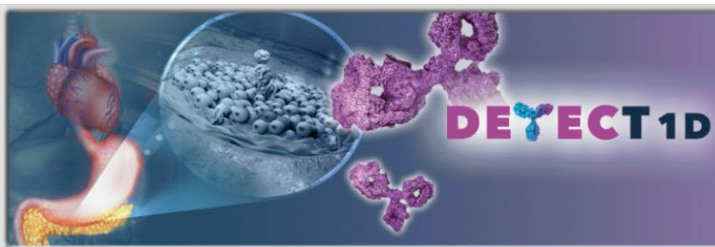


DETECT1D

From Awareness to Action:
Driving Multidisciplinary Application of
Screening and Disease Modifying Therapies in
EARLY STAGE T1D



This activity is provided by Med Learning Group.
This activity is supported by an educational grant from Sanofi US.



From Awareness to Action:
Driving Multidisciplinary Application of
Screening and Disease Modifying Therapies in
EARLY STAGE T1D

Introduction and Housekeeping

Type 1 Diabetes: Overview

Screening and Early Detection of T1D

Caregiver Perspective & Panel discussion: Screening for T1D

Informal discussion with faculty and Jeselyn, sample questions/conversation starters:

- *How did you find out about T1D screening?*
- *What was yours and your family's experience with screening?*
- *Did you or your family have any concerns about T1D screening? (also bring up the positive piece/experience of screening)*

How and Whom to Screen for T1D

Case #1 & Group Breakout Discussion

Follow-up & monitoring after T1D screening

Caregiver Perspective & Panel discussion: Follow-up After Screening Results –

Informal discussion with faculty and Jeselyn, sample questions/conversation starters:

- *What were the results of T1D screening?*
- *What questions did you or your family have about the results? Were the steps after screening explained adequately?*
- *How was the monitoring after screening handled?*

Advances in Delaying T1D Progression

BREAK

Caregiver Perspective & Panel discussion: Teplizumab for T1D

Informal discussion with faculty and Jeselyn, sample questions/conversation starters

- *If things were to change, would you consider (be open) to a disease-modifying therapy that can delay progression? (to get Jeselyn's thoughts on this)*

On the Horizon: DMTs in New Onset (Stage 3) T1D

Case #2 & Group Breakout Discussion

Implications & Practice Takeaways

Audience Q & A and Concluding Remarks

DETECT - From Awareness to Action: Driving Multidisciplinary Application of Screening and Disease Modifying Therapies in Early Stage T1D

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PROGRAM OVERVIEW

The DETECT T1D Live Summit series has been designed to bring together multidisciplinary faculty and a type 1 diabetes (T1D) patient advocate to discuss practical considerations in screening, follow-up, early referral, and treatment to delay T1D progression, as well as how to address both clinician and patient challenges to optimize early identification and patient selection. In addition, the program will feature small group breakout discussions to analyze relevant cases and offer an opportunity to access a learning gallery featuring additional educational aids and resources to reinforce engagement and boost understanding of evolving concepts in early-stage T1D.

TARGET AUDIENCE

This activity is designed to meet the educational needs of multidisciplinary clinicians who refer, treat or see patients with or at high risk for T1D is needed, including primary care clinicians, pediatricians, pediatric & adult endocrinologists, diabetes educators, infusion professionals and other allied healthcare professionals.

LEARNING OBJECTIVES

Upon completion of this activity, attendees will have improved ability to:

1. Identify criteria for T1D screening, focusing on high-risk patients to facilitate timely referral and monitoring
2. Incorporate evidence-based strategies for presymptomatic T1D screening into routine clinical practice to improve early detection
3. Develop workflows to appropriately monitor, follow-up, or refer individuals who are screened for T1D.
4. Interpret T1D screening results and effectively communicate next steps to support patient education and inform treatment decisions.
5. Develop strategies for establishing referral pathways and enhancing collaboration with specialists in order to enable earlier application of disease-modifying therapies for early stage T1D.
6. Identify appropriate patients who would benefit from treatment with disease-modifying therapies for delaying T1D progression based on clinical evidence
7. Implement protocols to support safe and efficient administration of disease-modifying therapies for T1D according to guidance and patient-specific factors.

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Faculty Member	Disclosures
Jay Shubrook, DO	Consulting fee: Abbott, Bayer, Eli Lilly, Insulet, Mardigal, Novo Nordisk and Sanofi Fees for Non-CME/CE Services: Corcept Contracted Research: Breakthrough T1D
Emily Sims, MD	Consulting fee: Diamond, Sanofi, Wink Therapeutics
David Baidal, MD	Contracted research: Sanofi, PI for clinical trial "FABULINUS"
Chuck Vega, MD FAAFP	Consulting fee: Boehringer Ingelheim and Exact Sciences
Jeselyn Luis Sauleda, LMHC	Has nothing to disclose

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DETECT – From Awareness to Action: Driving Multidisciplinary Application of Screening and Disease-Modifying Therapies in Early Stage T1D



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Disclosures

- **Dr Baidal** discloses that he has provided contracted research for Sanofi, PI for clinical trial "FABULINUS"
- **Dr Vega** discloses that he has received consulting fees from Boehringer Ingelheim and Exact Sciences
- **Jeselyn Luis** has nothing to disclose

During this lecture the faculty may mention the use of medications for both US Food and Drug Administration (FDA)-approved and non-FDA-approved indications.

All relevant financial relationships have been mitigated.

This activity is supported by an independent educational grant from Sanofi US.

Learning Objectives

- Identify criteria for type 1 diabetes (T1D) screening, focusing on high-risk patients to facilitate timely referral and monitoring
- Incorporate evidence-based strategies for presymptomatic T1D screening into routine clinical practice to improve early detection
- Develop workflows to appropriately monitor, follow-up, or refer individuals who are screened for T1D
- Interpret T1D screening results and effectively communicate next steps to support patient education and inform treatment decisions.
- Develop strategies for establishing referral pathways and enhancing collaboration with specialists in order to enable earlier application of disease-modifying therapies for early stage T1D
- Identify appropriate patients who would benefit from treatment with disease-modifying therapies for delaying T1D progression based on clinical evidence
- Implement protocols to support safe and efficient administration of disease-modifying therapies for T1D according to guidance and patient-specific factors

Polling Question

In your current practice, do you screen for T1D with islet autoantibodies in persons without symptoms and before they develop hyperglycemia?

a) Yes

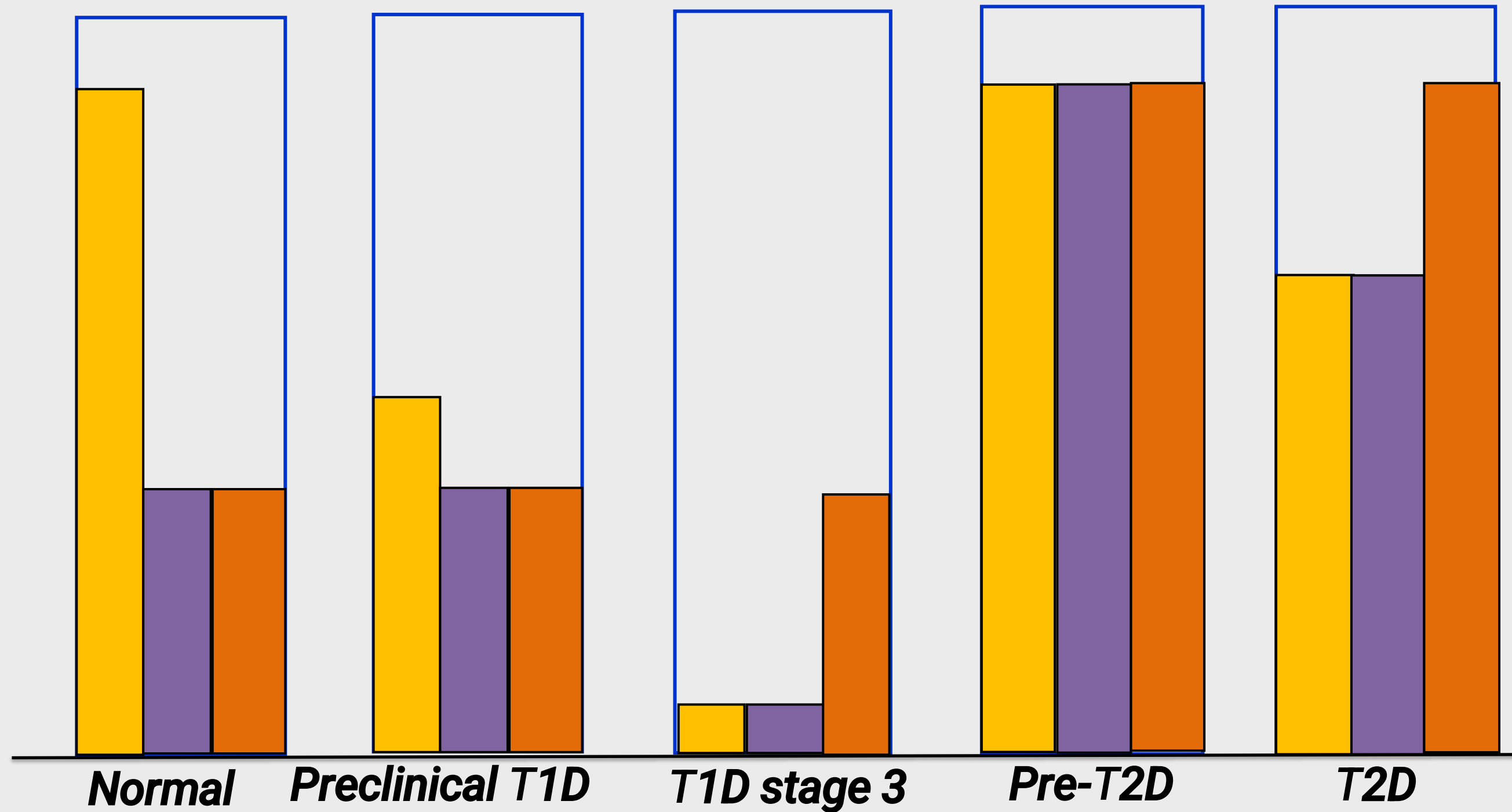
b) No

Type 1 Diabetes: Overview



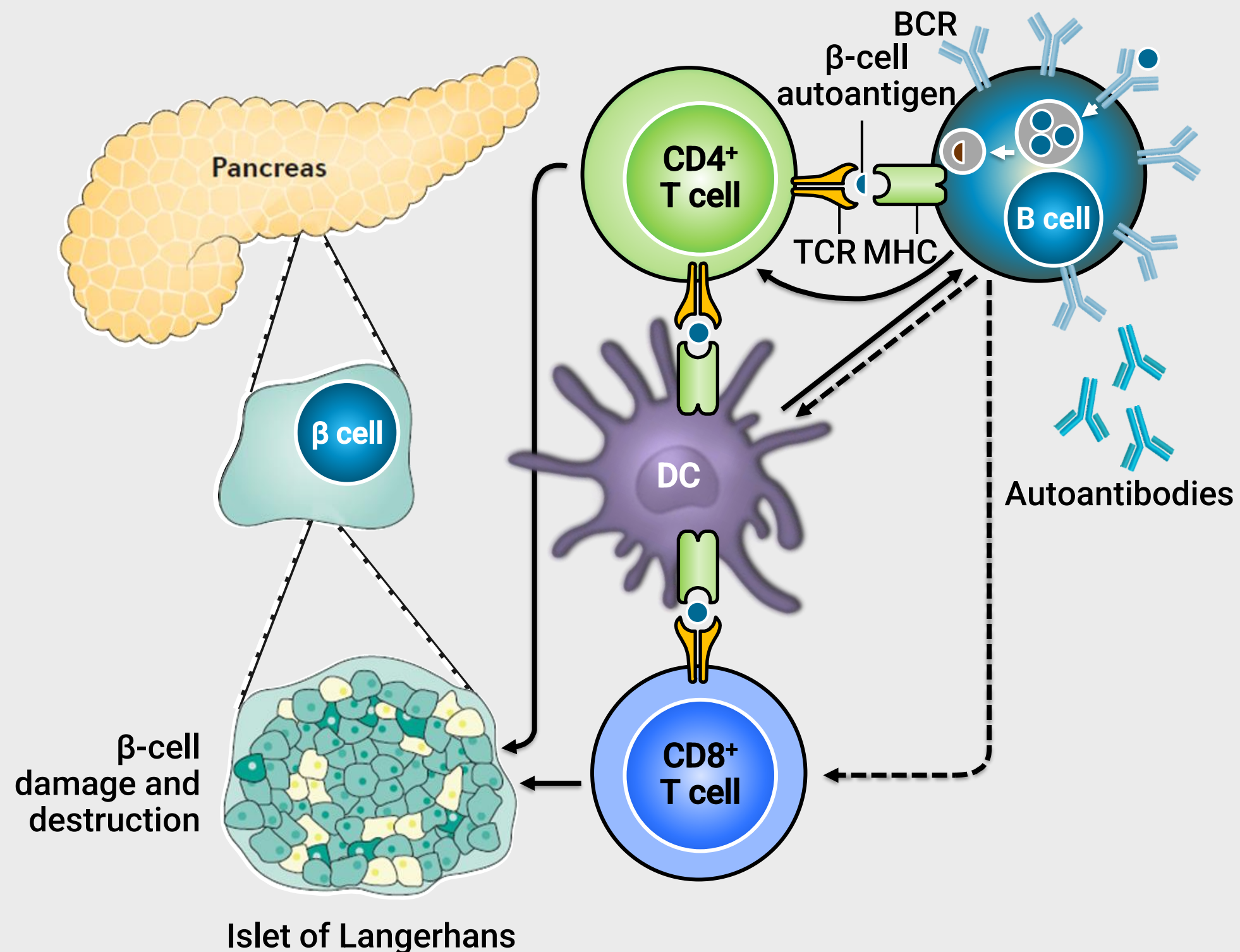
What Is Diabetes?

A Mismatch of Insulin Supply and Demand



Insulin production capacity vs secretion vs requirement

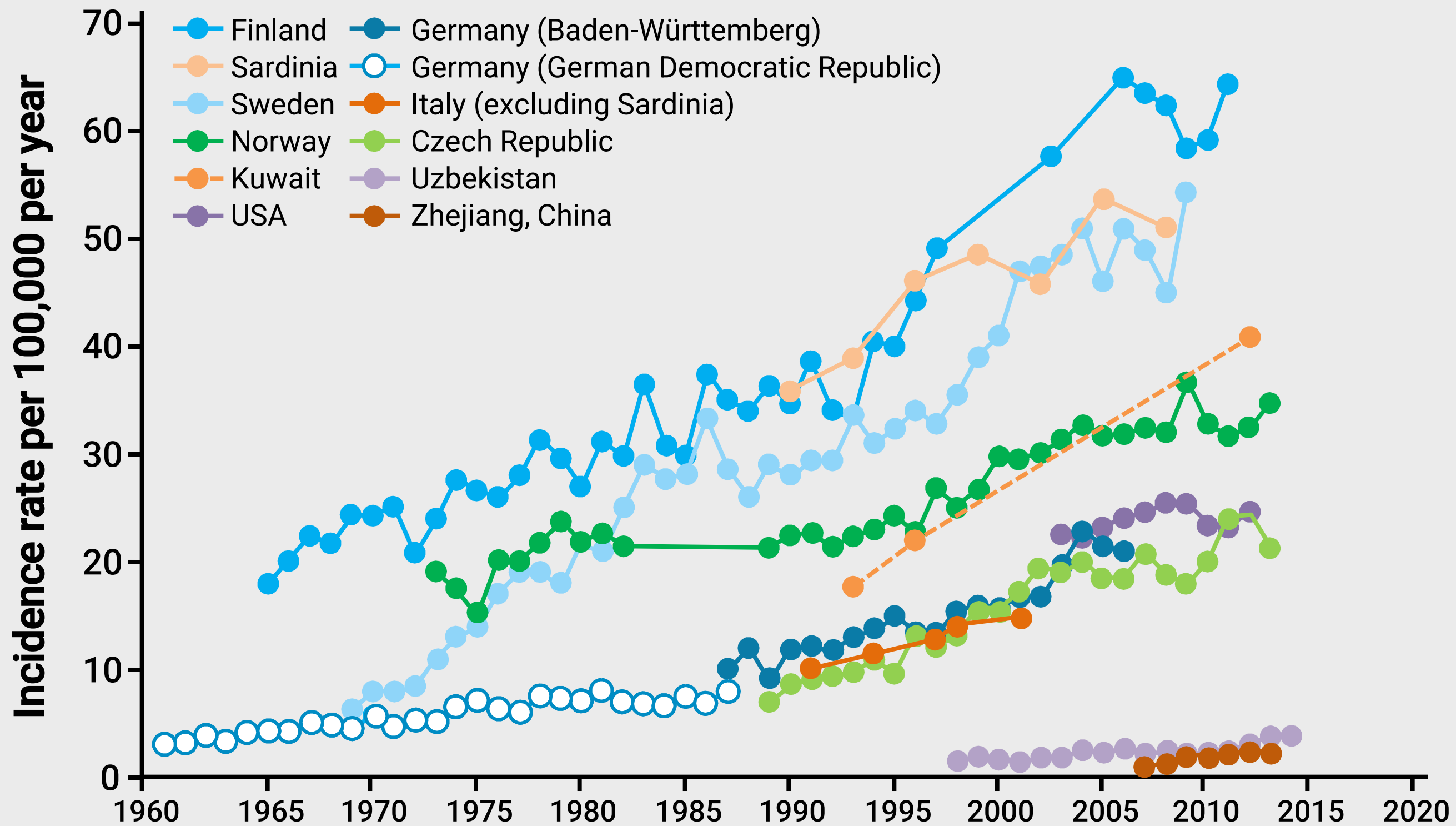
T1D Is a Chronic Autoimmune Disease



- APCs present β -cell antigens to T cells; normal T cells recognize these as “self” and ignore them (tolerance)
- T cells that have lost tolerance attack β cells
- Multiple genetic and environmental factors contribute to the loss of tolerance to β -cell antigens
- IAbs are released into the bloodstream by B cells; ***measuring these autoantibodies is used to detect autoimmunity***

APC = antigen-presenting cell; BCR = B-cell receptor; DC = dendritic cell; IAb = islet autoantibody; MHC = major histocompatibility complex; TCR = T-cell receptor.

