



Stakeholder Engagement in Screening

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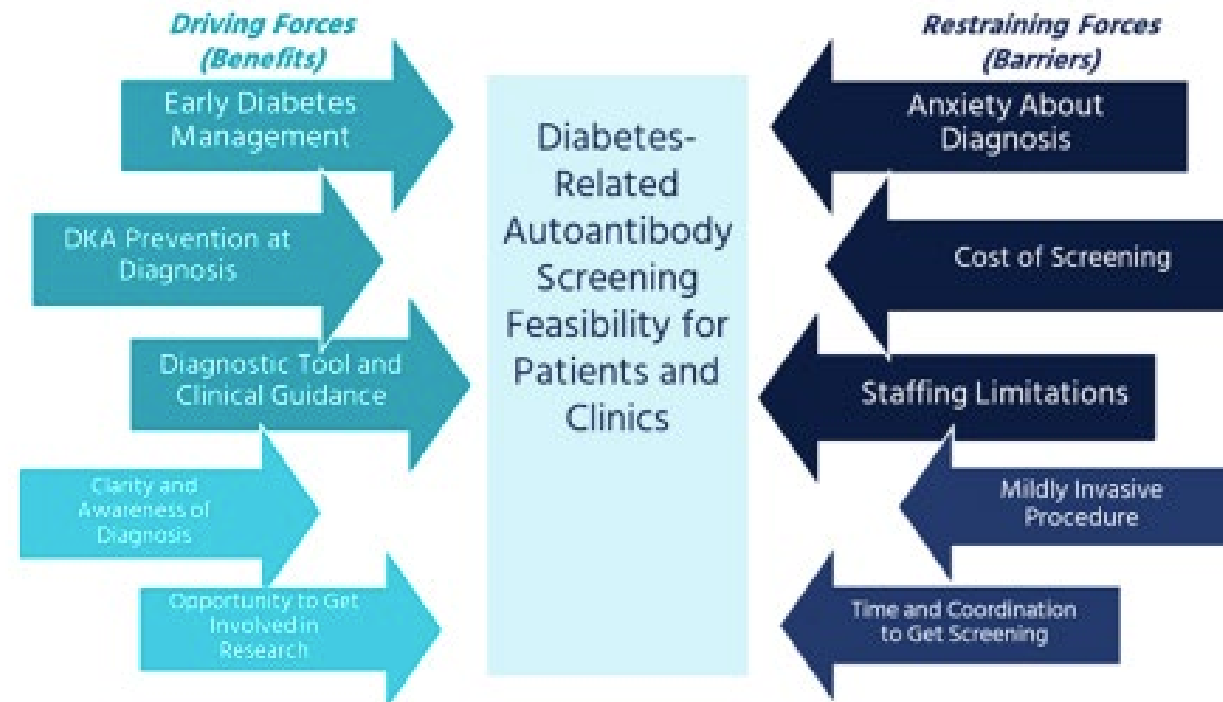


Who are our
stakeholders?

