



U.S. Coalition for Early T1D Action

November 10, 2025



8th Annual Symposium on General
Population Screening for T1D

Barbara Davis Center
November 10 - 11, 2025

U.S. Coalition for Early T1D Action

Francine Maloney, MPH
Director, Implementation



Disclosures

I have nothing to disclose

Thank You



Adam Lindsley



Ami Karlage



Asaf Bitton



Francine Maloney



Indigo Miller



Katherine Semrau



Maddy Pesec



Margaret Ben-Or



Tricia Vallabhaneni



Umila Singh

Overview

- Goals of the U.S. Coalition for Early T1D Action
- Work to date
- Looking Ahead

Goals of US Coalition for Early T1D Action

Context

- **The majority of children screened today have a first degree relative with T1D**
 - Up to 90% of children diagnosed with T1D have no known family history^{1,2}
- **Pediatric endocrinologists are the primary clinicians screening and monitoring children in the US today**
 - As of 2023, 1494 certified pediatric endocrinologists³
 - 2.0 per 100 000 children aged 0 to 18 years (range 0.6–7.2)³
- **General population screening and monitoring programs show promise**
 - Decreased the rate of diabetic ketoacidosis (DKA) at diagnosis by as much as 10-fold (from 25–62% to 4–6%) at diagnosis.⁴

¹ Haller MJ, Bell KJ, Besser REJ, et al. ISPAD Clinical Practice Consensus Guidelines 2024: Screening, Staging, and Strategies to Preserve Beta-Cell Function in Children and Adolescents with Type 1 Diabetes. *Horm Res Paediatr.* 2024;97(6):529-545. doi:10.1159/000543035

² Parkkola A, Härkönen T, Ryhänen SJ, Ilonen J, Knip M, Finnish Pediatric Diabetes Register. Extended family history of type 1 diabetes and phenotype and genotype of newly diagnosed children. *Diabetes Care.* 2013;36(2):348-354. doi:10.2337/dc12-0445

³ Haymond MW, Zeitler PS, Dabelea D, et al. Child health needs and the pediatric endocrinology workforce: Current status and prospects. *Pediatrics.* 2024;153(Suppl 2):e2023063678J. doi:10.1542/peds.2023-063678J

⁴ Sims EK, Besser REJ, Dayan C, et al. Screening for type 1 diabetes in the general population: A status report and perspective. *Diabetes.* 2022;71(4):610-623. doi:10.2337/dbi20-0054

To reach greatest impact, T1D screening and monitoring needs to happen for all children, outside of the specialist setting

Problem We Are Solving For

Current State

- Primary care providers do not have guidance to screen families for T1D.
- Families are often diagnosed at the point of DKA.
- The general population is largely unaware about T1D and screening.



Unaware
Families-at-Risk &
General Population



Underequipped
Primary Care
and Pediatricians

G
A
P

Future State

- Primary care providers can screen for early T1D, shifting diagnosis from crisis.
- T1D families have time to plan care, consider research participation, or possibly explore treatment to delay stage 3 onset.
- The general population is familiar with T1D, its signs, risks and screening.



Informed & Supported
Families-at-Risk &
General Population



Informed & Supported
Primary Care and
Pediatricians

Closing The Gap

■ **T1D Autoantibody Screening and Monitoring Solution:**

- Core clinical pathway for general population pediatric T1D autoantibody screening monitoring in primary care,
- Clinical tools, and
- Implementation guidance/resources

■ **Proposal to study the T1D Autoantibody Screening and Monitoring Solution at scale**

■ **Strategy to spread the T1D Autoantibody Screening and Monitoring Solution**



Coalition Members

Alisa Seo-Lee, MD	Daniel DeSalvo, MD	Kathryn Hilde	Lyn Nuse, MD	Martha Middlemist, MD, FAAP
Anna Floreen Sabino, MSW, CDCES	Denton Shanks, DO, MPH	Kit Nichols	Margaret Zylstra	Osagie Ebekezien MD, MPH, CPHQ
Ben Kruskal, MD	Franklin D. Hickey, PhD, RN, NEA-BC	Kurt Griffin, MD, PhD	Marian Rewers, MD, PhD	Rebecca Aguirre, MD, PhD
Carla Demeterco-Berggren, MD, PhD	Julianne Lally, DMSc, MHS, PA-C	Linda DiMeglio, MD, MPH	Marissa Lorenzetti	Ryan Lester, MPH
Colleen Buggs-Saxton, MD, PhD	Kate Millington, MD	Lisa Brown, MD, FAAP	Marlena Sherman, DNP, MPH, APRN, CPNP-PC	Sungeeta Agrawal, MD

How are we going to do it?