The Incidence of T1D Is Dramatically Increasing Worldwide for Unknown Reasons

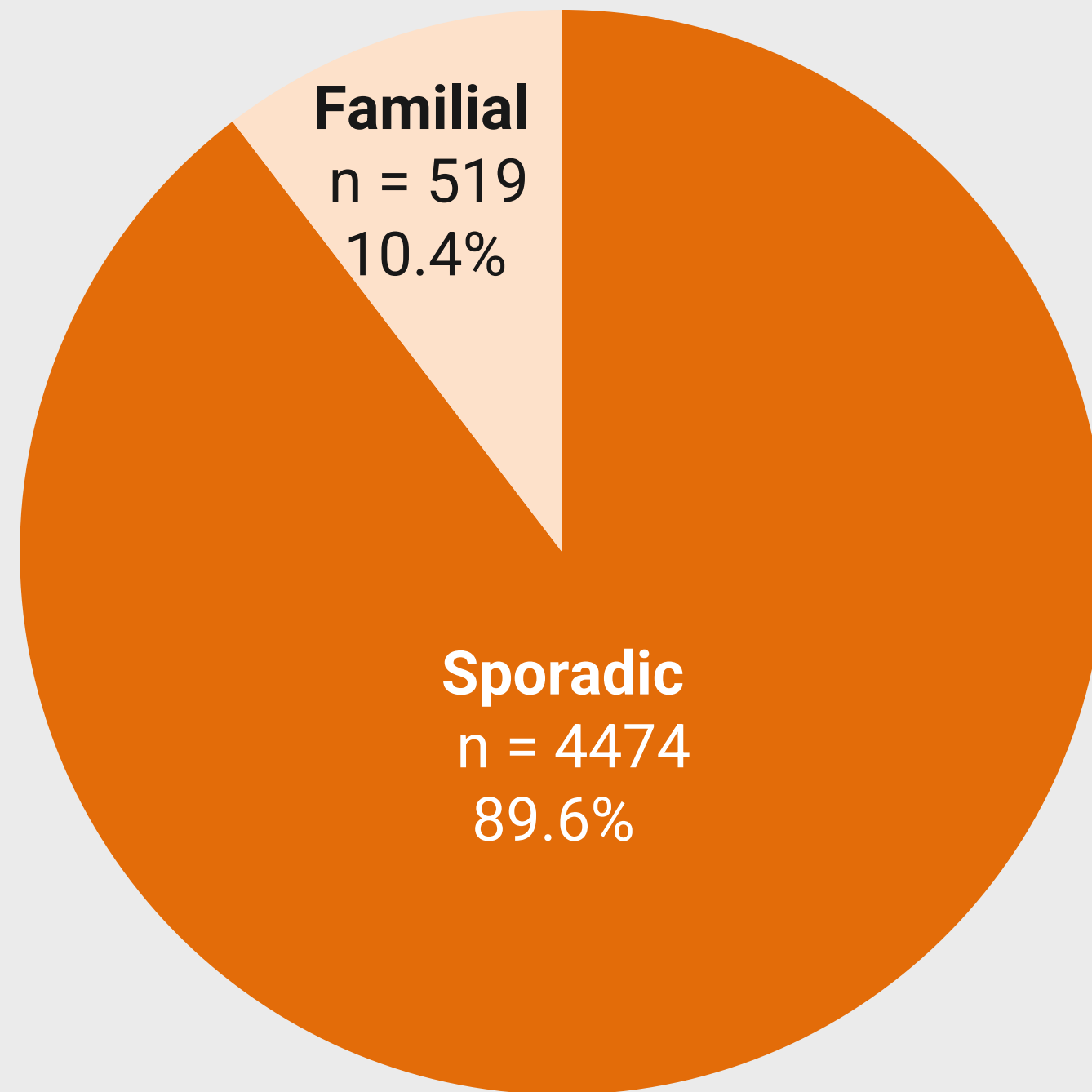


Genetic Susceptibility Is Important, But Not All of Those Who Are Susceptible Develop T1D

T1D risk in individuals who have an affected relative

	Risk of T1D	
General population	0.4%	1/250
Father with T1D	4%–7%	1/25–1/14
Mother with T1D	1.5%–3%	1/67–1/33
Sibling with T1D	6%–7%	1/17–1/14
Identical twin with T1D	30%–70%	1/3–1/1.4

Yet, Most New Cases Do Not Occur in Families With a First-Degree T1D Relative



- Risk of T1D is highest in family members of people with T1D (10x to 15x higher)
- Yet family history alone is insufficient as >85% of patients diagnosed with T1D do not have a family history of T1D
- General population screening is needed to identify the majority of people who are at risk of T1D development

Who Gets T1D? It Is Thought of as a Pediatric Disease, But It Is Actually Diagnosed More Frequently in Adulthood

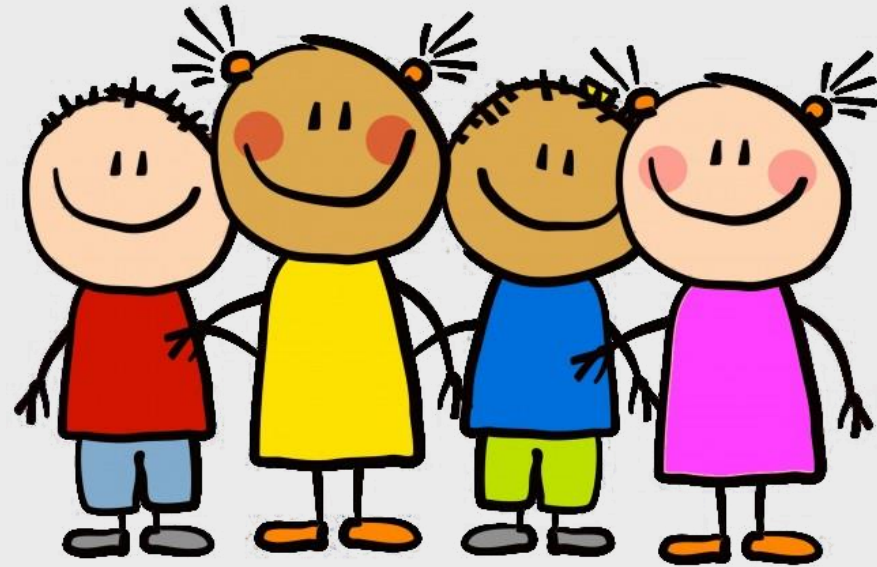
- The median age at T1D diagnosis is ~35 years (**global population estimates, with considerable variation*)
- There is considerable information about the development of diabetes in children; much less is known in adults
- In adults T1D is often misdiagnosed as T2D
- In children the reverse is sometimes true, with other forms of diabetes misdiagnosed as T1D
- No single clinical feature confirms T1D—not age, not body mass index, not DKA
- Misdiagnosis can lead to DKA due to prescribing the wrong therapy



DKA = diabetes-related ketoacidosis.

Thomas NJ, et al. *Diabetes Care*. 2023;46:1156-1163. Gregory GA, et al. *Lancet Diabetes Endocrinol*. 2022;10:741-760.

Clinical Presentation of T1D Differs Between Children and Adults

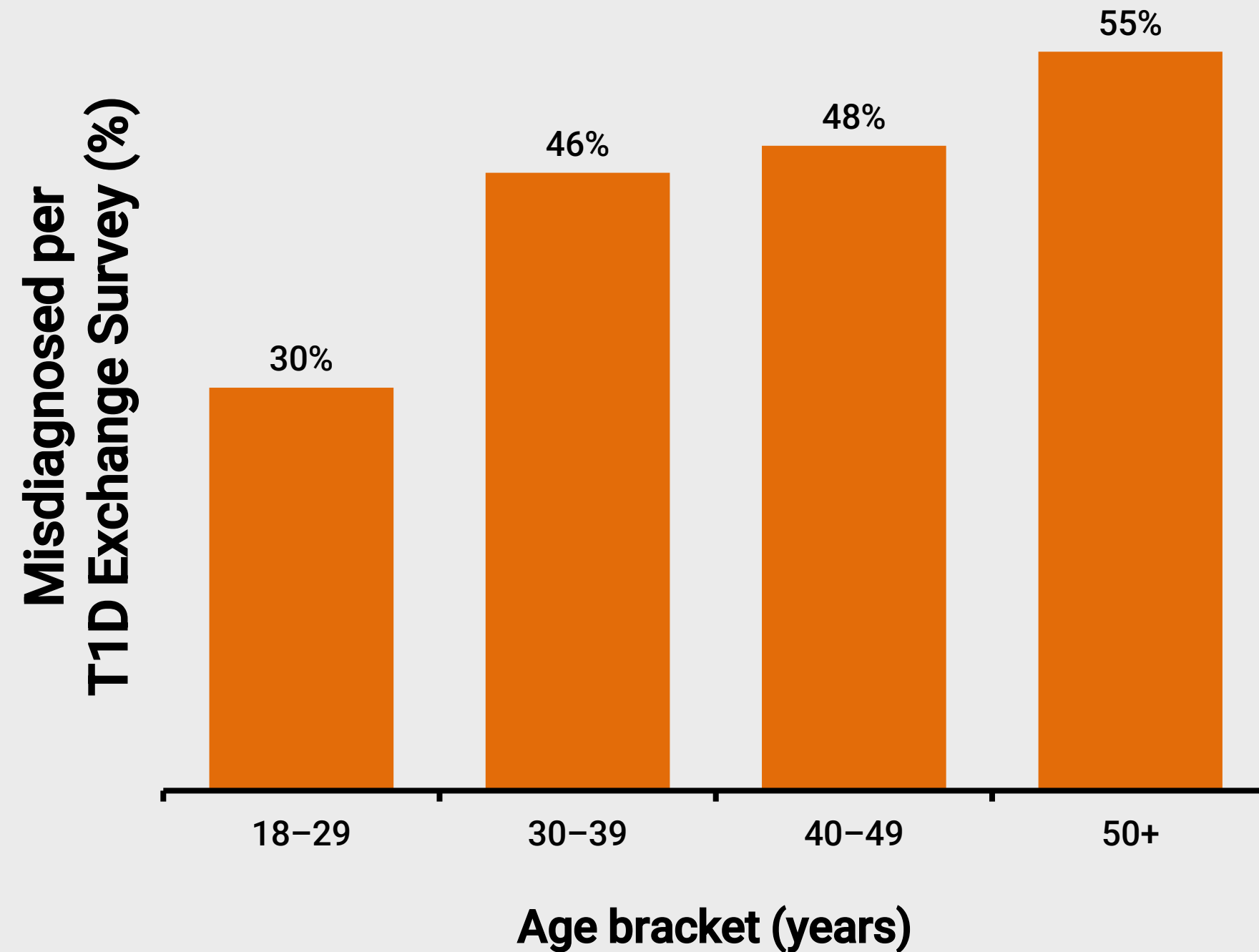


- Acute presentation typical
- Classic symptoms of polyuria, polydipsia
- Usually significant weight loss
- 30% to 50% present in DKA



- The autoimmune process is slower
- Presentation variable
- Eventually presents with polyuria, polydipsia, and weight loss
- Lower rates of DKA at presentation

Misdiagnosis in Adults Is Common and Often Mistaken for T2D



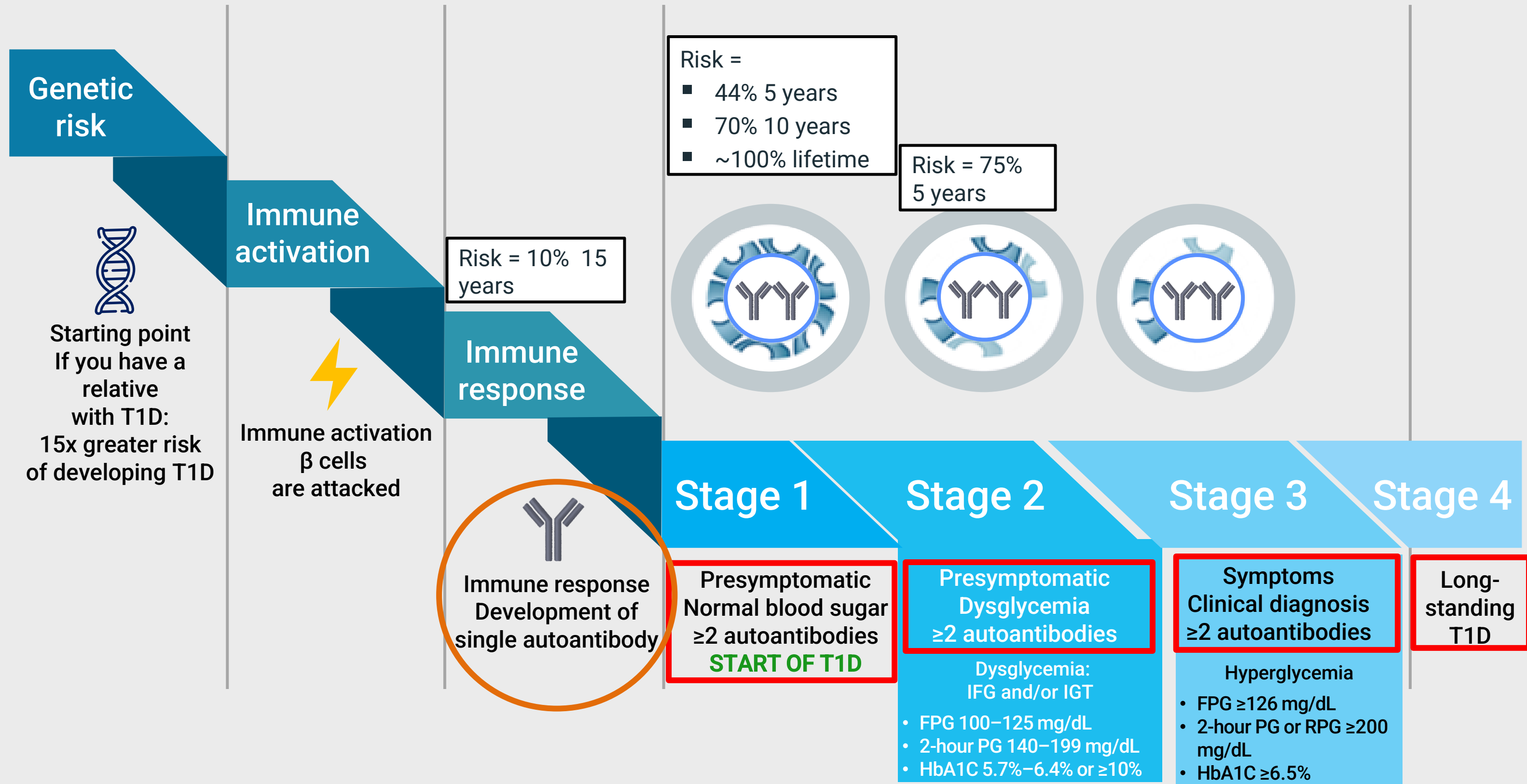
Misdiagnosed conditions

	Adult diagnosis (n = 856)	Pediatric diagnosis (n = 1670)
T2D*	76.8%	4.1%
Other	18.4%	38.2%
Flu/viral infection*	8.6%	53.7%
Urinary tract infection†	6.3%	7.7%
Dehydration	3.5%	10.6%
Strep/bacterial infection†	2.5%	19.1%
Psychiatric condition	2.9%	5.3%
Mononucleosis	0.3%	4.5%

* $P < .001$; † $P < .05$. Boldface type indicates statistical significance.

>40% of those developing T1D after age 30 years are initially treated as T2D.

T1D Develops in Predictable Stages Related to Risk



FPG = fasting plasma glucose; HbA1C = glycosylated hemoglobin; IFG = impaired fasting glucose; IGT = impaired glucose tolerance; PG = plasma glucose; RPG = random plasma glucose.

American Diabetes Association (ADA) Professional Practice Committee. *Diabetes Care*. 2025;48(suppl 1):S27-S49. Haller MJ, et al. *Horm Res Paediatr*. 2024;1-17. Insel RA, et al. *Diabetes Care*. 2015;38: 1964-1974. Sims EK, et al. *Diabetes*. 2022;71:610-623. Phillip M, et al. *Diabetologia*. 2024;67:1731-1759.

Screening and Early Detection of T1D



Polling Question

What are your biggest barriers in screening for early stage T1D?

Select all that apply.

- a) Lack of knowledge/evidence about screening
- b) Lack of knowledge on when to screen
- c) Lack of knowledge on how to screen
- d) Uncertainty about how to identify whom to screen
- e) Difficulty with interpreting screening results and next steps
- f) Addressing patient/caregiver anxiety about screening in the absence of symptoms

Terminology

- **IAbs** = Islet autoantibodies

Insulin (IAA)	Glutamic acid decarboxylase (GAD65)	Islet antigen-2 (IA-2)	Zinc transporter 8 (ZnT8)	Islet cell antibodies (ICA)*
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*Has largely been replaced by the 4 more specific biochemical autoantibodies.