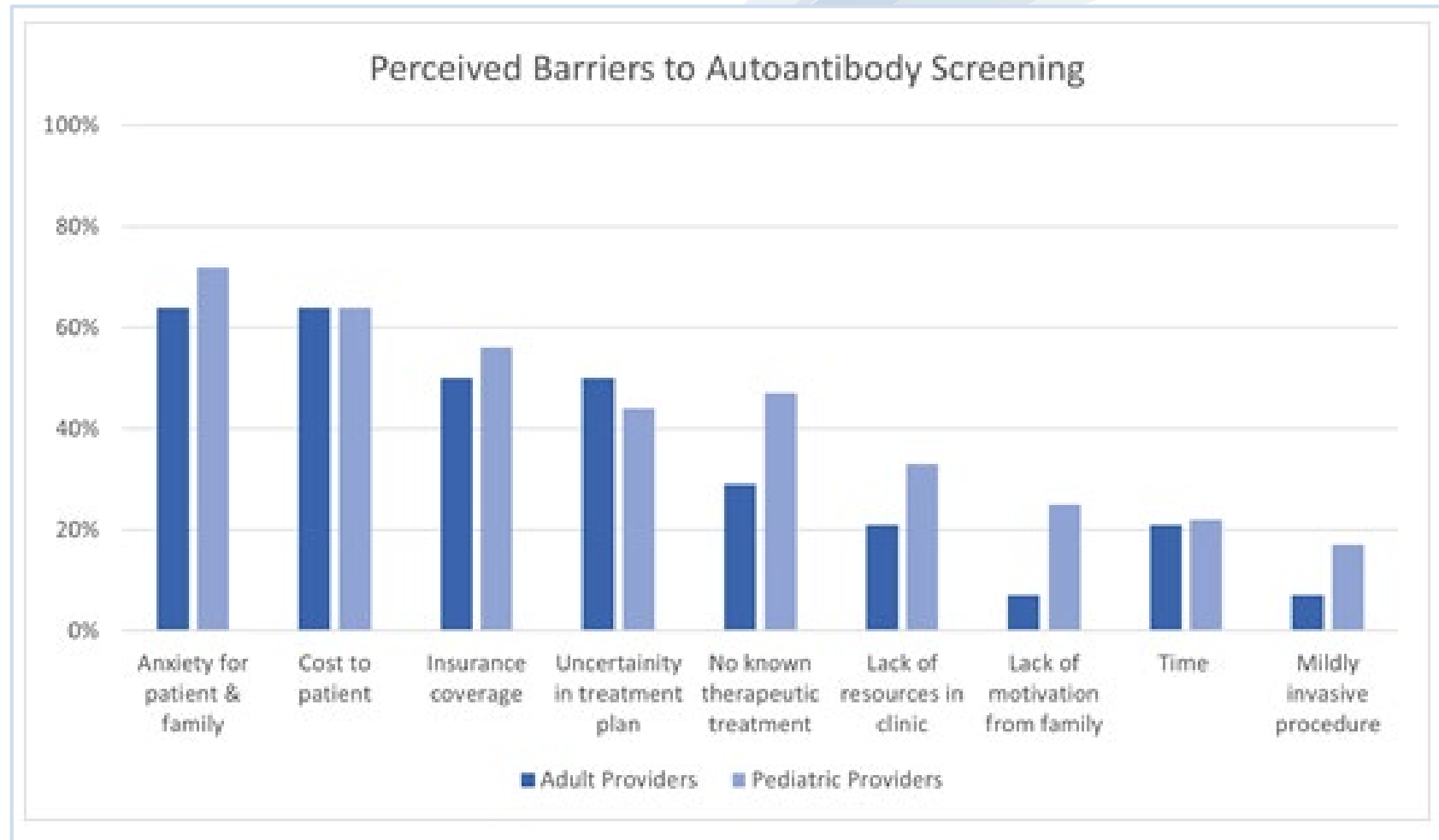
- Health Care Providers
- Parents & Caregivers
- Youth
- Pharmaceutical Companies
- Scientists
- Payers

Understanding Providers' Readiness and Attitudes Toward Autoantibody Screening: A Mixed-Methods Study

Emma Ospelt,¹ Holly Hardison,¹ Nicole Riales,¹ Nudrat Noor,¹ Ruth S. Weinstock,² Kristina Cossen,³ Priyanka Mathias,⁴ Allison Smego,⁵ Nestoras Mathioudakis,⁶ and Osagie Ebekozen,^{1,7} on behalf of the T1D Exchange Quality Improvement Collaborative

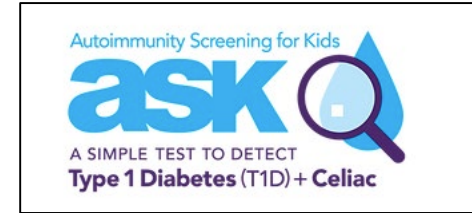


What do health care providers think?





- NIH-funded longitudinal study to identify environmental triggers of T1D in children at high genetic risk for T1D
- Eligible if identified as high risk as baby; enrolled <4.5 months
- Monitored for development of islet autoantibodies (IA) until develop T1D or reach age 15 years
- Of the 12540 approached, 4975 enrolled (39%)