Convening 1

April 29-30, 2025

BOSTON

Convening 2

November 12-13, 2025

COLORADO

Convening 3

May 12-13, 2026

BOSTON

LANDSCAPE UPDATE

Literature Review
Interviews

WORKGROUPS

Co-design prototype
clinical pathway &
clinical tools

WORKGROUPS

Prototype feedback & iteration
Co-design implementation materials
Develop test and spread strategy

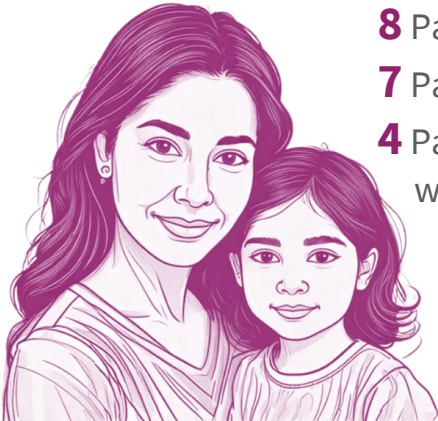
FINALIZE OUTPUTS

Work To Date

Design User Interviews—Who We Spoke to:

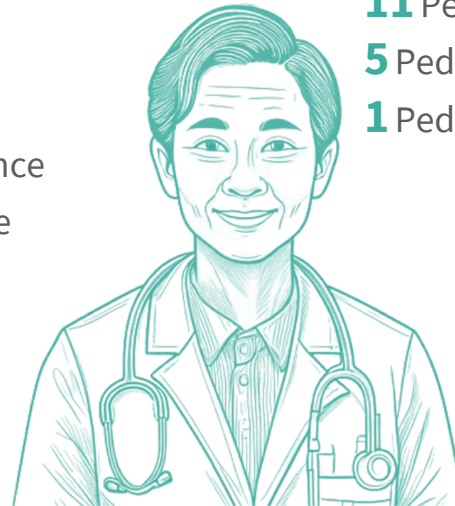
20 Caregivers

- 4** Parents with screening experience
- 8** Parents of children with T1D
- 7** Parents with no T1D experience
- 4** Parents with lived experience with T1D



17 Clinicians

- 11** Pediatric Endocrinologists
- 5** Pediatricians/PCPs
- 1** Pediatric Psychologist



“I think it will be difficult to get traction universally, but for the families who this is important to, it’s unbelievably important.”

— A PARENT WITH LIVED EXPERIENCE WITH T1D

Current State

- Primary care providers do not have guidance to screen families for T1D.
- Families are often diagnosed at the point of DKA.
- The general population is largely unaware about T1D and screening.



Unaware
Families-at-Risk &
General Population



Underequipped
Primary Care
and Pediatricians

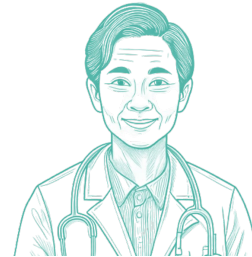


Future State

- Primary care providers can screen for early T1D, shifting diagnosis from crisis.
- T1D families have time to plan care, consider research participation, or possibly explore treatment to delay stage 3 onset.
- The general population is familiar with T1D, its signs, risks and screening.



Informed & Supported
Families-at-Risk &
General Population



Informed & Supported
Primary Care
and Pediatricians

Gaps in our Current Primary Care Ecosystem

In the current state of T1D screening and monitoring, we identified four key gaps.