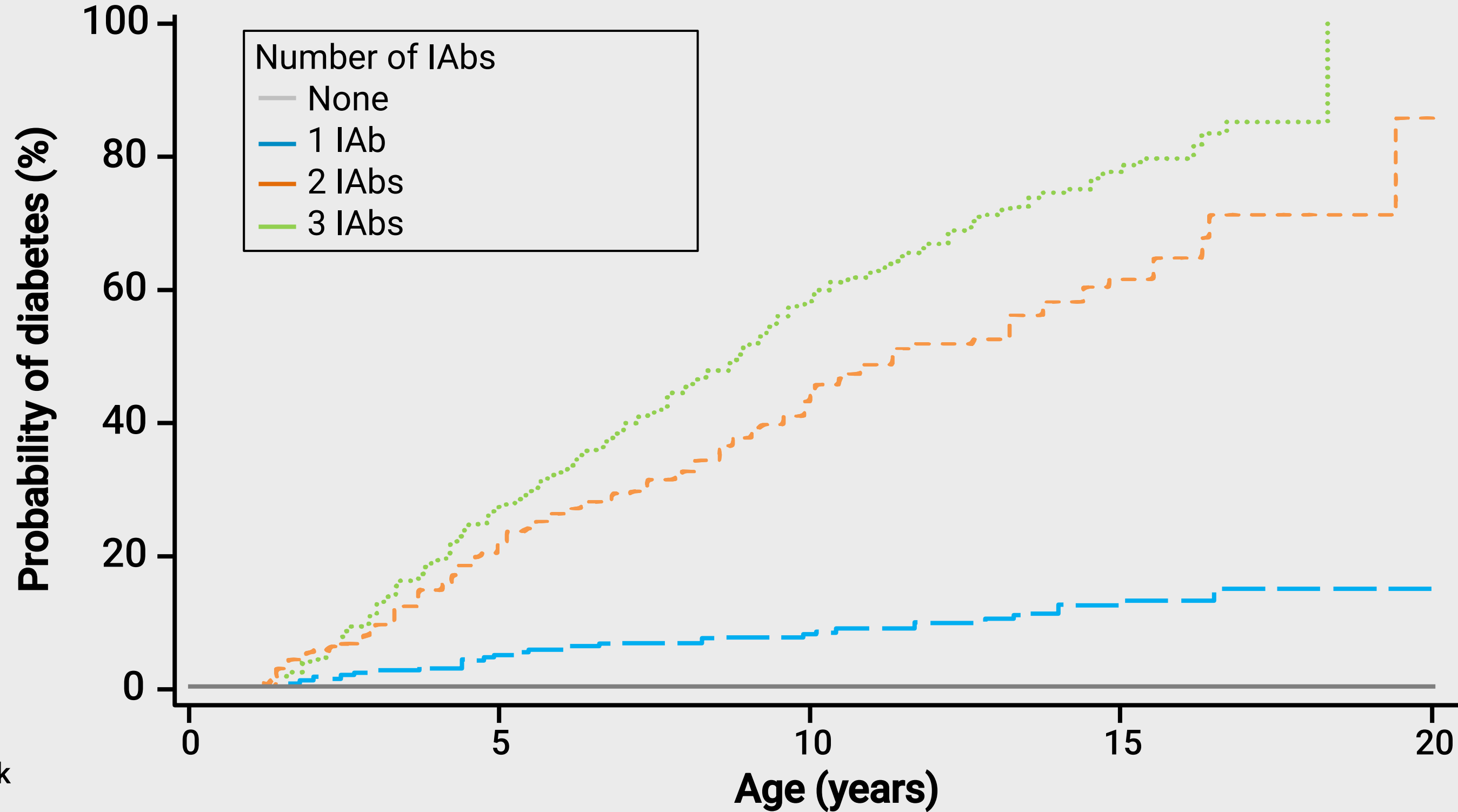
- **Screening** = Testing for IAbs

- **Monitoring** = Following individuals who are IAb+ for progression

- **Prevention**

- Primary prevention: Aim to prevent development of positive IAbs (stage 1) in genetically at-risk individuals
- Secondary prevention: Aim to prevent progression to hyperglycemia (stage 3) in individuals with IAb
- **New-onset studies:** Aim to preserve the remaining 15% to 30% of β cells and prolong the time of endogenous insulin production (“the honeymoon”)

We Can Identify Asymptomatic T1D With Autoantibody Screening



Number at risk
IAbs, Number

3 IAbs	358	250	112	20	
2 IAbs	227	168	82	19	1
1 IAb	474	430	272	118	9
None	12318	8875	5253	1161	44

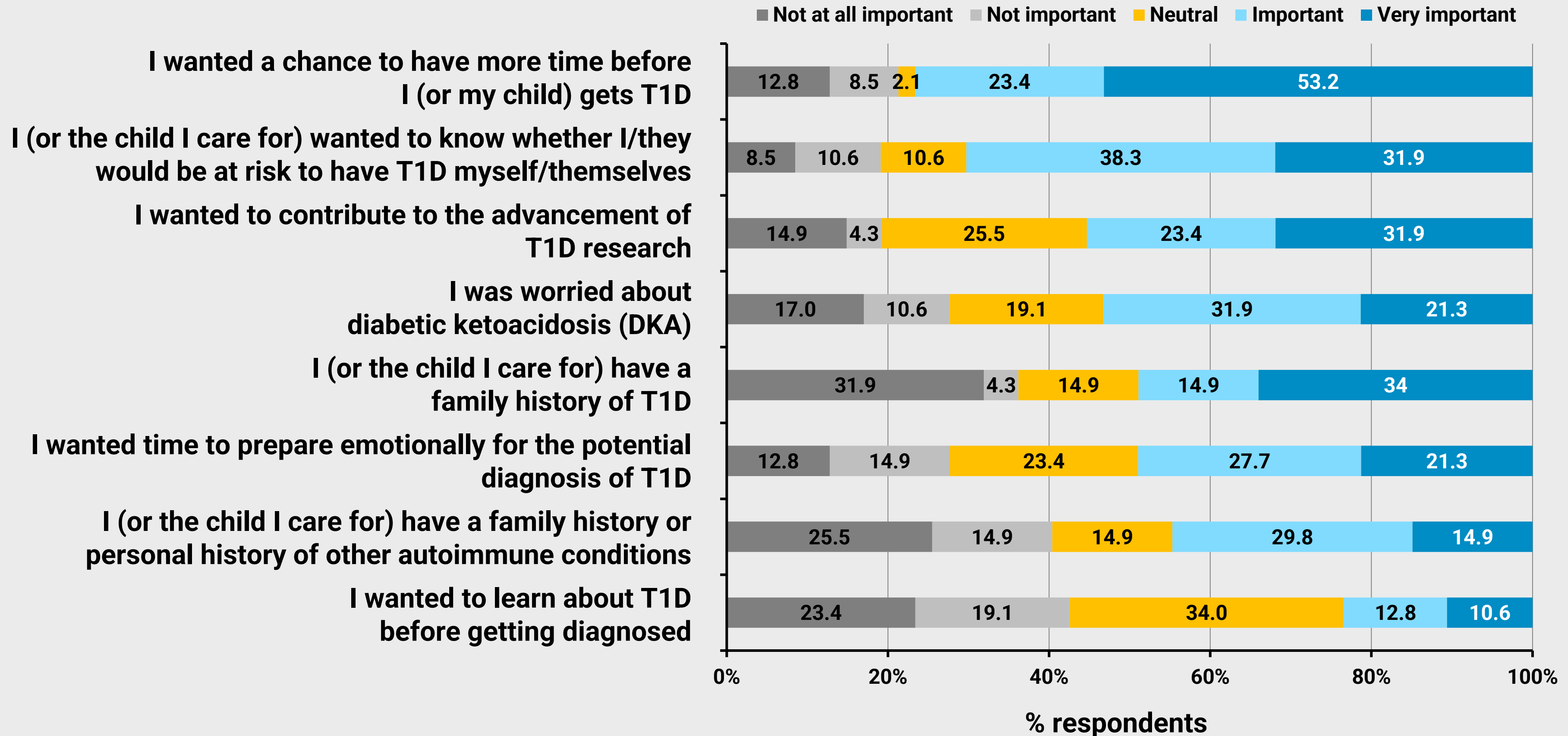
Why Screen? What's in It for Patients?

- Gives patients and family members time to emotionally prepare for a T1D diagnosis
- Less likelihood of DKA or need for hospitalization at diagnosis
- Identifies patients who may benefit from approved therapies or want to enroll in clinical trials to delay disease progression

DKA = diabetes-related ketoacidosis.

Sims EK, et al. *Diabetes*. 2022;71:610-623.

Reasons to Get Screened for T1D: Responses From a Patient Survey

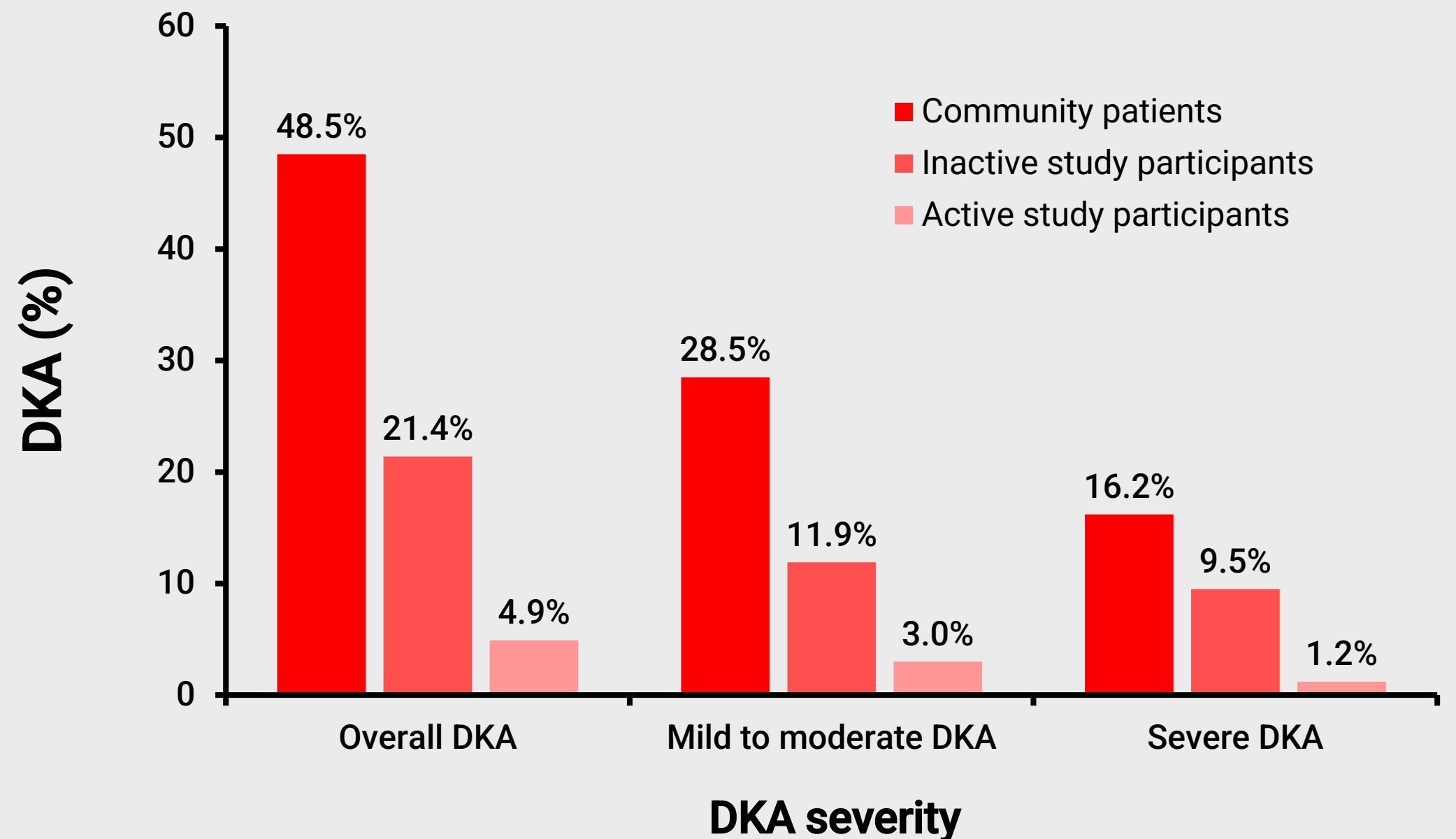


Screening and Routine Follow-Up Reduces the Risk of DKA at Stage 3

- In Colorado youth, individuals diagnosed in the community between 2005 and 2021 presented in DKA 48.5% of the time; DKA decreased to 21.4% in youth screened before diagnosis and to 4.9% in those participants who actively engaged in research monitoring and follow-up visits

Similar DKA reductions were seen in other T1D screening and follow-up studies (DAISY, TEDDY, BABYDIAB, DIPP, TRIGR).

DKA percentage by severity



Caregiver Perspective and Panel Discussion: Screening for T1D



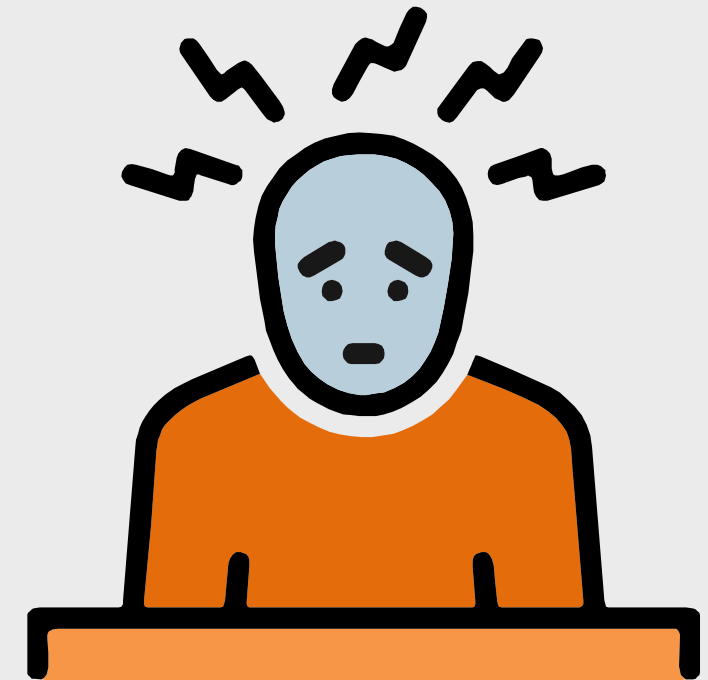
Jeselyn Luis Sauleda, LMHC

T1D Patient Advocate



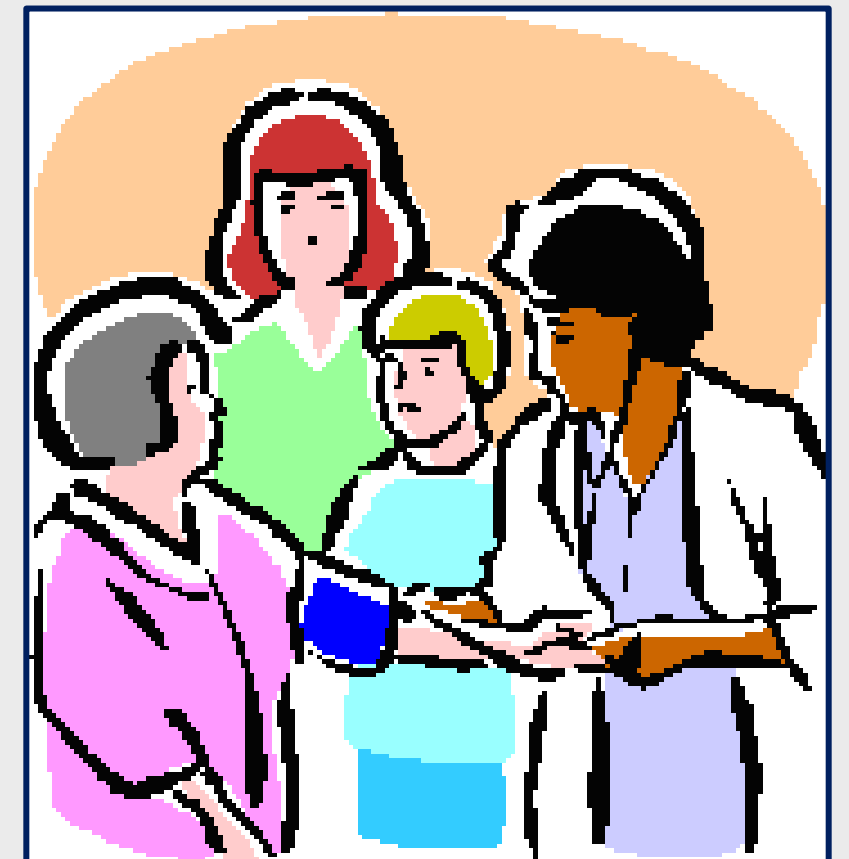
What Are the Concerns About Screening?

- >70% of caregivers of T1D autoantibody-positive children in the general population reported high anxiety about their child's T1D risk
- 45% to 70% of autoantibody positive 10- to 15-year-olds reported high anxiety about developing T1D



How Do We Address Those Concerns?

- Listen and acknowledge concerns
- Be clear in communication of risk and timeline
- Make sure the patient and family are involved in all decisions that are made
- Link them to other people who have had similar experiences
- Bring behavioral health in as part of your team when necessary



How and Whom to Screen for T1D

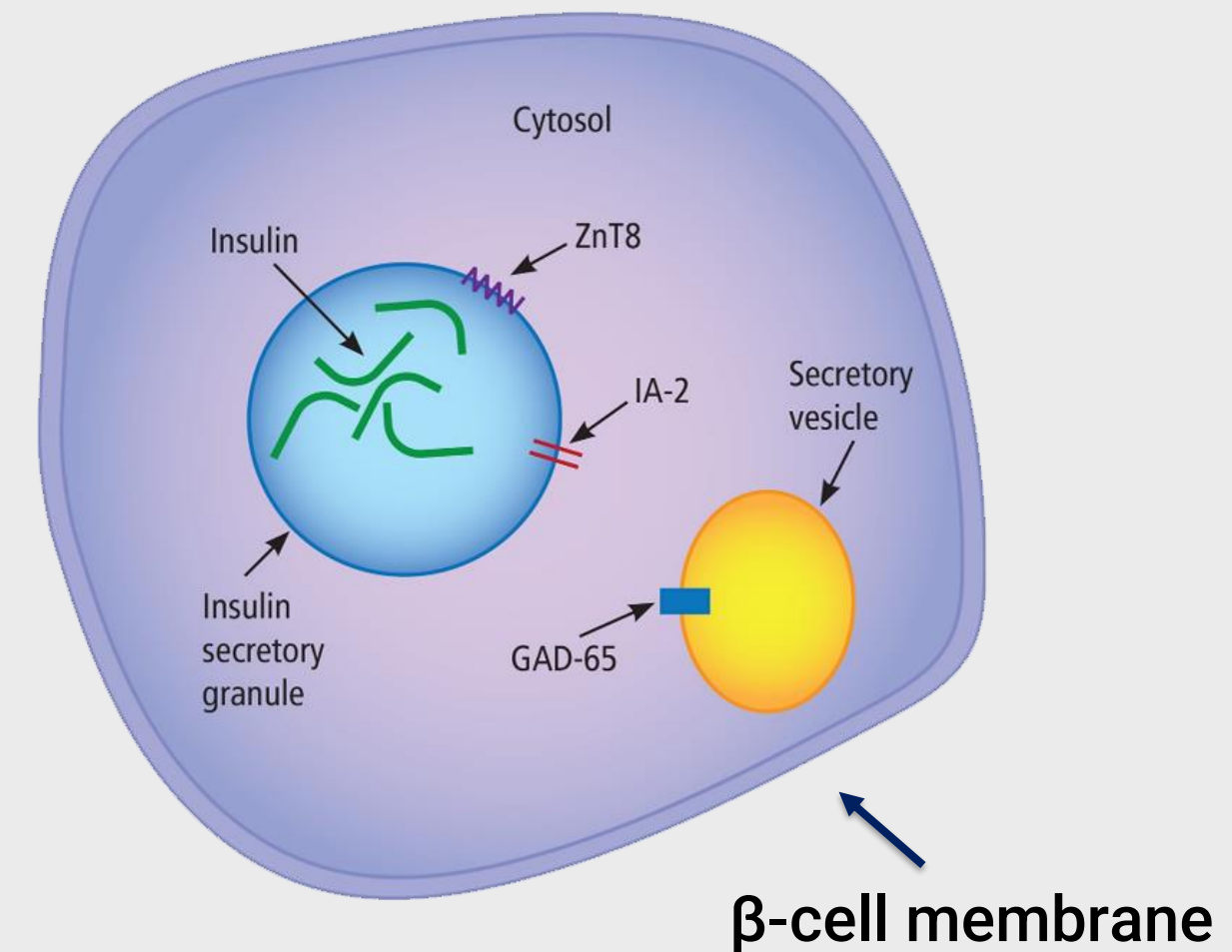


How Do We Screen for T1D?



IAb screening is the cornerstone; testing for all 4 recommended IAbs increases the chance of detecting T1D

- IAA
- GAD65
- IA-2
- ZnT8



- Some studies first screen populations for high-risk *HLA* genes, then test autoantibodies
- Some studies use *HLA* plus other genes to calculate a genetic risk score, then test autoantibodies

IAb Testing: In Whom?