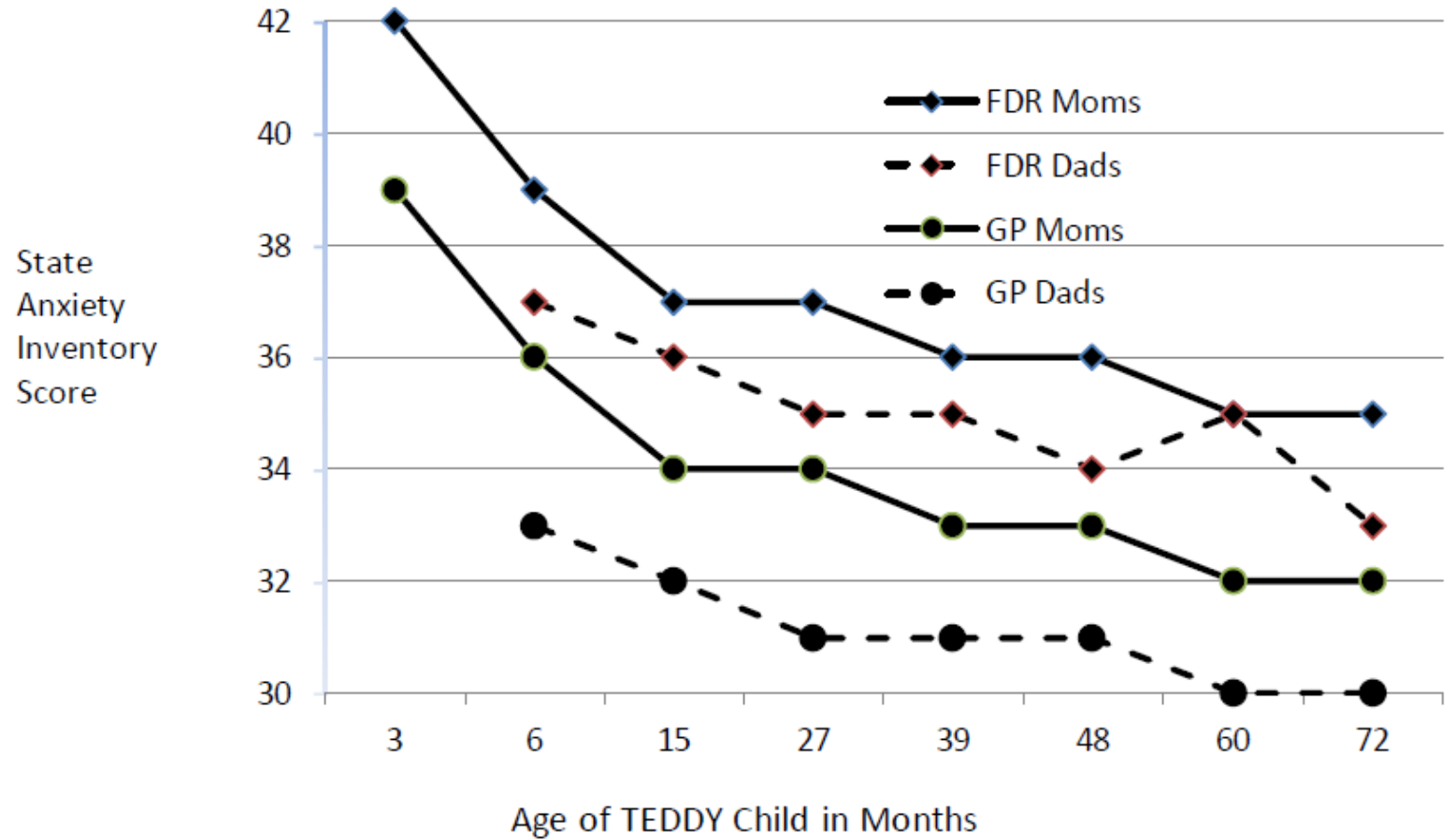


- JDRF & The Helmsley Charitable Trust funded program to screen youth in general population for IA and Celiac disease
- NO genetic testing
- Any age between 1-17 yrs
- Of the >100,000 approached, 33,229 screened (33%)

