The T1D Early Detection Pocket Guide

A quick-reference guide to early-stage type 1 diabetes (T1D) detection for primary care providers and pediatricians

This guide has been developed in line with the latest clinical guidelines and published scientific literature; however, implementation of T1D early detection in your country may differ depending on healthcare infrastructure, and the availability of early detection pathways and screening methodologies.

This information is intended for healthcare professionals only.

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New frontiers in type 1 diabetes

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1. Why Screening Matters

Most children who will develop type 1 diabetes (T1D) are already in your clinic - months or years before the emergence of symptoms.[1]

T1D is a progressive autoimmune disease

In T1D, the immune system attacks the body's own insulin-producing cells, progressing through early stages until clinical onset (Stage 3).[2]

The early stages are silent

Stages 1 and 2 are presymptomatic: The child looks and feels well even as the disease advances.[2,3]

But they're detectable

Islet autoantibodies (IAbs) are markers of early-stage T1D that appear in the blood months to years before clinical onset and can be detected through routine labs.[3,4]

For many, T1D starts in crisis

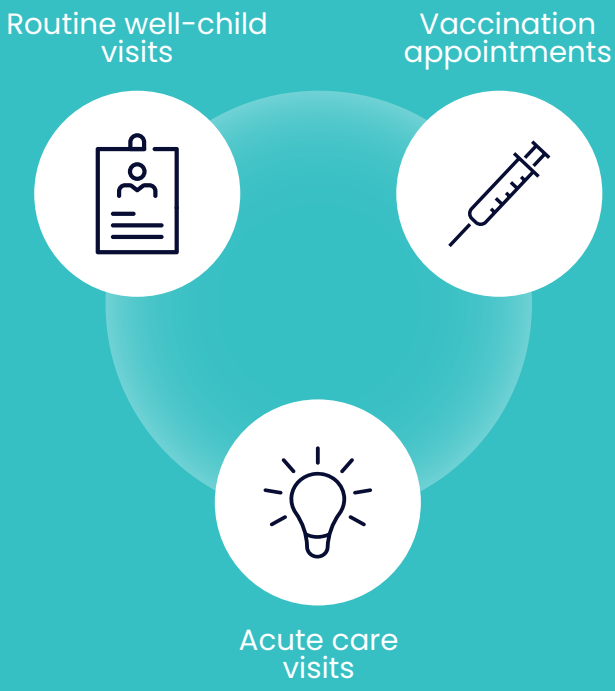
T1D is primarily diagnosed at clinical onset (Stage 3), often as diabetic ketoacidosis (DKA), a life-threatening emergency that can cause lasting harm.[5]

Early detection changes this

It enables DKA prevention, gives time to prepare for clinical onset, and allows access to approved therapies or clinical trials.[1,6-8]

Your Advantage: You see children regularly, making you ideally positioned to play a role in T1D early detection care pathways.[9]

Key primary care provider and pediatric touchpoints for raising awareness and screening[9]



2. Proposed Early Detection Care Pathway

Primary care plays a role across the early detection pathway. The exact role depends on your healthcare system and the available early detection pathways in your country.[9]

1 Disease awareness and identification[9]

Primary care providers, diabetologists/ endocrinologists*

- Community awareness campaigns
- Interactions with a healthcare provider

2 Initial detection and confirmation[9]

Primary care providers, diabetes specialist nurses, pediatric and adult endocrinologists (with the support of psychologists)

- IAb early detection and confirmation

*In some healthcare systems, psychologists may support with awareness and identification.[9]

Location of activity[9]

- Community
- Primary care
- Secondary/tertiary care

3 Staging[9]

Pediatric and adult endocrinologists, diabetes specialist nurses (with the support of psychologists)

- T1D staged by metabolic testing (if ≥2 IAbs confirmed)

4 Monitoring and Education[9]

Primary care providers, diabetes specialist nurses, pediatric and adult endocrinologists, diabetologists/endocrinologists