To *screen* for T1D in

- Relatives of a person with T1D
- Person with history of other autoimmune disease(s)
- Relatives of a person with other autoimmune disease(s)
- Elevated genetic risk score (if tested)
- Population screening in organized programs

To *clarify diagnosis* of T1D

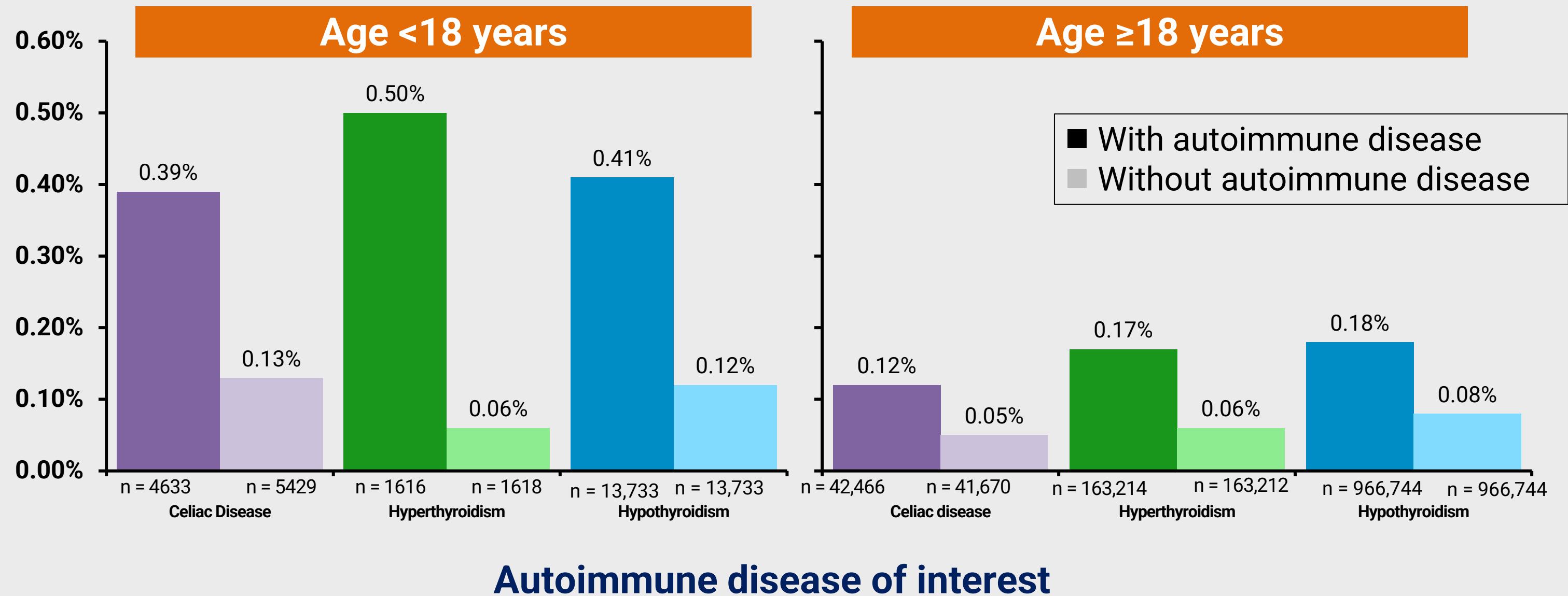
- History of hyperglycemia (misdiagnosis is possible)
 - Illness, stress, or steroid-induced hyperglycemia
 - Gestational diabetes
- Persons with new-onset diabetes to evaluate for T1D vs other forms of diabetes

In all IAb+ patients, a full venous IAb panel should be done within 3 months of the first test to confirm.

Education, especially for a patient with abnormal or high glucose levels, should not be delayed while waiting for confirmation.

Risk of Developing T1D in Individuals with Other Autoimmune Conditions

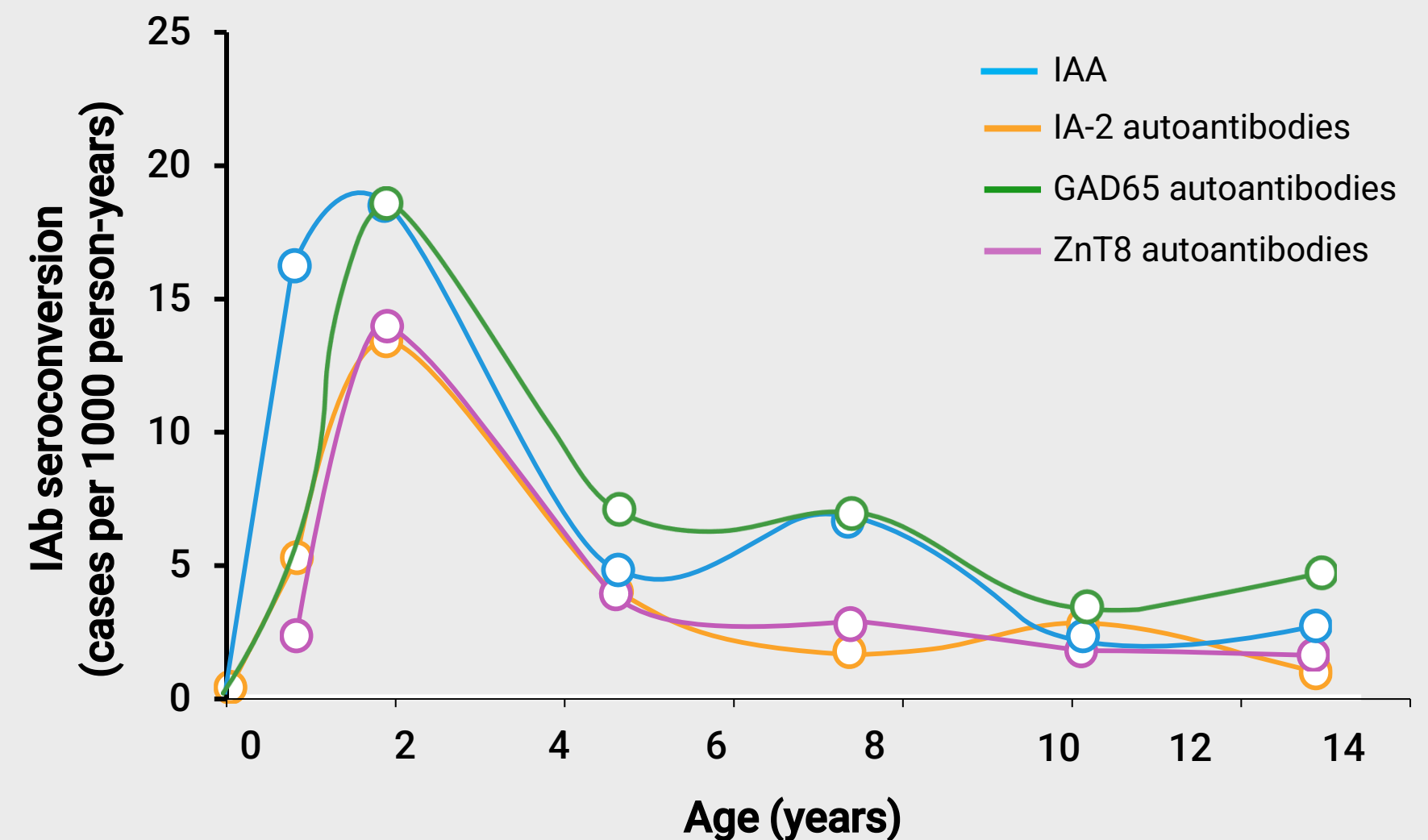
Percentage that developed T1D



Screening for Islet Autoimmunity Should Occur at Multiple Times During Childhood

- In genetically at-risk individuals, T1D autoantibody seroconversion peaks **between 9 months and 2 years of age**
- Insulin autoantibodies may develop **earlier than GAD65, IA-2, or ZnT8 autoantibodies**
- **Screening at ages 2 and 6 years** may optimize sensitivity and positive predictive value for predicting T1D during childhood, while an additional testing at age 10 years may aid in predicting T1D during adolescence

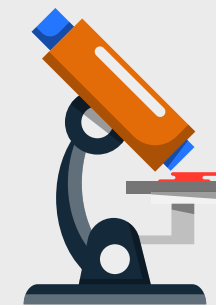
Incidence of specific T1D autoantibodies by age



Major T1D Screening Programs in the United States

Research-based screening programs (no HCP order required)

Name and available locations	Age to participate
ASK (United States)	Children and adults aged 1–99 years (no family history of T1D required)
TrialNet (United States)	<p>Aged 2–45 years with a parent, brother/sister, or child with T1D; or have tested positive for ≥ 1 T1D autoantibody outside of TrialNet</p> <p><i>OR</i></p> <p>Aged 2–20 years with aunt/uncle, cousin, grandparent, niece/nephew, or half-sibling with T1D</p>



Clinical laboratory

Quest Diagnostics, LabCorp, and Mayo Clinic Laboratories

All ages, HCP order required. CPT codes*

- 86341 (GAD65, IA-2, ZnT8 antibodies)
- 86337 (insulin antibody)

Not a comprehensive list of available screening programs; may be subject to change.

*CPT codes may be subject to change, and specific codes may differ between laboratories. Not all antibodies may be available under a specific laboratory or under a CPT code.

CPT = Current Procedural Terminology; HCP = healthcare provider.

ASK (<https://www.askhealth.org>). TrialNet. Pathway to prevention (<https://www.trialnet.org/our-research/risk-screening>). Breakthrough T1D (formerly JDRF) (<https://www.breakthrough1d.org/early-detection/>). Ask the Experts (<https://www.asktheexperts.org/for-providers>). URLs accessed 7/16/2025.

Case #1 and Group Breakout Discussion



Case #1: Challee (introduction)

- Challee is a 10-year-old girl who presents to the office for an ED follow-up
- She was playing soccer and developed an ankle sprain and went to the ED
- In the ED they checked her glucose, and it was 212 mg/dL
- Ankle pain is improving with ankle support
- No systemic signs or symptoms; no symptoms from hyperglycemia
- Past medical history: None, normal developmental milestones
- Family history: Dad has celiac disease
- Medications/allergies: None
- Physical examination normal



**Now we will
break out for
case discussion.**



The selected delegate person at each table should answer the question discussed by your group.

Group Breakout Discussion

Please select 1 delegate person for your table to answer the questions below.

Patient case: Challee

1. What do you recommend to follow-up on the glucose value from the ED?
2. Does she have any risk factors for T1D, and if so, how would you screen for T1D?
3. How would you confirm T1D diagnosis, and what would be your next steps?



Follow-Up and Monitoring After T1D Screening

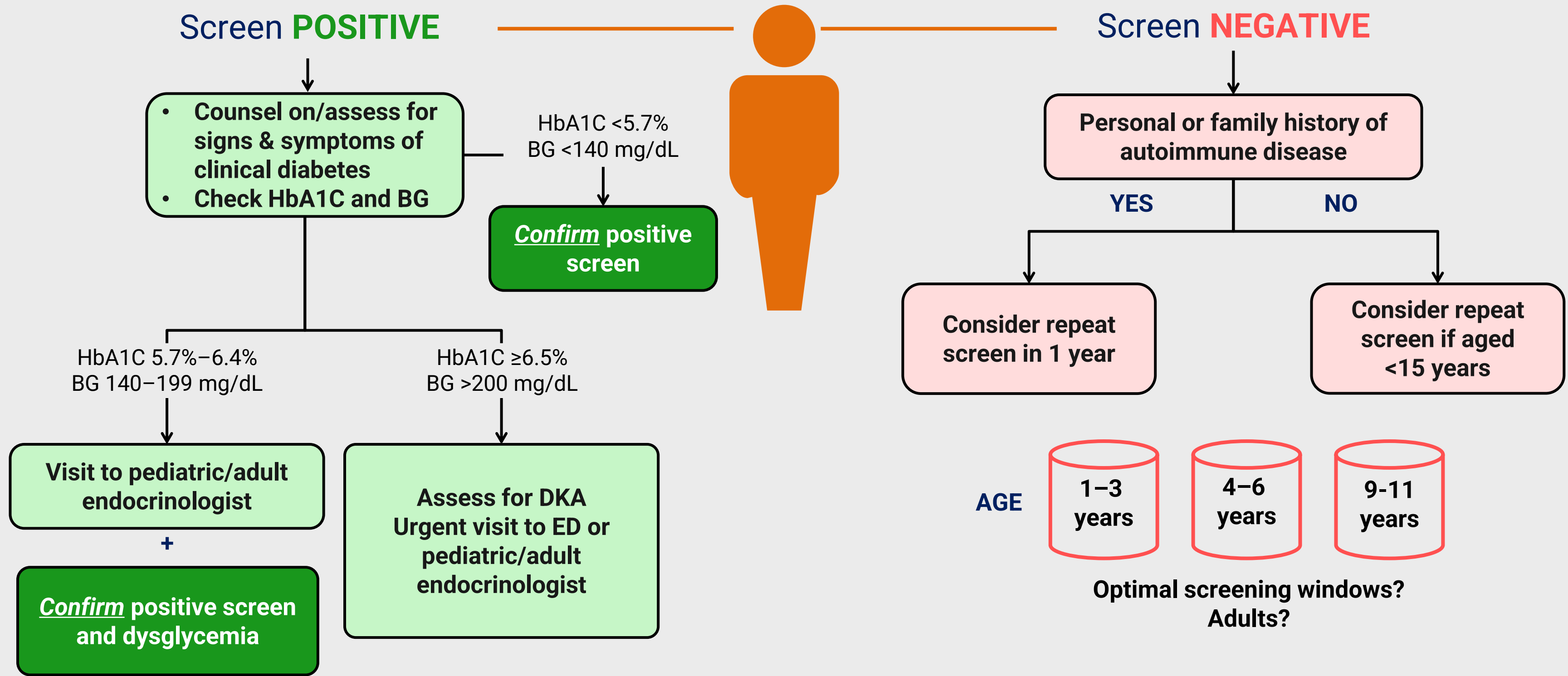


Polling Question

To whom do you usually refer patients for confirmation of T1D staging and specialized management? **Select all that apply.**

- a) Endocrinologist/diabetologist
- b) Pediatric endocrinologist
- c) Immunologist
- d) Diabetes specialty nurse
- e) Diabetes educator
- f) None, I don't know whom to refer to or don't have the resources
- g) Other

If a Patient Has Positive Autoantibodies, Rule Out Clinical T1D



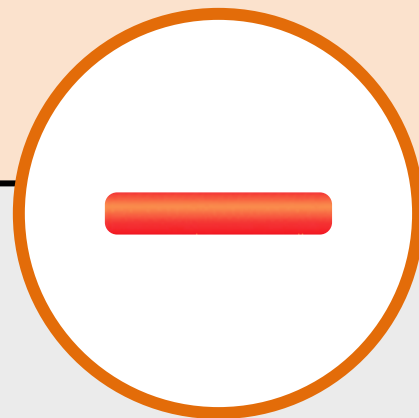
BG = blood glucose.

Modified from Simmons KMW, et al. *Diabetes Technol Ther.* 2023;25:790-799.

How to Interpret T1D Screening Results

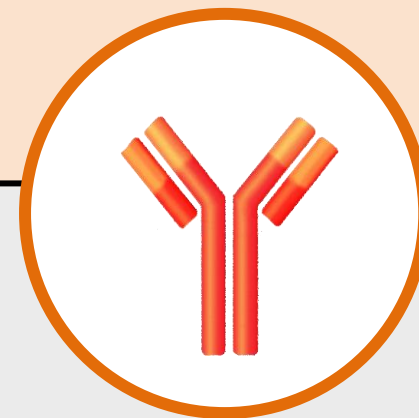
0 autoantibodies

- Lower risk for developing T1D
- Rescreening may be considered in individuals with family history of T1D or in children <15 years of age



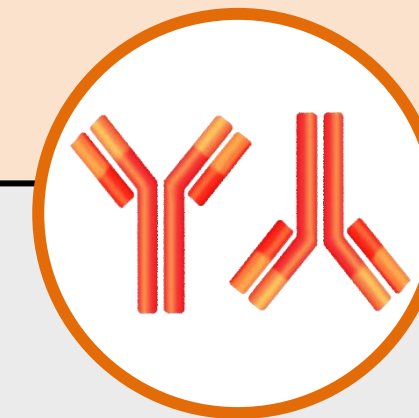
1 autoantibody

- Higher risk for developing T1D than those with no autoantibodies
- Autoantibody status should continue to be monitored, along with BG



≥2 autoantibodies

- Already in early stage T1D
- Metabolic staging and symptom evaluation
- If asymptomatic or no hyperglycemia, patient may be eligible for DMT to delay progression to clinical T1D, or for clinical research prevention trials



DMT = disease-modifying therapy.