AWARENESS GAP

Limited primary care clinician and public understanding of T1D screening

EARLY DETECTION GAP

Lack of implementation of screening protocol/guidelines in primary care

RESULTS GAP

Lack of primary care understanding of T1D autoantibody testing and risk implications

MONITORING GAP

Current challenges in applying monitoring guidelines for managing the progression of T1D in primary care

16 Key Opportunity Areas

Awareness

1 | Clinical Rationale

2 | Clinician Awareness

3 | Family Awareness
and Education

Early Detection

4 | Clinical Screening
Protocol

5 | Patient Identification

6 | Provider Training

7 | Clinician Support

8 | Provider-Patient Shared
Decision Making

9 | Patient Education
on Screening

10 | PCP-Endocrinology
Collaboration

16 Key Opportunity Areas

Results

11 | Clinician Training
on Results

12 | Patient-Provider
Communication on
Results

13 | Staging

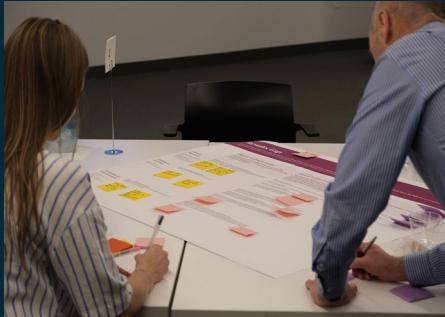
Monitoring

14 | Ongoing Monitoring
Clinical Protocol

15 | Family Counseling and
Meeting Needs of
Families

16 | PCP-Endocrinology
Collaboration

U.S. Coalition for Early T1D Action



*Ariadne held a
convening ...*

Clinical pathway brainstorming



T1D Screening & Monitoring Clinical Pathway

Screening

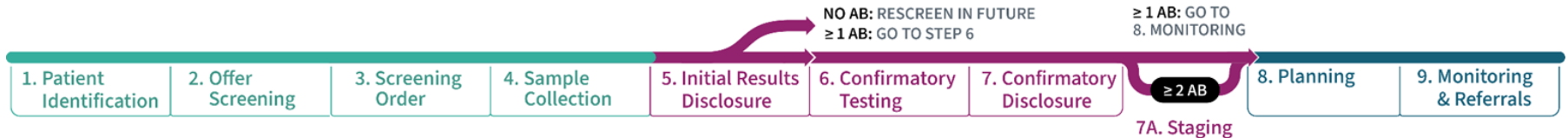
Clinical team identifies eligible children, offers screening and education, and supports shared decision making. Clinical team order screening and facilitates sample collection.

Results

Clinical team reviews results and guides patients on next steps.

Monitoring

Clinical team facilitate monitoring & treatment based on staging, progression, guidelines, and shared decision making with family



T1D Screening & Monitoring Clinical Pathway & Prototypes

Screen



FOR CLINICANS

FOR FAMILIES

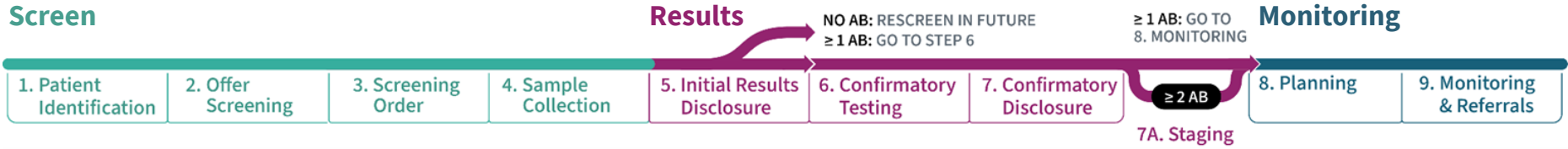
The collage includes the following documents:

- Screening Flowchart**: A flowchart detailing the screening process from patient identification to sample collection.
- T1D Monitoring Conversation Guide**: A guide for discussing monitoring with patients, including preparation, support, and follow-up.
- Monitoring Flowchart Confirmation**: A flowchart for the confirmatory testing phase.
- Monitoring Flowchart One T1D AB Monitoring**: A flowchart for monitoring patients with one autoantibody.
- Monitoring Flowchart Multiple T1D AB Monitoring**: A flowchart for monitoring patients with multiple autoantibodies.
- Family Monitoring Plan (One Autoantibody)**: A form for planning monitoring for patients with one autoantibody, including sections for understanding results, planning, and next steps.
- Understanding Your Child's Type 1 Diabetes (T1D) Screening Results**: An informational document explaining screening results to families.
- Understanding Your Child's Type 1 Diabetes (T1D) Screening Results**: Another informational document for families.
- Understanding Type 1 Diabetes (T1D)**: An informational document explaining the disease to families.
- A Guide to Understanding Type 1 Diabetes Monitoring**: A guide explaining the importance and methods of monitoring for families.
- Screen Early, Stay Healthy**: An informational document about the importance of early screening.
- Symptoms of T1D**: A document listing common symptoms of Type 1 Diabetes.

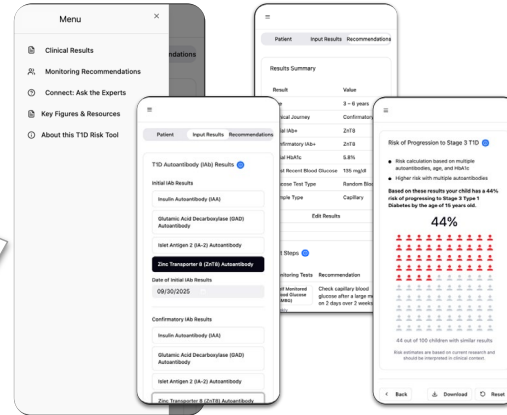
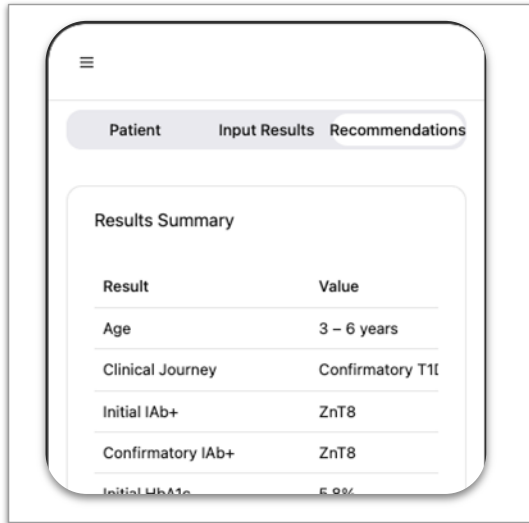
Prototype within our Clinical Pathway

Digital Tool

Screen



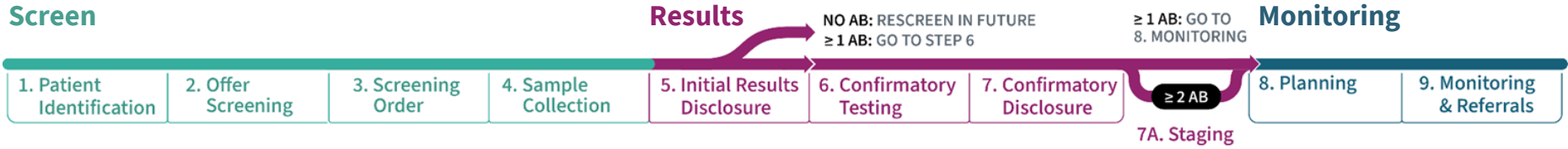
Digital Tool



Prototype within our Clinical Pathway

T1D Family Monitoring Plan

Screen



T1D Family Monitoring Plan

Patient Name: _____ Date: _____ FOR FAMILIES

Early Stage Type 1 Diabetes

Family Monitoring Plan (One Autoantibody)

We're here to help on this complex journey—Early stage type 1 diabetes monitoring can feel complicated, but we'll listen, answer your questions, and support your family so we're working through this together.

Understanding Your Child's Results

- Autoantibodies:** Your child has tested positive for 1 autoantibodies. This means your child may be at risk for type 1 diabetes. We will want to monitor.
- Blood Sugar Results**
Hemoglobin A1C (HbA1c): Shows the average blood sugar levels over the past 3 months. Date:
- Random Blood Glucose (RBG):** Shows the blood sugar levels at any time. Date:

Planning for Monitoring

- How Will We Monitor?**
 Based on your child's age and results, it is recommended that we test for autoantibodies, blood sugar, and HbA1c: Every 6 Months Every Year For years.
- What Are Your Concerns at the Moment?**
 Are there any questions, needs, or concerns your family would like to talk about?
- What Could Help?**
 Let us know what resources you need to help you succeed.