- Repeat metabolic testing and IAb testing

3. Screening and Staging

Stage	Defined by	Symptoms
 Stage 1	≥2 IAbs, normal glucose[2,10,11]	None[2,10, 11]
 Stage 2	Usually multiple IAbs, dysglycemia[2,10*]	None[2,10, 11]
 Stage 3	Clinical onset, hyperglycemia[2,10,11]	May be present[2,10, 11]
 Stage 4	Long-standing T1D[10]	Insulin dependent[10,11]

*Dysglycemia is defined as IFG: FPG 100–125 mg/dL (5.6–6.9 mmol/L) or IGT: 2-h PG 140–199 mg/dL (7.8–11.0 mmol/L) or A1C 5.7–6.4% (39–47 mmol/mol) or ≥10% increase in HbA1c.[3]

Screening can identify T1D before the onset of symptoms[3]

The four primary IAbs tested in screening are[3,4,12]

IAA

Insulin autoantibody

IA-2A

Insulinoma-associated antigen 2 autoantibody

GADA

Glutamic acid decarboxylase autoantibody

ZnT8A

Zinc transporter 8 autoantibody

ICA

Islet-cell autoantibody

ICAs are not generally used or recommended for screening[12]

Although testing for all four IAbs is recommended, not all four are required to detect T1D.[4,12] Screen in line with local available assays.[9] **Any positive result should be confirmed on a second, independently collected sample.**[4,9,11]

Why staging matters

Staging informs clinical care and key next steps.[2,9] This includes discussions around risk of progression, frequency of monitoring, and access to approved therapies or clinical trials. Importantly, any confirmed presence of IAbs may warrant specialist referral.[2,3,9]

4. Who Should I Screen?

Test or refer sooner: people with increased risk of T1D compared with the general population

- **Family history** - Individuals with a first-degree relative with T1D[10]
- **Other autoimmune conditions** - Personal or family history of autoimmune disease (e.g., thyroid, celiac disease)[3,9]
- **Incidental dysglycemia** or hyperglycemia on any routine test[9]

Consider T1D in adults who present with dysglycemia or hyperglycemia but don't have risk factors for T2D and/or are of a younger age (<35 years).[3,9]

Screening should be offered to the general public if policy and infrastructure are in place[13]

- ~90% of people who develop T1D have no family history[1]
- Screening at more than one point during childhood may identify more children, because the timing of IAb development varies[10,13]

Examples of established screening programs

- EDENT1FI (Europe) www.edent1fi.eu
- Fr1da (Germany) www.typ1diabetes-frueherkennung.de/participation-in-the-fr1da-study/index.html
- ASK (USA) https://www.askhealth.org
- ELSA (UK) https://www.elsadiabetes.nhs.uk

5. Referral and Care Pathways

Before screening anybody, ensure you have identified an appropriate referral and care pathway in your country.[13]

Use what already exists. Adapt current diabetes and autoimmune referral routes rather than building new ones.[14]

Three things every pathway needs

1. **Clear referral criteria**
   Who goes where, and when
2. **Standardized monitoring protocols**
   Shared between primary and specialist care
3. **Access to education and support**
   Diabetes educators, psychologists, and support groups[11]

Work together. Collaboration between providers keeps care transitions seamless.[14]

Fill in for your practice

My local specialist contact

_____

My local laboratory / assay

_____

6. How to Screen

1 **A simple blood test**
Capillary (finger-prick) or venous sample.[15]
Test for IAbs based on available methodologies in your country (see Early Detection Toolkit for more details)[3]

2 **Several validated laboratory methods exist**
Enzyme-linked immunosorbent assay (ELISA) is the most commonly available in standard clinical practice.[16] Your local laboratory can advise what is available.

3 **Confirm every positive result** on a second, independently collected sample - venous preferred - as soon as possible, and at least within three months, or refer to a specialist for confirmation.[11]

Confirmation matters. A single positive sample is not enough to act on. Confirmation should follow within three months.

7. Communicating Results

Communicating the risk of developing T1D or **confirming a diagnosis** of early-stage T1D to affected people **should only happen after the second** (confirmatory) **test**.