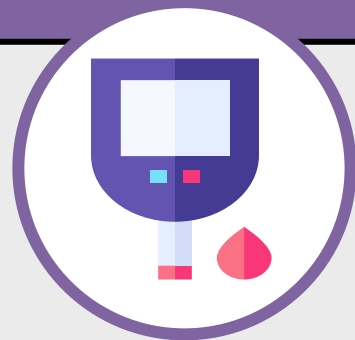
Follow-Up After Screening and Strategies for Monitoring

- OGTT – gold standard to differentiate stage 1, stage 2, and stage 3 T1D

Follow-up with monitoring

- HbA1C, and/or
- SMBG, and/or
- CGM, and/or
- Periodic OGTTs

Monitoring tools



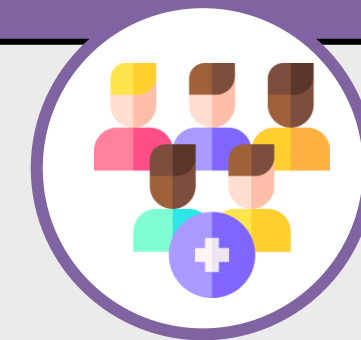
- Educate on need for monitoring, symptoms of DKA
- Provide written instructions, give SMBG meters/strips

Education



- Collaboration is needed between the primary care provider, pediatric and adult endocrinologist, and individuals who are antibody positive
- Consider referring to a behavioral health provider to give patients and caregivers appropriate psychosocial support

Multidisciplinary care

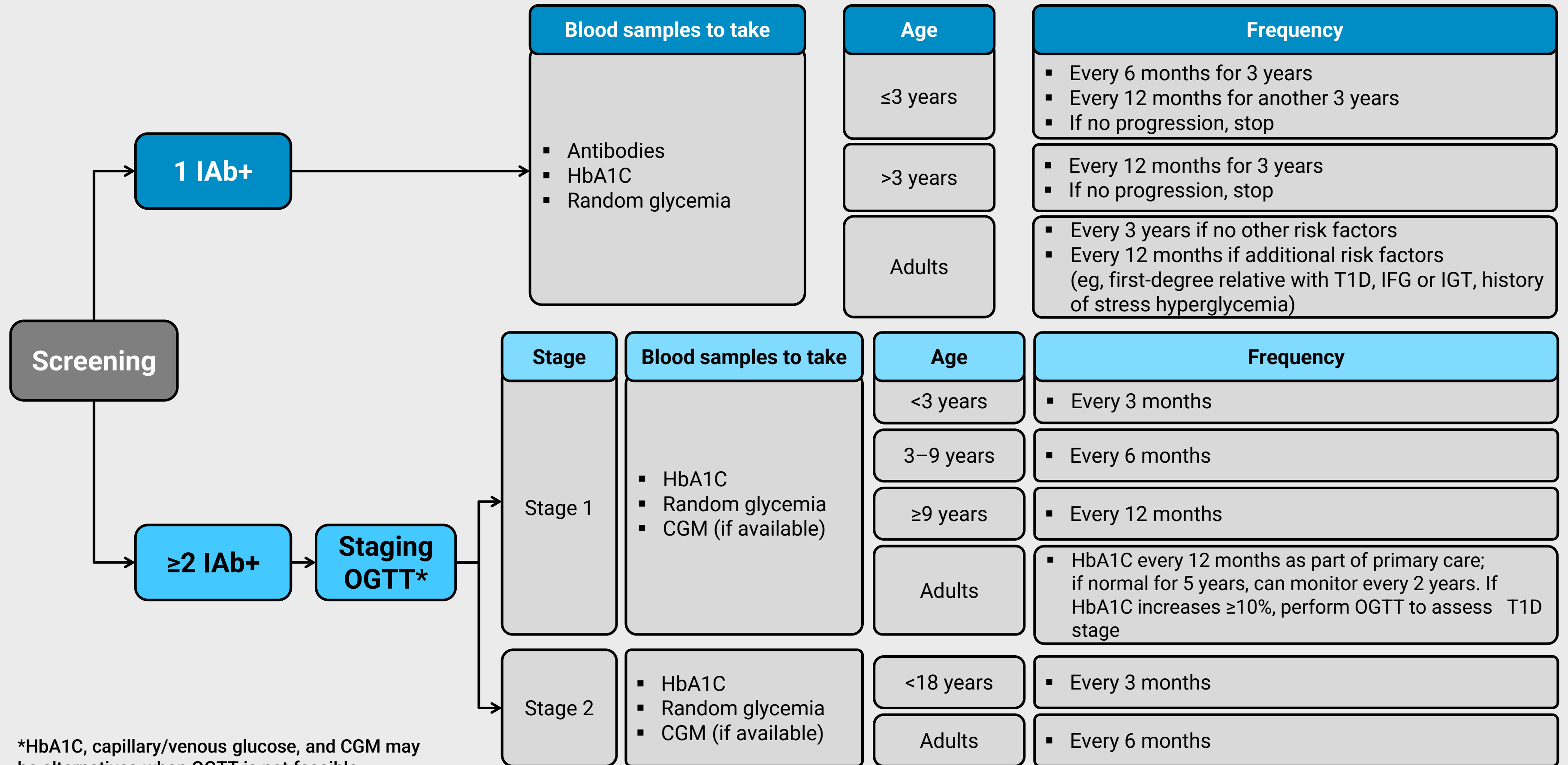


More frequent monitoring in children is needed due to increased risk and faster rate of T1D progression. Detailed monitoring and follow-up can be found in the international consensus monitoring guidance.

CGM = continuous glucose monitor; OGTT = oral glucose tolerance test; SMBG = self-monitoring blood glucose.

Adapted from Phillip M, et al. *Diabetes Care*. 2024;47:1276-1298.

Monitoring Individuals With Confirmed IAb+



*HbA1C, capillary/venous glucose, and CGM may be alternatives when OGTT is not feasible.

Modified from Phillip M, et al. *Diabetes Care*. 2024;47:1276-1298 and Haller MJ, et al. *Horm Res Paediatr*. 2024:1-17.

The Primary Goals of Education for Care of Antibody-Positive People and Their Families

1

To prevent DKA, promote safe monitoring practices, and reduce occurrence of symptoms of T1D

2

To minimize the requirement for emergency care, hospital admission, and need for intensive care at diagnosis of T1D

3

To improve appropriate risk perception at each monitoring milestone

4

To understand specific outcomes (eg, prevention of DKA, initiation of insulin therapy)

5

To understand available interventions

6

To explore and understand the benefits of individual participation in research studies

7

To provide education that supports psychosocial interventions to optimize general health and mental health for affected individuals and their families



Caregiver Perspective and Panel Discussion: Follow-Up After Screening Results



Jeselyn Luis Sauleda, LMHC

T1D Patient Advocate





Common Questions That Patients or Caregivers Ask After Being Screened for T1D

- How long will it be until I get my results?
- If negative: Do I need to screen again?
- If positive
 - Are you sure these results are accurate?
 - Why did this happen to me?
 - How will this impact my insurance?
 - Is there anything I can do to prevent T1D from progressing (ie, diet, supplements, other medications)?
 - How long will it be until I need insulin?
 - What symptoms do I look for?

Advances in Delaying T1D Progression



Polling Question

What are your biggest barriers in treating early-stage T1D to delay progression to clinical disease? **Select all that apply.**

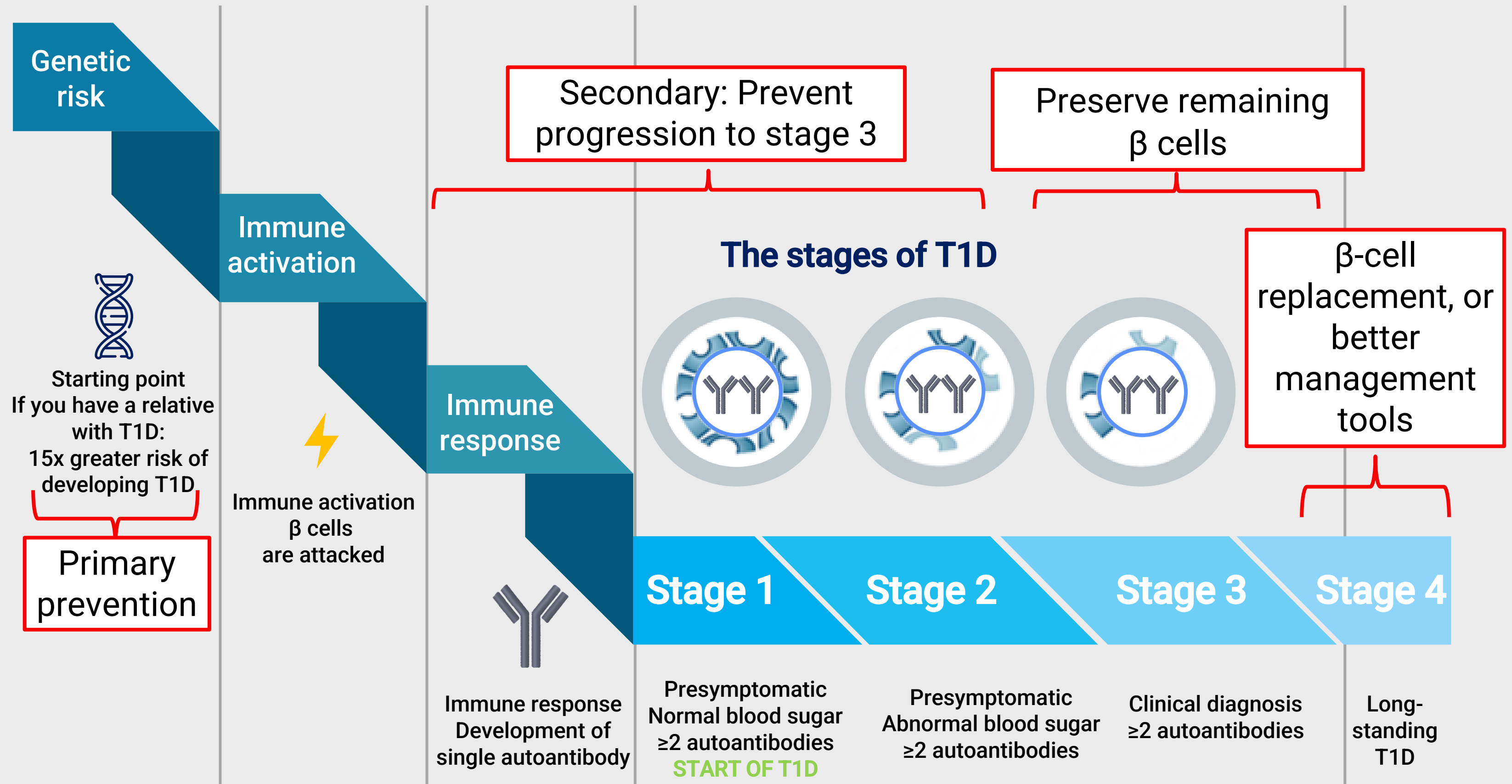
- a) Difficulty identifying eligible patients (eg, patients with stage 2 T1D)
- b) Lack of knowledge/evidence about teplizumab or other DMTs for T1D
- c) Lack of knowledge about where or how to refer for teplizumab treatment
- d) Lack of available infusion programs (in my practice or in my area)
- e) Uncertainty about the safety profile of teplizumab and/or how to manage AEs
- f) Insurance and patient access issues
- g) Uncertainty about where teplizumab infusions should take place
- h) Lack of nursing support
- i) Lack of support from leadership within your practice/institution
- j) Weekend availability for 14-day consecutive infusions

Why Try to Delay T1D Progression?

1. High disease burden
2. We are not doing a good job in achieving the tight metabolic control we know is necessary to prevent complications
3. Maintaining even some β -cell function (measured as stimulated C-peptide) improves diabetes control, reduces risk of hypoglycemia, and reduces complications

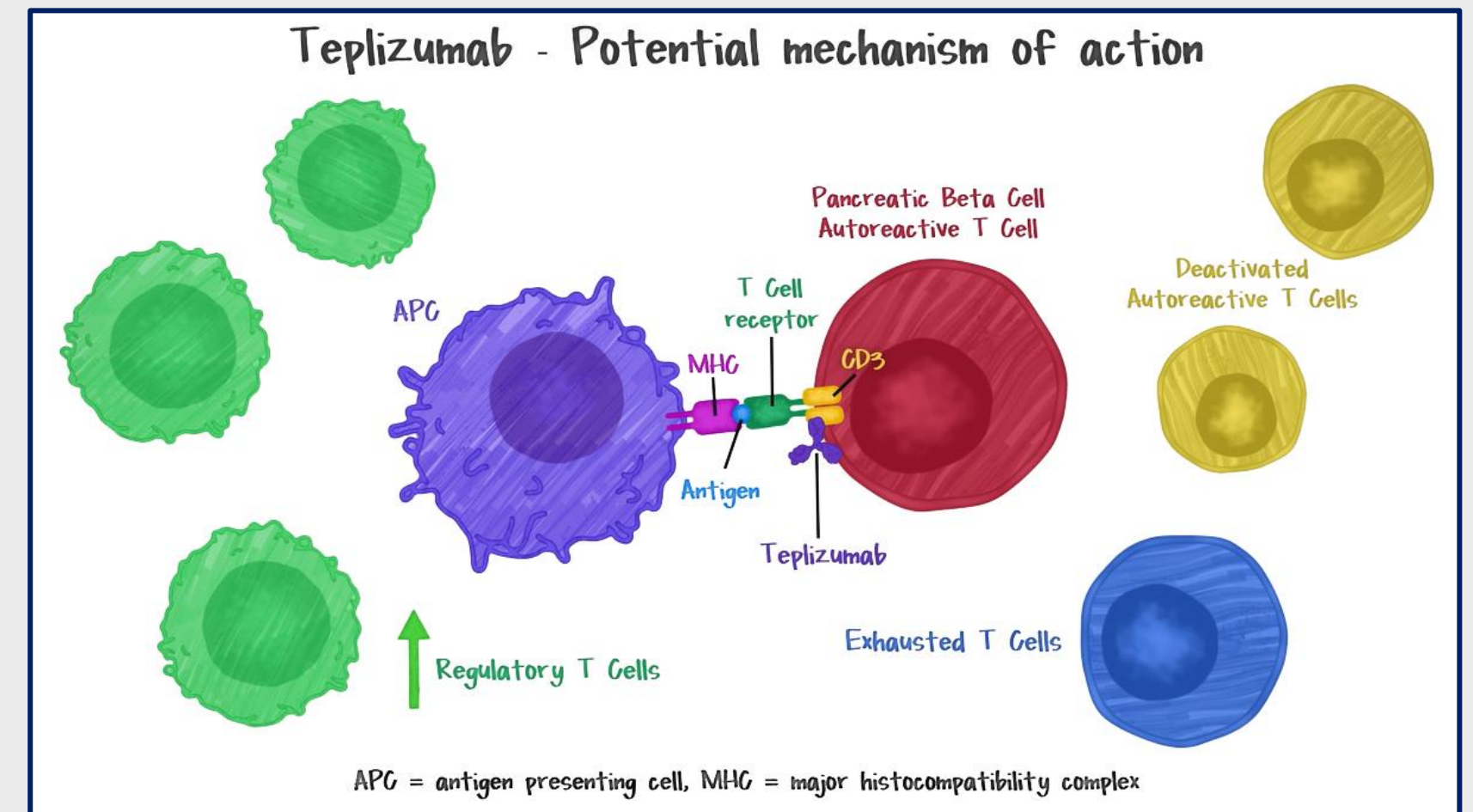


The Stages of T1D Inform Our Therapy Approach—Most Studies Focus on T1D Stages 1 and 2 Where Risk of Progression Is Highest

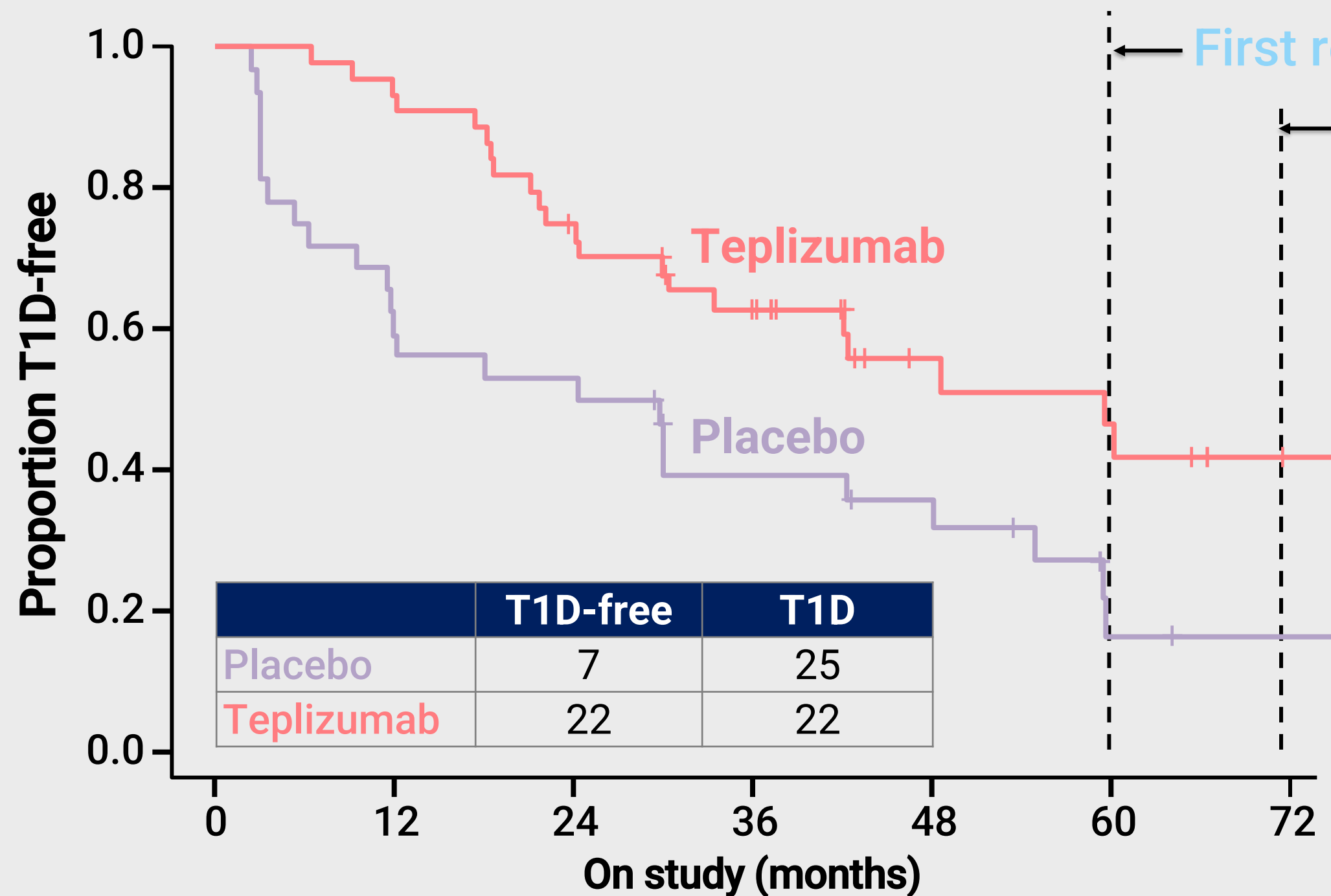


TrialNet TN10 Study—Teplizumab Slowed Progression From Stage 2 to Stage 3 T1D

- Humanized anti-CD3 monoclonal antibody that binds to the T-cell receptor-CD3 complex, inhibiting immune attack on β cells
 - Autoreactive CD8⁺ T-effector cells become “exhausted” (disabled)
- It was first studied in stage 3 T1D where it slows β -cell loss and is well tolerated; this set the stage for the TrialNet TN10 stage 2 prevention trial
- November 2022: FDA approved teplizumab as the first drug that can delay onset of clinical T1D for individuals aged ≥ 8 years with stage 2 T1D



TN10 Results: Effect of Teplizumab in Children and Adolescents With Stage 2 Diabetes