Patient Name: _____ Date: _____ FOR FAMILIES

Early Stage Type 1 Diabetes

Family Monitoring Plan (One Autoantibody)

We're here to help on this complex journey—Early stage type 1 diabetes monitoring can feel complicated, but we'll listen, answer your questions, and support your family so we're working through this together.

Understanding Your Child's Results

- Autoantibodies:** Your child has tested positive for 1 autoantibodies. This means your child may be at risk for type 1 diabetes. We will want to monitor.
- Blood Sugar Results**
Hemoglobin A1C (HbA1c): Shows the average blood sugar levels over the past 3 months. Date:
- Random Blood Glucose (RBG):** Shows the blood sugar levels at any time. Date:

Planning for Monitoring

- How Will We Monitor?**
 Based on your child's age and results, it is recommended that we test for autoantibodies, blood sugar, and HbA1c: Every 6 Months Every Year For years.
- What Are Your Concerns at the Moment?**
 Are there any questions, needs, or concerns your family would like to talk about?
- What Could Help?**
 Let us know any resources that could provide support.

Next Steps

Lab Testing	Date	Time	Location
1st Repeat Screen:			
Blood Sugar:			<input type="radio"/> RBG <input type="radio"/> HbA1c

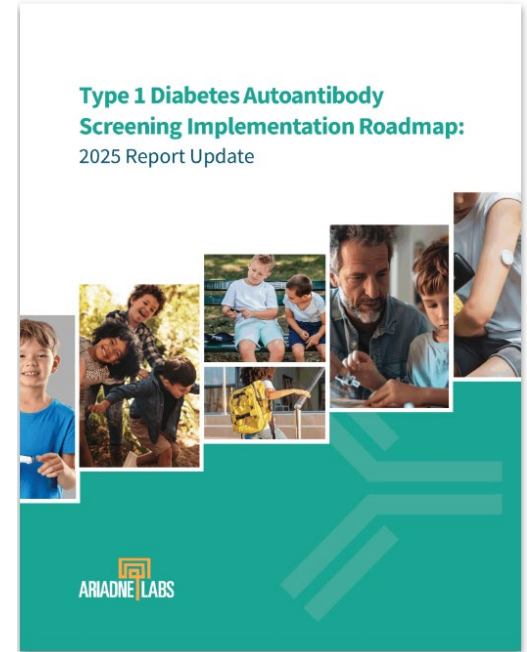
Referrals:

Referral	Date	Time	Location

Referrals:

Landscape Analysis

- Refresh on the 2022 Milken Report, providing a broader contextual understanding of the T1D screening, monitoring, and evaluation environment following Teplizumab approval
- Focuses on new discoveries and activities in the field as well as updating ongoing approaches



Looking Ahead

Key Dates

CONVENING 2

November 12 - 13, 2025

COLORADO

- Simulate the use of pathway materials & eliciting additional implementation considerations
- Discuss aims for testing solution in primary pediatric care for general population screening

CONVENING 3 (FINAL)

May 12-13, 2026

BOSTON

- Holistic review of solution—clinical pathway materials with implementation resources
- Discuss co-developed test and spread strategies

WORKSTREAMS

November 2025 - April 2026

- Refine pathway materials based on convening learnings
- Rapid cycle testing of pathway materials
- Co-develop implementation resources
- Develop a plan to test solution in primary pediatric for general population screening
- Co-develop a plan to spread solution

FINALIZING

May 2026 - August 2026

- Refine/update solution based on convening learnings
- Finalize co-developed test and spread strategies

Thank You

Contact: Francine Maloney (fmaloney@ariadnelabs.org)

ARIADNE LABS is a joint center for health systems innovation at Brigham and Women's Hospital and the Harvard T.H. Chan School of Public Health.



Brigham and Women's Hospital
Founding Member, Mass General Brigham



HARVARD T.H. CHAN
SCHOOL OF PUBLIC HEALTH