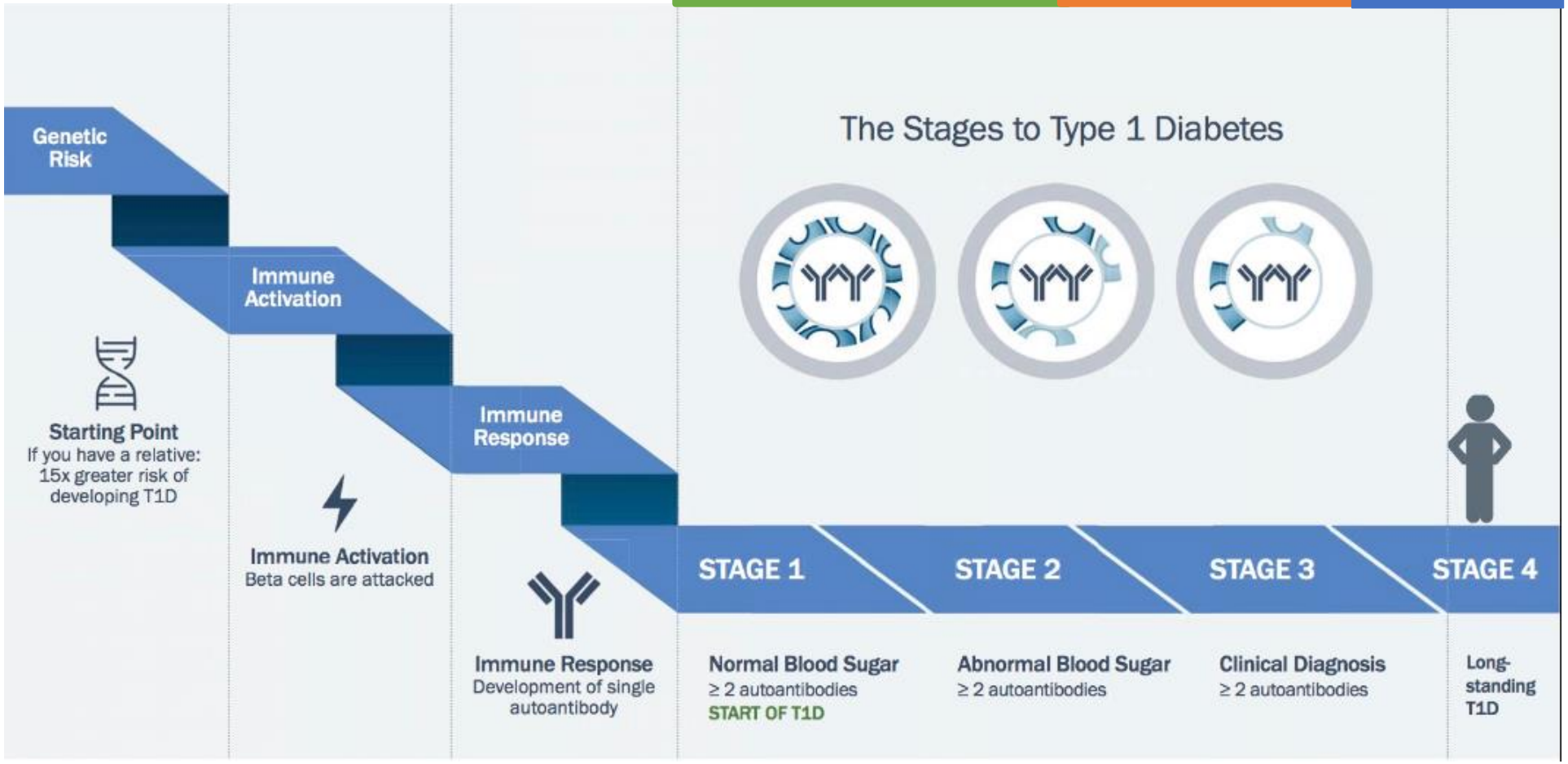
Prevent progression to Stage 3

Preserve Remaining Beta Cells

Cell Therapy/ Replace Beta Cells



# Type 1 Diabetes Prevention Clinic

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- Clinic program for patients with stage 1 and stage 2 type 1 diabetes
- Will also see patients or families that want to be screened for type 1 Diabetes

- **Education and Monitoring for patients with 1 positive Aab, Stage 1 and Stage 2**
  - HbA1c, glucose (home monitoring)
  - CGM
  - OGTT
  - Antibody testing

- **Offer Teplizumab (Tzield) Treatment**
  - 14 day infusion
  - Where? Infusion Center at main campus (Burnet)
  - Ages 1 and older (yes, we will infuse adults)

- Opportunity to take part in other clinical trials

# Summary

- T1D is a lifelong autoimmune condition affecting children, adolescents and adults of all genders and races
- T1D is characterized as 3 stages of progressive T-cell mediated destruction of the pancreatic beta cells leading to hyperglycemia
- The presence of 2 or more antibodies constitutes the diagnosis of pre-symptomatic T1D and most with 2 or more antibodies will develop T1D in their lifetime
- Screening and early detection of T1D minimizes the risk of DKA, provides time and knowledge and opportunities to delay progression
- Primary care providers play a key role to incorporate antibody screening for those at risk

# Next Steps

Screening and Referral Program

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- Wave 1 Ohio AAP's T1D Quality Improvement (QI) program with pediatric primary care providers in Ohio is happening now
- Wave 2 Ohio AAP's T1D QI program will expand to include out-of-state providers and will launch in early 2027

- For more information
  - Brooke Powell, Program Manager
  - bpowell@ohioaap.org

@aapohio

# Thank you for listening…

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Screening and Referral Program