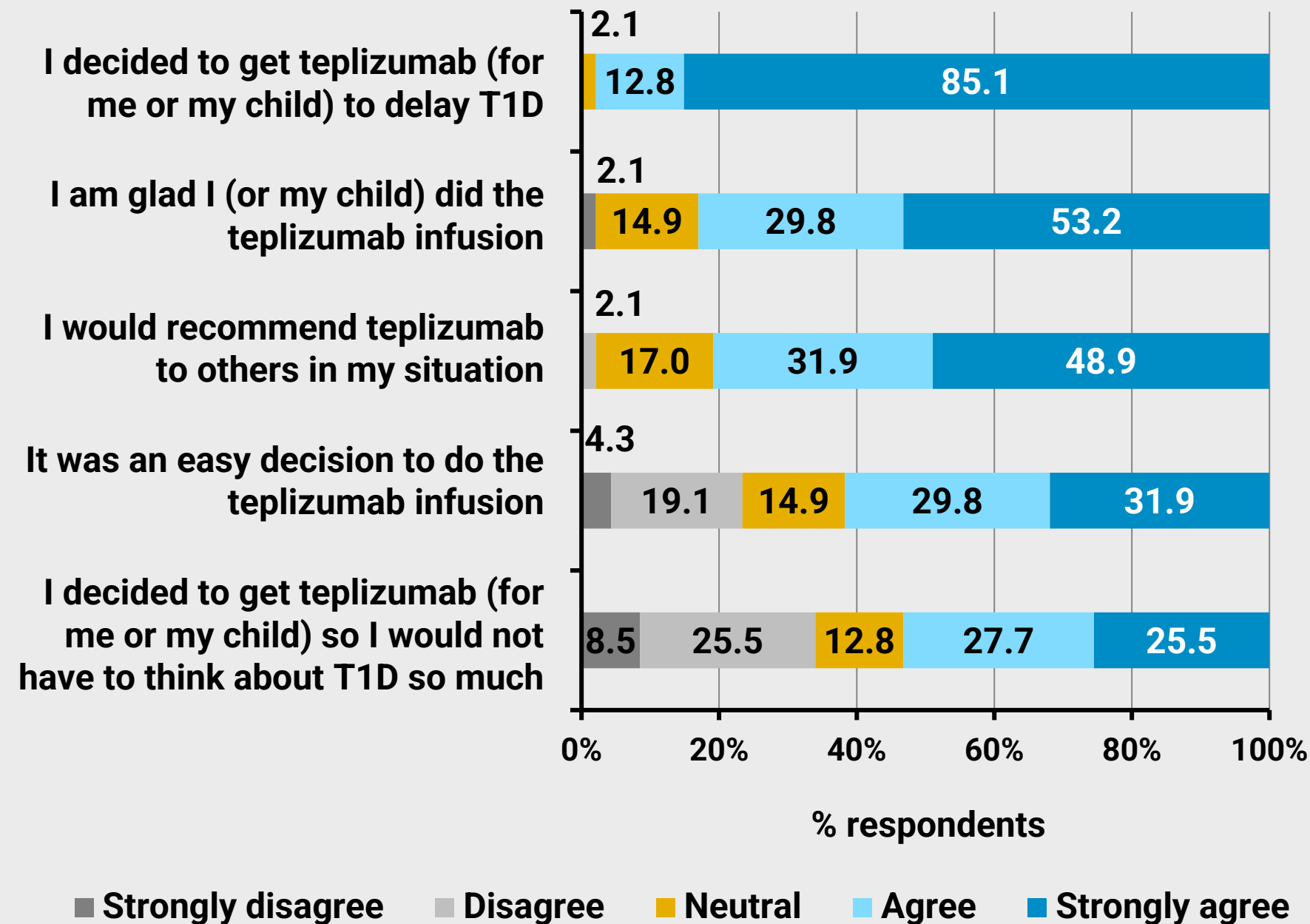
- In the first report (5 years), the time to stage 3 was delayed by 2 years with teplizumab
- 12 months later there was a 32.5-month delay
- By 6 years 50% of teplizumab-treated subjects were diabetes-free compared with 22% of those in the placebo group

Number at risk

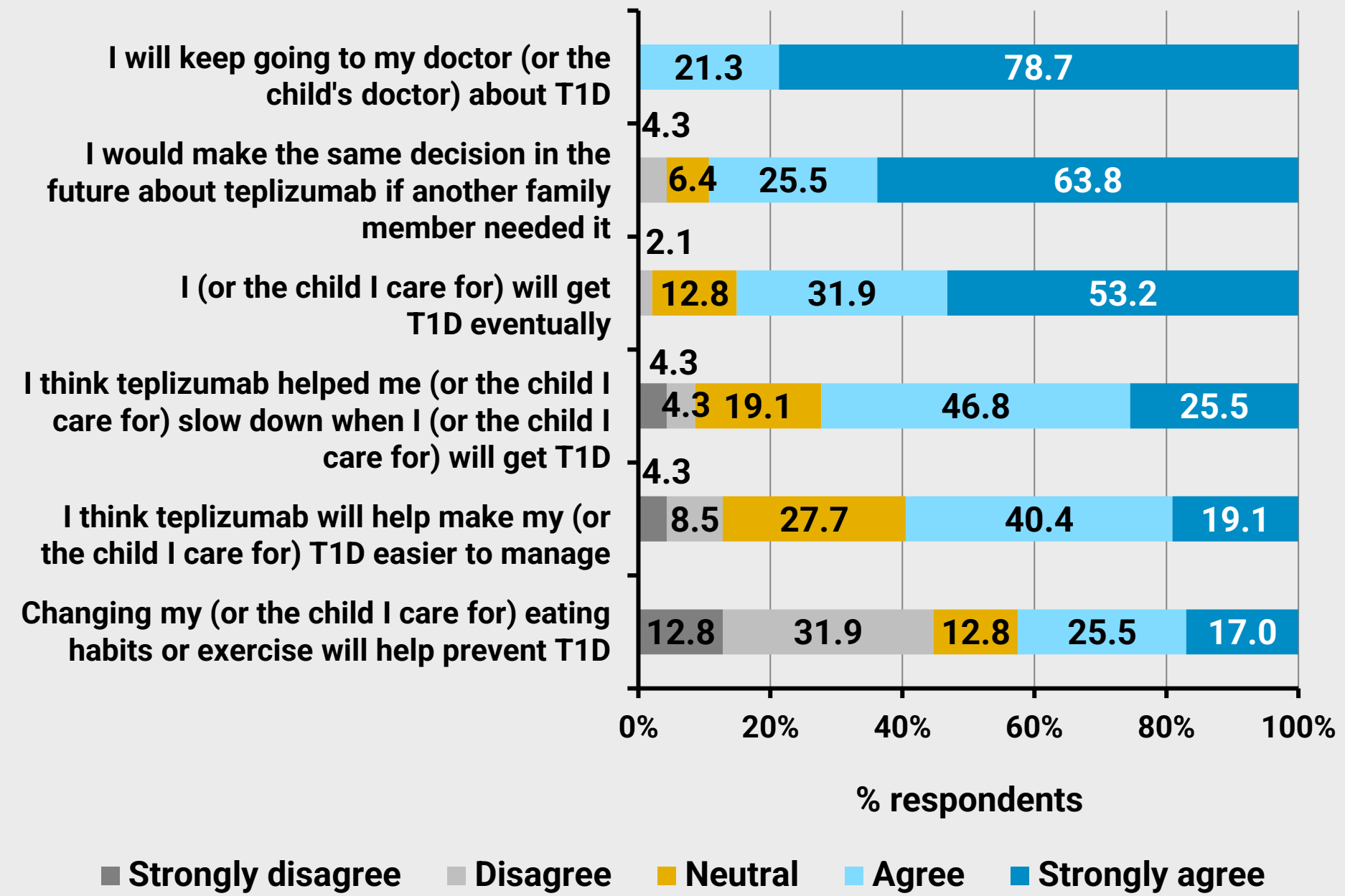
Placebo	32	24	19	18	17	14	11	11	9	7	3	2	2
Teplizumab	44	44	41	39	32	29	23	19	12	11	10	8	4

Real-World Experience With Teplizumab: Survey Results of Individuals Treated With Teplizumab for Stage 2 T1D

Views and expectations associated with teplizumab



Outlook after teplizumab treatment



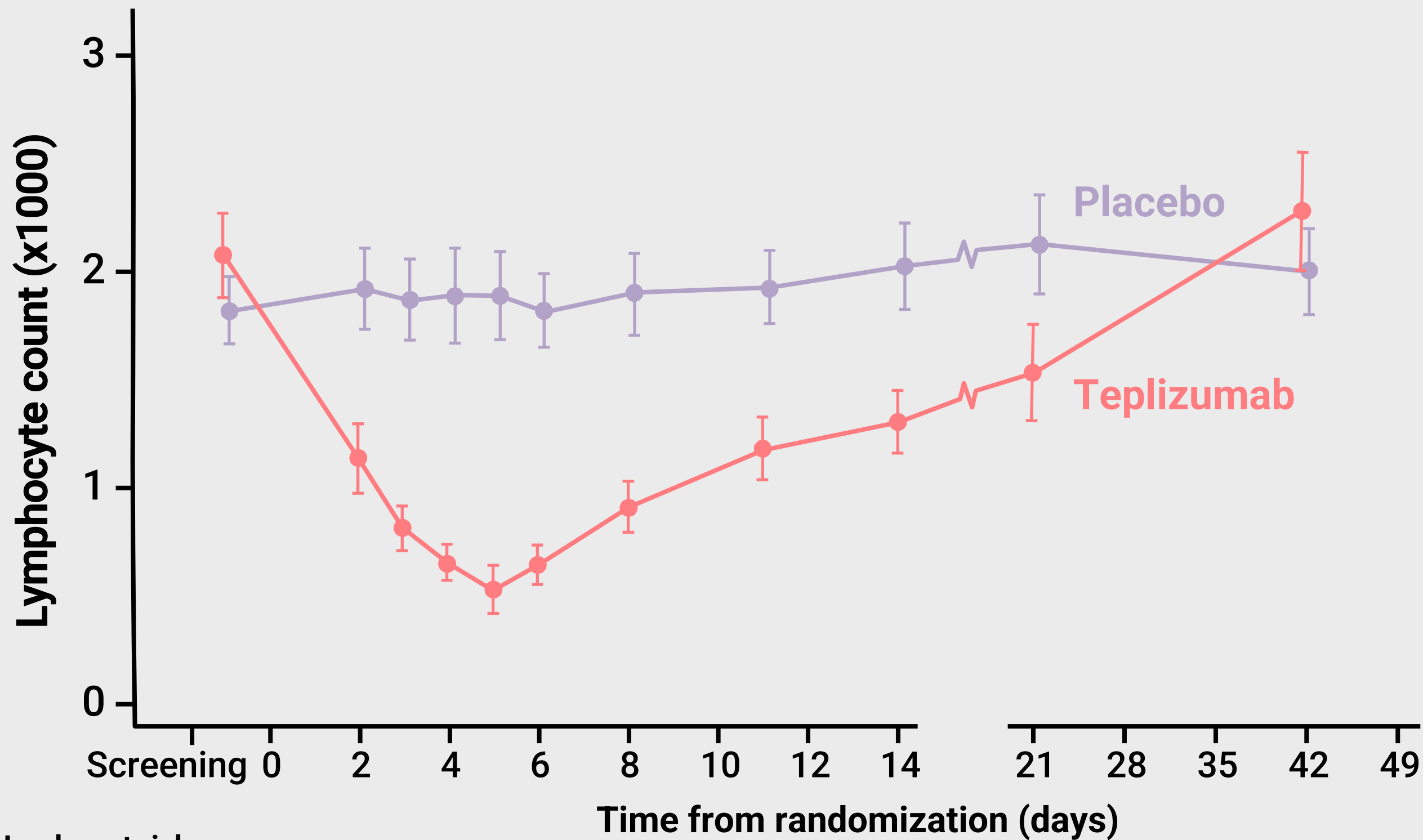
TN10 Results: Teplizumab AEs

AE category	Teplizumab		Placebo	
	Events, n	Subjects, n (%)	Events, n	Subjects, n (%)
Blood/bone marrow*	45	33 (75)	2	2 (6.2)
Dermatology/skin*	17	16 (36.4)	1	1 (3.1)
Pain	11	5 (11.4)	5	3 (9.4)
Infection	8	5 (11.4)	5	3 (9.4)
Gastrointestinal	5	4 (9.1)	3	3 (9.4)
Metabolic/laboratory	7	4 (9.1)	2	2 (6.2)
Pulmonary/upper respiratory	6	4 (9.1)	0	0 (0)
Constitutional symptoms	3	2 (4.5)	0	0 (0)
Allergy/immunology	2	2 (4.5)	0	0 (0)
Cardiac/general	1	1 (2.3)	1	1 (3.1)
Endocrine	0	0 (0)	2	2 (6.2)
Vascular	1	1 (2.3)	1	1 (3.1)
Neurology	1	1 (2.3)	0	0 (0)
Ocular/visuals	1	1 (2.3)	0	0 (0)
Musculoskeletal/soft tissue	2	1 (2.3)	0	0 (0)
Hepatobiliary/pancreas	0	0 (0)	1	1 (3.1)
Syndromes	1	1 (2.3)	0	0 (0)
Hemorrhage/bleeding	1	1 (2.3)	0	0 (0)
Total/events and subjects	12	44 (100)	23	32 (100)

*P < .001 teplizumab vs placebo.

- AEs were primarily related to cytokine release syndrome (CRS) in the first few days of infusions
- With premedication therapy (acetaminophen, diphenhydramine, ondansetron), most AEs were not severe and resolved without other intervention
- Most common AEs included lymphopenia, rash, and headache

TN10 Results: Lymphocytes Are Transiently Suppressed



Number at risk

Placebo	32	30	30	30	29	30	31	32	30	29	31
Teplizumab	44	41	41	41	41	42	43	43	41	42	42

Teplizumab Challenges

- Cost for drug plus infusion center/staff (premedications, laboratory tests, registered nurse [RN], medical doctor [MD])
 - Public vs private insurance coverage
- Length of treatment (14 consecutive days)
- Identifying stage 2 T1D (screening) and monitoring of these patients before and after treatment
- While the drug has an excellent safety record, it was given under protective research conditions; community users may not be able to be as thorough, or unanticipated problems might become evident with larger numbers
- How are we going to track safety and efficacy now that it is no longer part of a study?
- What about children aged <8 years? (PETITE-T1D* study results pending)

Practical Tips for Teplizumab Therapy Based on TrialNet Protocol and Experience

Locale for drug administration—ideally, an infusion center with an onsite provider comfortable with cytokine release syndrome/drug reactions (eg, chemotherapy/rheumatology centers); emergency medications on hand in case of hypersensitivity reaction

- Particularly important during the 5 days—while the prescribing information states infusions can be given at clinic or in the home via home health, during the first 5 days the patient is likely to experience some degree of cytokine release syndrome so an acute care setting is the safest way to provide the availability of rapid and experienced emergency care
- For additional information—including preinfusion vaccine recommendations, premedications, and drug withholding criteria—refer to the 2024 PES guidance statement on teplizumab treatment
- ICD10 codes specific to early stage T1D
 - E10.A0 = T1D, presymptomatic, unspecified
 - E10.A1 = T1D, presymptomatic, stage 1
 - E10.A2 = T1D, presymptomatic, stage 2

ICD-10 = *International Classification of Diseases, Tenth Revision.*

PES = **P**ediatric **E**ndocrine **S**ociety.

Adapted from Mehta S, et al. *Horm Res Paediatr.* 2024:1-12.



Teplizumab Eligibility

Aged ≥ 8 years with stage 2 T1D confirmed by

- ≥ 2 T1D relevant antibodies (GAD65, IA-2, IAA, ZnT8, ICA)
- Dysglycemia
 - The OGTT is the gold standard test, with dysglycemia defined as
 - Fasting glucose: 100–125 mg/dL, OR
 - OGTT 30-, 60-, 90-minute postprandial glucose: ≥ 200 mg/dL, OR
 - 2-hour postprandial glucose: 140–199 mg/dL, OR
 - HbA1C: 5.7%–6.4% or $\geq 10\%$ increase in HbA1C even in the normal range
- No symptoms associated with T1D (eg, increased urination, excessive thirst, weight loss)
- Ensure that the patient's clinical history and diagnostic codes do not suggest overt hyperglycemia (FPG ≥ 126 mg/dL or 2-hour postprandial glucose ≥ 200 mg/dL)
- Ensure that the clinical history of the patient does not suggest T2D
- All age-appropriate vaccinations were administered prior to starting teplizumab
- Screenings for active CMV, EBV infection, hepatitis, HIV, and tuberculosis are negative
- Discussed potential risks and benefits and potential AEs with patient and family

ICD-10 diagnostic codes specific to early stage T1D

- E10.A0 = T1D, presymptomatic, unspecified
- E10.A1 = T1D, presymptomatic, stage 1
- **E10.A2 = T1D, presymptomatic, stage 2**

ICA = islet cell antibody; ICD-10 = *International Classification of Diseases, Tenth Revision*.

Considerations for Infusion Setting With Teplizumab

Infusion setting*	Pros	Cons
Doctor's office	Supervised by provider	Limited scheduling flexibility, limited personal attention in a busy clinic setting
Infusion centers	Specialized staff and equipment, experience with immunotherapy infusions	Possible travel required
At home with nurse	Convenience	Lack of immediate medical assistance, especially during the first 5 days when cytokine release syndrome is common

*For insurance purposes, infusion setting must be determined prior to starting therapy. In-home infusions for a pediatric population should be ideally avoided and limited to adult patients. Infusions for pediatric patients are recommended to be done in a controlled clinical setting with nurses who are trained in PALS.

- This can vary based on resources and experience of the team
- Careful balance of accessibility to medication and optimizing patient care and monitoring

Type 1 Diabetes TrialNet
Centers of Excellence Locations
<https://www.trialnet.org/locations>

National Infusion Center Association – Infusion Center
Locator (can sort by medication type, including
teplizumab)
<https://locator.infusioncenter.org/>

DETECT-T1D Infusion Portal
<https://infusion.detect-t1d.com/>

PALS = Pediatric Advanced Life Support.

Mehta S, et al. *Horm Res Paediatr.* 2024:1-12.

Caregiver Perspective and Panel Discussion: Treatment With Disease Modifying Therapies for T1D



Jeselyn Luis Sauleda, LMHC

T1D Patient Advocate





Common Questions That Patients or Caregivers Ask About Treatment With Teplizumab

- What are the side effects of treatment? Are there long-term side effects?
- Can I work or go to school during my treatment?
- How much will it cost? Will insurance cover it?
- Is there a chance that treatment can make me progress faster?
- How long will it take to get the medication approved? When will I be able to schedule treatment?
- How soon do we need to receive treatment once we find out we have stage 2 T1D?
- Can I get this medication more than 1 time?
- Will I be able to receive treatment again if my blood sugar levels start to rise?
- What will happen if we don't choose to move forward with the treatment?