Confirmed result	What it means
Negative	No sign of the autoimmune process at this time. Re-screening may be advised depending on age and risk factors.[4]
Single IAb positive (no dysglycemia)*	An increased likelihood, not a diagnosis. About half of children revert to negative; where a single IAb persists, 10-year risk of Stage 3 is ~14.5%.[11]
≥2 IAbs, normal glucose; Stage 1	Early-stage T1D. Around 30% of children will progress to Stage 3 within 5 years, and almost all within their lifetime.[17]
Usually multiple IAbs + dysglycemia; Stage 2	Early-stage T1D, further along. Around 47.6–60.4% of children progress to Stage 3 within 5 years.[17]

*Individuals with a single confirmed IA-2A should be monitored similarly to individuals with multiple IAbs, as IA-2 IAb positivity is an independent risk factor for progression.[3] Progression data come from children followed after IAbs were first detected.

Talking to families



Explain the difference between "a diagnosis of early-stage T1D" (based on detection of ≥2 IAbs) versus "an increased likelihood of developing" (based on detection of one IAb)[11]

1 2 3

Use one kind of number - "about a 1 in 3 chance in the next 5 years", not "a 5-year risk of 30%"[17]



Use plain language and ask families to repeat back key information[18]

Anxiety is normal. Knowing early allows health risks to be managed proactively and helps prevent sudden complications - and families are supported at every step.[11]

8. What Happens Next?

Referral triggers

Stage 1 - Confirmed ≥2 IAbs with normal glucose: Specialist referral[11]

Stage 2 - Usually multiple IAbs with dysglycemia: Specialist referral[11]

Single IAb (no dysglycemia) - Monitor; consider referral based on age, autoantibody type* and family history[11]

For people with a single IAb present and normoglycemia, monitoring may occur in primary or specialist care depending on the country and screening infrastructure.[11]

Urgent. If you suspect symptomatic hyperglycemia, or any concern for DKA (vomiting, abdominal pain, deep or rapid breathing, dehydration, altered consciousness, acetone breath) - seek emergency care.[5]

Age	Monitoring frequency
Under 3 years	Every 6 months for 3 years, then yearly for 3 years
3–<18 years	Yearly for 3 years
Adults	Every 3 years

In children, metabolic monitoring means HbA1c plus random blood glucose. A ≥10% rise in HbA1c from confirmed IAb positivity may signal progression, even if the value stays within the normal range, and warrants an OGTT to assess stage.[11] Periodic CGM can also be used in monitoring.[11]

At every contact provide symptom education and a psychosocial check-in.[11]

9. Key Resources

Islet autoantibody Screening and Referral Ecosystem Compendium (ISEC)

IAb screening and referral pathways with resources by country.

Scan to open

ISPAD Clinical Practice Consensus Guidelines 2024

Evidence-based recommendations for managing diabetes in children, adolescents, and young adults.

Scan to open

Note: Link to publisher's site not controlled by Sanofi.

The Early Detection Library

Browse our digital library and download practical T1D tools.

Scan to open

BR1DGE Early Detection Toolkit

A practical toolkit for healthcare professionals setting up T1D screening programs.

Early-Stage T1D Communication Toolkit

Created to support healthcare professionals to tailor screening and diagnosis conversations.

BR1DGE Caregiver Handbook

A companion handbook to support consultations with caregivers.

Voyage T1D & T1D Jungle Explorer

Age-appropriate companion materials to support consultations and education about early-stage T1D with children and families.

Reference List

The following sources provide useful information about T1D and have been used in the creation of this document.

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Abbreviation List

DKA, diabetic ketoacidosis; CGM, continuous glucose monitor; ELISA, enzyme-linked immunosorbent assay; FPG, fasting plasma glucose; GADA, glutamic acid decarboxylase autoantibody; HbA1c, glycated hemoglobin; IAA, insulin autoantibody; IA-2A, insulinoma-associated antigen-2 autoantibody; IAb, islet autoantibody; ICA, islet-cell autoantibody; IFG, impaired fasting glucose; IGT, impaired glucose tolerance; ISEC, Islet autoantibody Screening and Referral Ecosystem Compendium; OGTT, oral glucose tolerance test; PCP, primary care provider; PG, plasma glucose; T1D, type 1 diabetes; T2D, type 2 diabetes; ZnT8a, zinc transporter 8 autoantibody.

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