On the Horizon: Disease Modifying Therapies in New-Onset (Stage 3) T1D



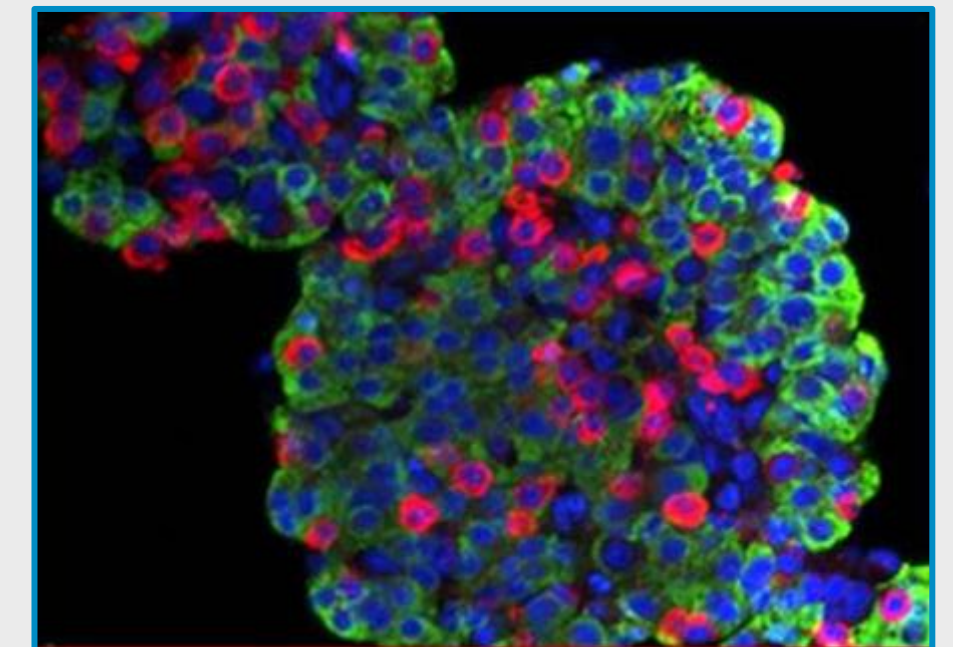
Disease Modifying Therapies for New-Onset (Stage 3) T1D

Rationale for halting disease progression in new-onset T1D

- Maintaining endogenous insulin secretion
- Reducing the need for exogenous insulin
- Prolonging the honeymoon period
- Lower risk of complications; per 50% increase in c-peptide,* there was
 - 8.9% lower risk of severe hypoglycemia ($p < .0001$)
 - 24% reduced risk of sustained retinopathy ($p = .0030$)

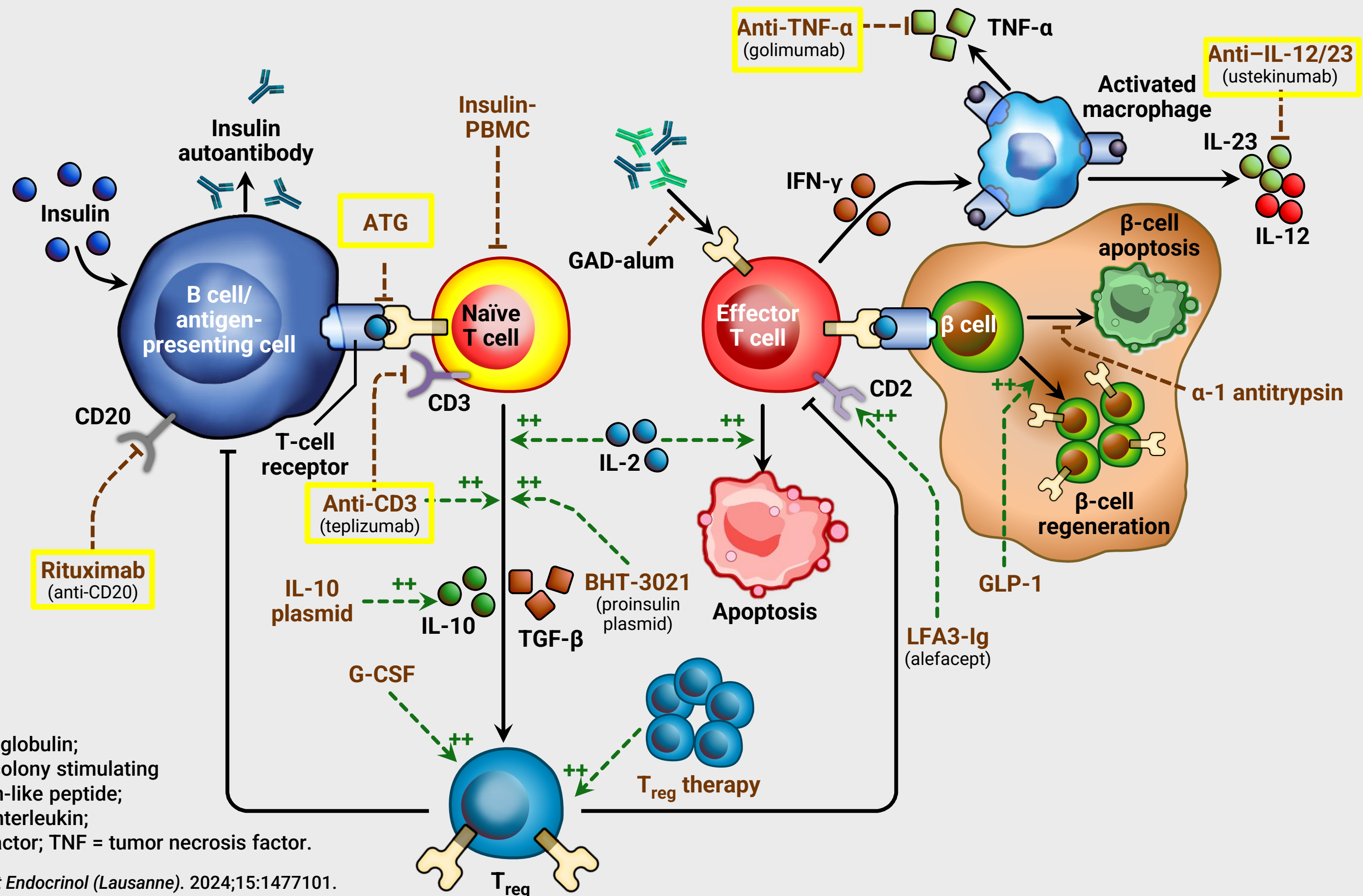
- Current research approaches seek to combine agents or use new agents to achieve a more long-lasting preservation of β cells
- These studies need to be done while patients still have enough β cells to preserve, typically within 100 days of stage 3 diagnosis

So talk about research to your patients with new-onset stage 3 T1D early in the initial education process!



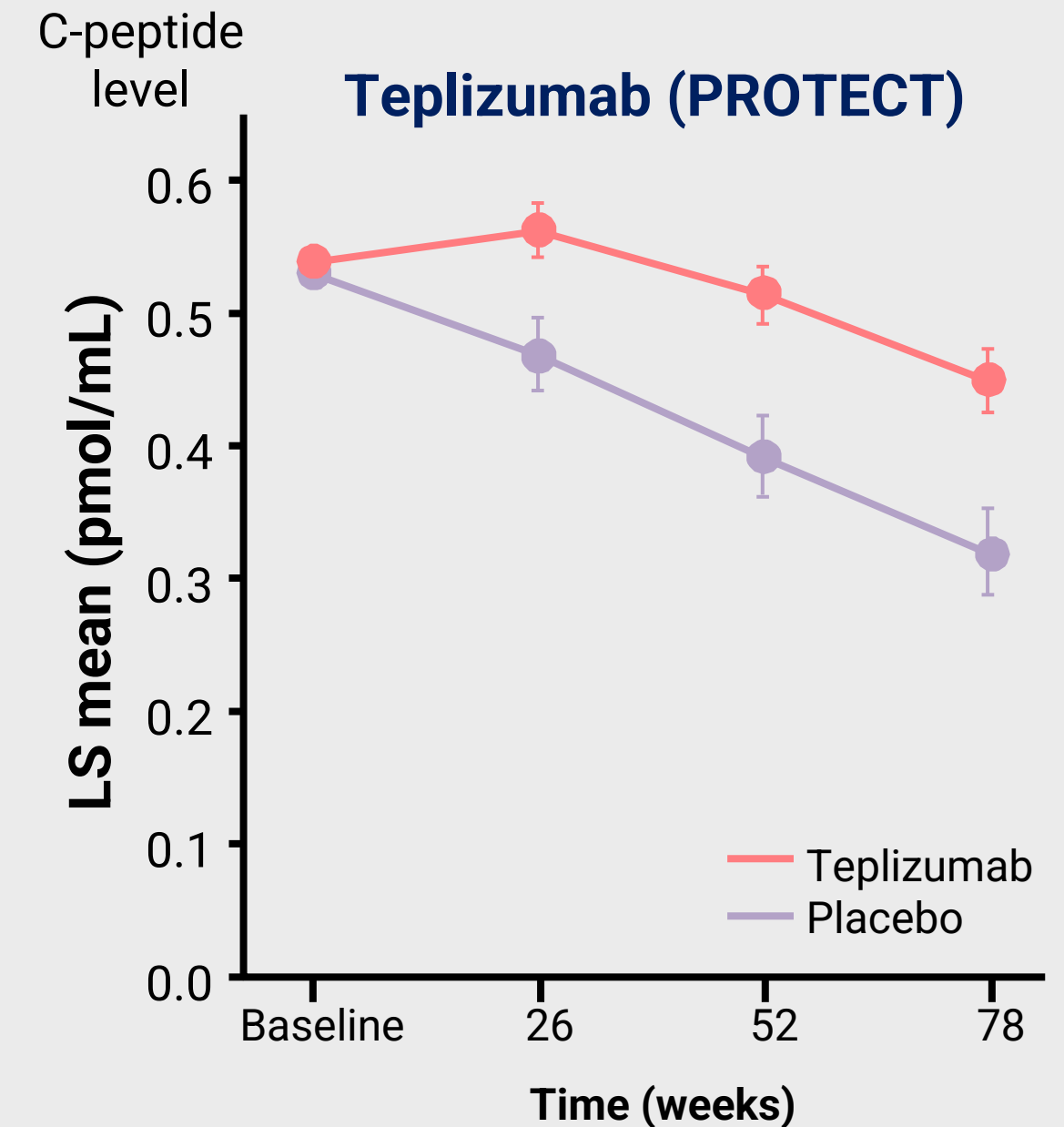
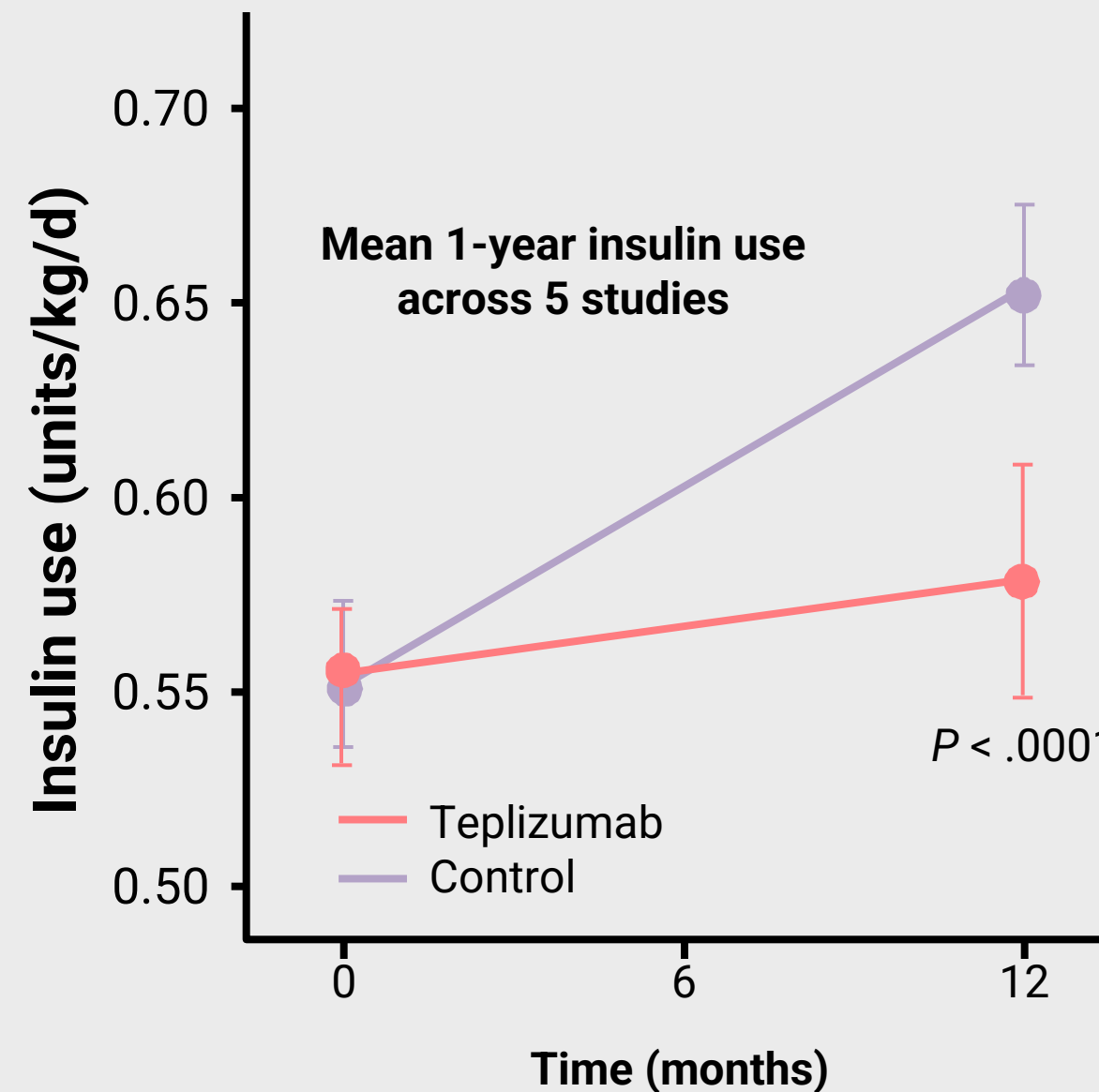
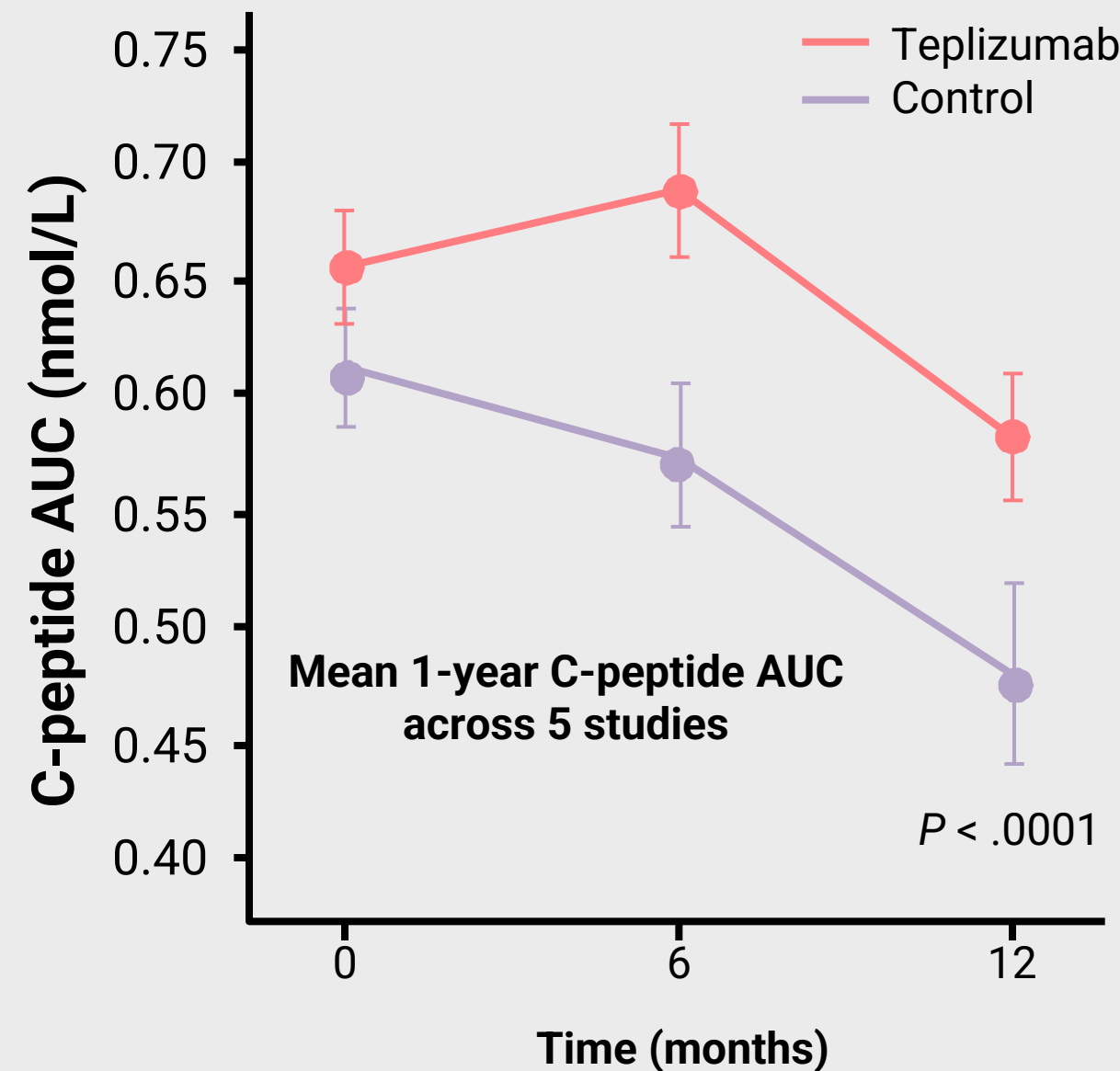
*Adjusted for entry A1C and status of complications at entry.

Several Treatment Targets Are Being Investigated in New-Onset T1D



ATG = anti-thymocyte globulin;
 G-CSF = granulocyte-colony stimulating factor; GLP = glucagon-like peptide;
 IFN = interferon; IL = interleukin;
 TGF = tumor growth factor; TNF = tumor necrosis factor.

Stimulated C-Peptide and Insulin Use Were Significantly Improved in Stage 3 Participants With T1D Treated With Teplizumab



AUC = area under the curve; LS = least squares.

Positive Outcomes in Stage 3 New-Onset T1D Human Trials

- Teplizumab (anti-CD3)
- Abatacept (CTLA4 immunoglobulin)
- Rituximab (anti-CD20)
- Alefacept (LFA3 Ig)
- ATG, low-dose ATG (G-CSF)
- Golimumab (anti-TNF α)
- Anti-IL-21/liraglutide
- Verapamil (calcium channel blocker)
- Baricitinib (JAK inhibitor)
- Ustekinumab (anti-IL-12/23)
- Imatinib (tyrosine kinase inhibitor)

Select ongoing trials awaiting results:

- Iscalimab (anti-CD40)
- Frexalimab (anti-CD40L)
- Rituximab + abatacept
- JAK inhibitor (abrocitinib, ritlecitinib)

** Not a complete list of trials or agents under investigation or ongoing trials.*

JAK = Janus kinase.

O'Donovan AJ, et al. *Front Endocrinol (Lausanne)*. 2024;15:1477101. Jacobsen LM, Schatz D. *Horm Res Paediatr*. 2024;1-10.

Current Directions for New-Onset Stage 3 T1D

- Various agents in new-onset and prevention trials temporarily slow β -cell loss in some subjects, but it appears less and less likely that a single course of a single agent will completely prevent clinical diabetes or will be effective in all people
- Multiple agents are in trials or under consideration, especially in combination, often targeting different things (eg, T cells, B cells, inflammation, β -cell health, insulin resistance, viruses, microbiome)
- Some investigators are considering “induction” with an agent to temporarily alter the T-/B-cell milieu (eg, teplizumab, ATG, abatacept, rituximab), followed by maintenance with agents that are safer and more practical for chronic use (antigens, verapamil, anti-inflammatory agents, etc)
- Breakthrough T1D (formerly JDRF) and TrialNet are good resources to discuss study availability



Case #2 and Group Breakout Discussion



Case #2: Robert (introduction)

- Robert is a 32-year-old man who presents to you for a diabetes recheck; he was diagnosed 3 years ago at his time-of-work physical for the police force and was not feeling well at the time; was urinating a lot and had lost weight (~10 lbs over 3 months); and then started metformin, which was increased to 1000 mg twice a day, and sitagliptin 100 mg daily
- Not sure how well the medications work, but he has gone on a ketogenic diet, which prevents his sugars from spiking so high
- He has no family history of diabetes; he has only had sports-related injuries in the past
- No tobacco, alcohol, or recreational drug use; single—lots of exercise at work
- Initial HbA1C was 8.7%



Case #2: Robert (follow-up)

- Physical examination

- Blood pressure: 116/82 mm Hg, pulse: 64 beats/minute, respiratory rate: 12 breaths/minute, body mass index: 24 kg/m²
- Physical
 - Normal examination
- HbA1C 7.5% (3 months into ketogenic diet)

- Total cholesterol: 184 mg/dL
- High-density lipoprotein: 54 mg/dL
- Low-density lipoprotein: 105 mg/dL
- Triglycerides: 78 mg/dL

- Basic metabolic panel: Normal
- Thyroid-stimulating hormone: Normal
- Complete blood count: Normal

**Now we will
break out
for case
discussion.**



The selected delegate person at each table should answer the question discussed by your group.

Group Breakout Discussion

Please select 1 delegate person for your table to answer the questions below.

Patient case: Robert

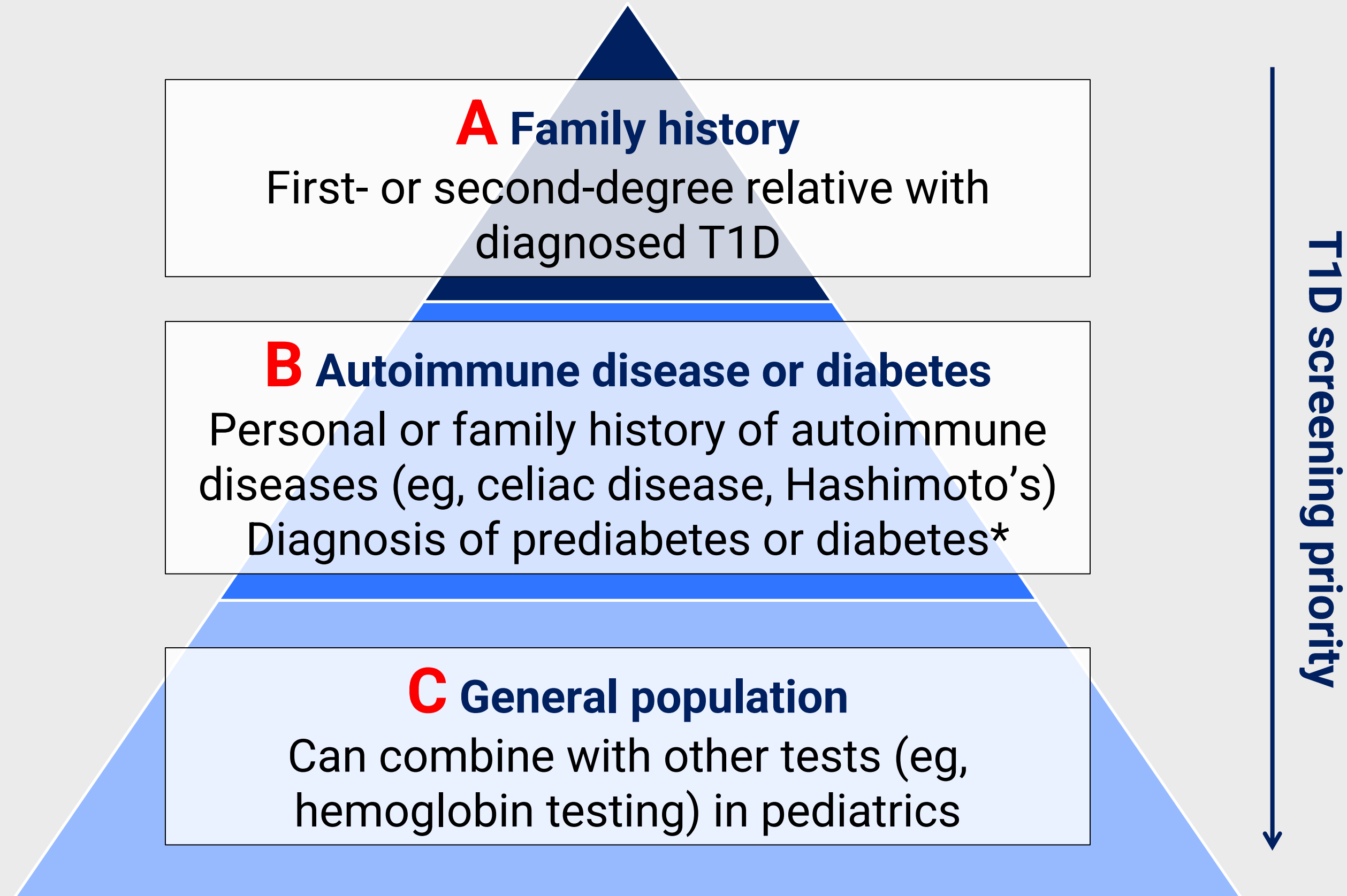
1. Given his history and presentation, what laboratory tests would you order next for Robert?
2. Would you screen Robert for T1D, and if so, why?
3. If Robert screened positive for ≥ 2 IAbs and his glucose level was 165 mg/dL, what would be your next steps for treatment?



Implications and Practice Takeaways



Suggested Risk Stratification Approach for Autoantibody Screening Programs for Presymptomatic Type 1 Diabetes



*For patients without typical features of T2D.

Modified from Leichter SB, et al. *J Clin Endocrinol Metab.* 2025;dgaf194.

Establishing A Clinical T1D Autoantibody Screening Program

Process Considerations

Communication

- Benefits of screening
- Differences between T1D and T2D
- Options for screening, monitoring, and treatment
- Consent for screening
- Cost(s)

Reaching family members

- Discuss screening of family members with T1D patients.
- Provide informational handout about screening options, including information on free IAb screening through research programs

Timing of screening

- From 9 months of age
- Can combine with other routine testing, e.g.:
 - 1–2 years – hemoglobin
 - 4–6 years – vaccinations
 - 9–11 years – lipid screening

ICD-10 diagnostic codes

Screening:

Z13.1 – encounter for screening for diabetes

Z83.3 – family history T1D

Z83.49 – family history endocrine, nutritional, metabolic

E34.9 – endocrine, unspecified

Monitoring (presymptomatic T1D):

E10.A0 – unspecified

E10.A1 - stage 1

E10.A2 - stage 2

Ordering IAb panels

Streamline ordering for clinical IAbs:



GAD IAA IA-2 ZnT8

Quest Diagnostics: 13621

Labcorp: 504050

CPT codes: 86341 (GAD65, IA-2, ZnT8) & 86337 (IAA)

Teplizumab—Considerations for Establishing a Clinical Infusion Program

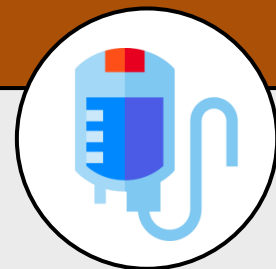
- It takes some effort to set this up--if you are only planning to treat one or two patients it may make more sense to refer them to an established center with a larger case volume

Work closely with hospital and nursing leadership to create a protocol, determine logistics, and address prior authorization and billing. Seek mentorship from experienced centers

Do you have a plan/set-up to perform confirmatory eligibility screening including OGTTs?



Where and when will a long-arm (midline or PICC) IV line be placed?



Where will the infusion take place?

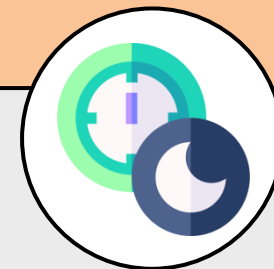
- For a least the first 5 days, close nursing supervision must be available, with nurses experienced in hypersensitivity reactions and cytokine release syndrome (usually chemotherapy/ rheumatology infusion centers).
- Are they open on weekends? A crash cart and an emergency response team should be available. There must be capacity for STAT pre-infusion labs. Someone must assess the pre-infusion labs and the patient's health daily to ensure the infusion can proceed.



The pharmacy needs a protocol for teplizumab and other study meds including those the patient will be sent home with.



Who is available to check in or to trouble-shoot problems with the patient overnight?



Conclusions

- There are practical benefits in diagnosing preclinical T1D
- Autoantibody screening identifies individuals at high risk for progression to clinical stage 3 T1D; this can be done locally or through established programs such as TrialNet
- If ≥ 2 IAbs are present, the next step is an OGTT for staging, then close follow-up
- Stage 1 or 2 T1D: May be eligible for therapy (teplizumab in stage 2, other drugs as they become available) or may be eligible to participate in a prevention study
- Patients with new-onset T1D may be eligible for a study, but this usually needs to be initiated within the first couple months of diagnosis
- Information can be found through TrialNet or Breakthrough T1D

Q & A



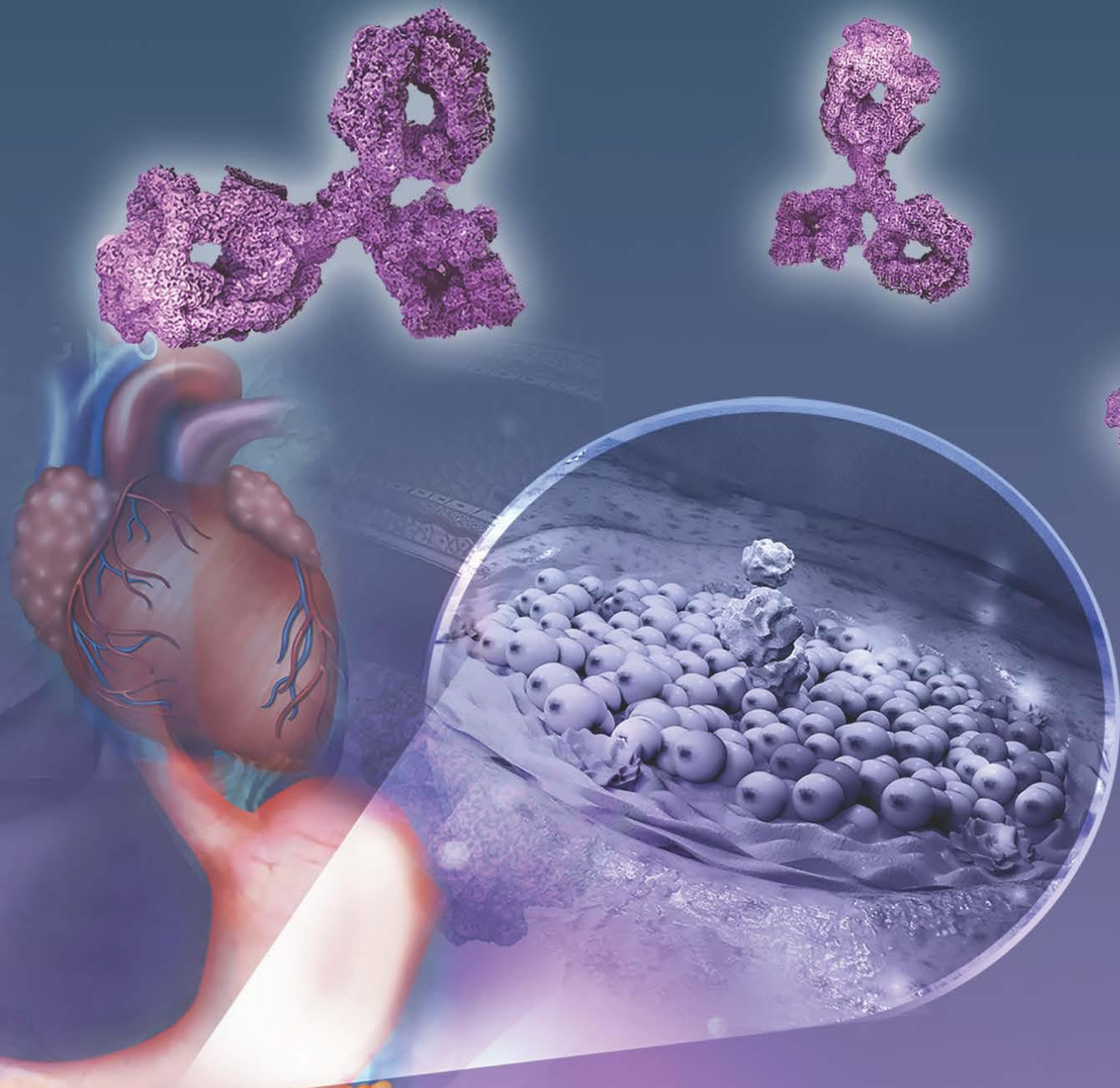
From Awareness to Action:
Driving Multidisciplinary Application of
Screening and Disease Modifying Therapies in
EARLY STAGE T1D

PROGRAM RESOURCES



<https://detect-t1d.com/>

- CREATE a complimentary personalized office poster & pocket card
- VIEW supplemental resources and animations
- REGISTER for a variety of CME activities



DETECT 1D



This activity is provided by Med Learning Group.
This activity is supported by an educational grant from Sanofi US.



SIGN UP NOW

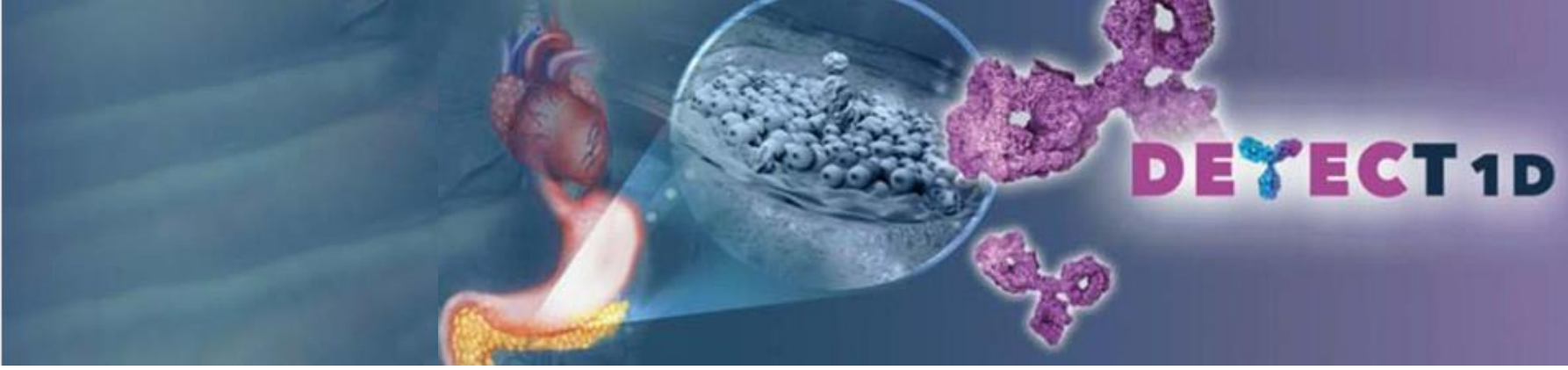


DETECT^{1D}

**BECOME AN
AMBASSADOR**

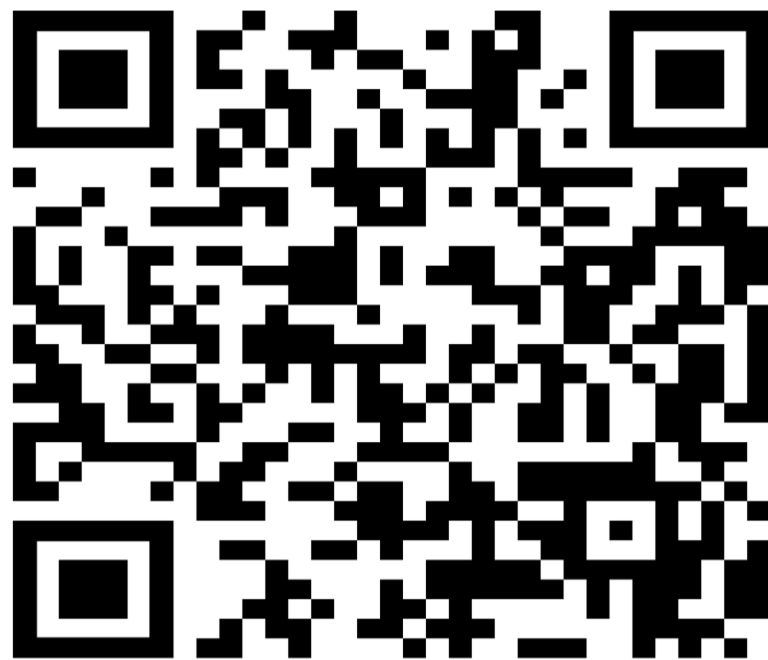
<https://detectambassador.com>





From Awareness to Action:
Driving Multidisciplinary Application of
Screening and Disease Modifying Therapies in
EARLY STAGE T1D

The Insights to Action Collaboration Platform



- **Connect with our T1D experts & peers in your region**
- **Explore various resources & support around screening, early detection, and treatment of T1D**

Thank you!



From Awareness to Action: Driving Multidisciplinary Application of Screening and Disease-Modifying Therapies in Early-Stage T1D

Toolkit

Guidelines and Practice Parameters

Resource	Address
American Diabetes Association Professional Practice Committee. 2. Diagnosis and classification of diabetes: Standards of care in diabetes—2025. <i>Diabetes Care</i> . 2025;48(suppl 1):S27-S49.	https://diabetesjournals.org/care/article/48/Supplement_1/S27/157566
American Diabetes Association Professional Practice Committee. 3. Prevention or delay of diabetes and associated comorbidities: Standards of care in diabetes—2025. <i>Diabetes Care</i> . 2025;48(suppl 1):S50-S58.	https://diabetesjournals.org/care/article/48/Supplement_1/S50/157550
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University of Colorado – Barbara Davis Center for Diabetes. Screen TO Prevent Type 1 Diabetes – stopT1D.	https://www.stopt1dprogram.org/

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