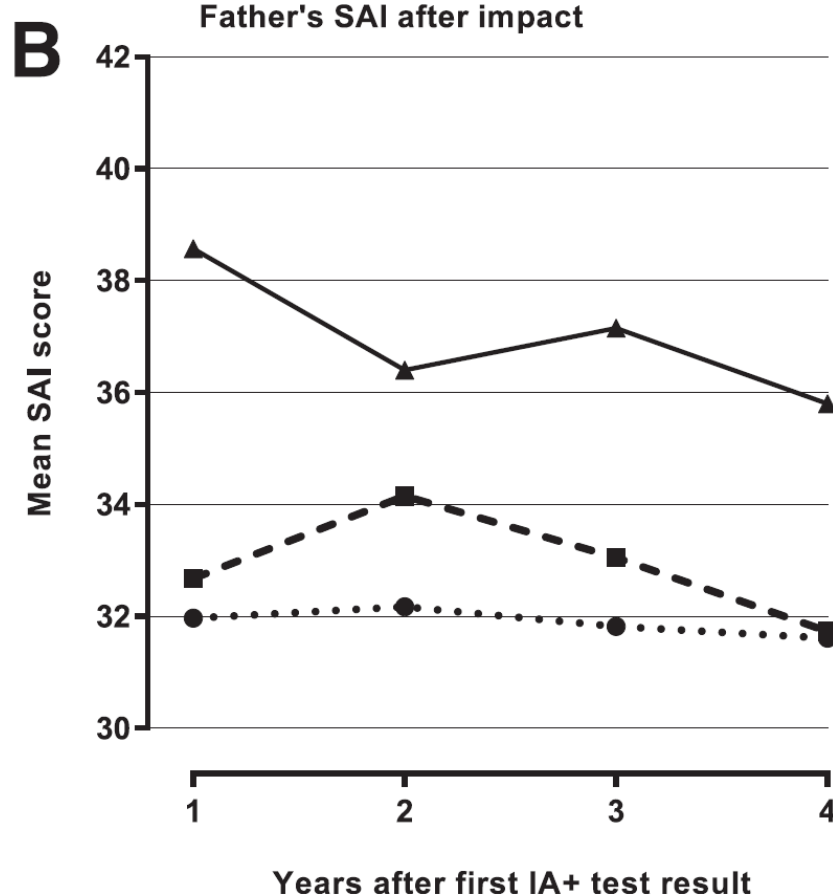
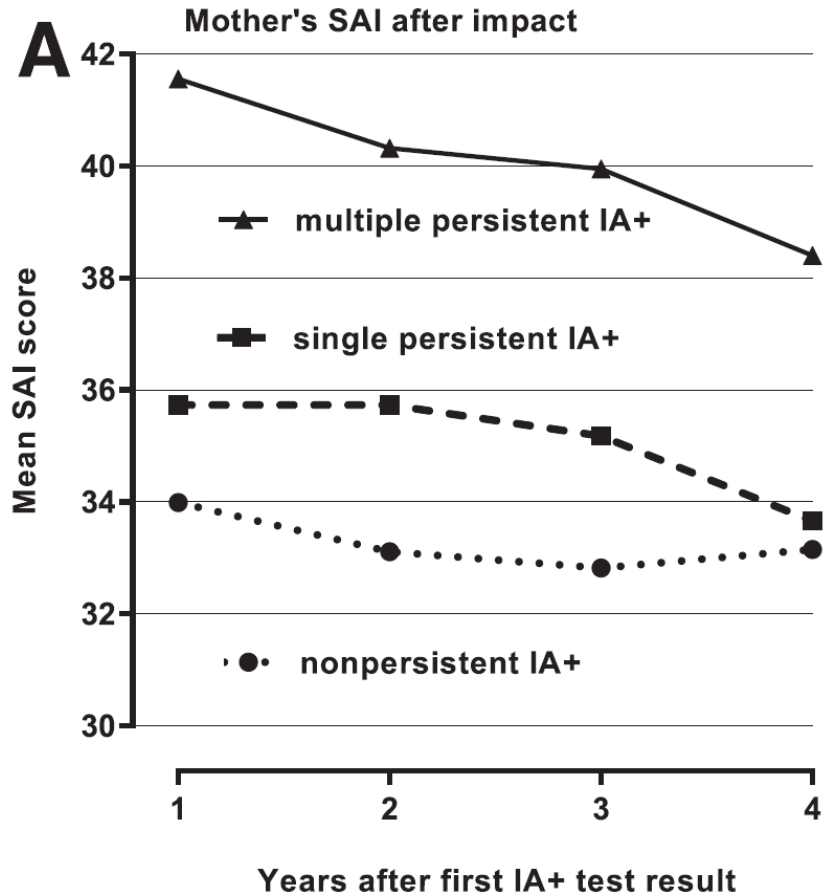
How do we assess anxiety?

- Most studies assessing anxiety in response to T1D risk have used the State Anxiety Inventory (SAI)
- The SAI measures feelings of tension, anxiety, and nervousness at a single point in time
- Participants are asked to think about their own T1D risk or their child's T1D risk when responding to items such as "I feel worried" "I feel calm"
- We use a 6-item short form of the SAI for parents
- We use a 6-item short form of the SAI-C with children starting at age 10
- Scores of ≥ 40 in parents and ≥ 37 in children are considered high

TEDDY SAI Scores: Parents of IA- Children Across Time by General Population/First Degree Relative Status



Parents Anxiety After an IA+ Test Result Monitored Over 4 Years in TEDDY

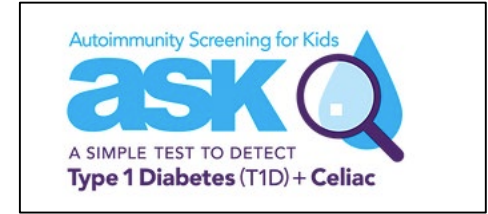


Parent Anxiety after IA+ Confirmed in ASK

Table 1—Baseline characteristics of participants (N = 280)

	Total sample	Multiple IA+ (n = 69 [24.6%])	Single IA+ by two methods (n = 65 [23.2%])	Single IA+ by one method (n = 146 [52.1%])
Caregiver				
Mother	250 (89.3)	59 (85.5)	57 (87.7)	134 (91.8)
Father	24 (8.6)	6 (8.7)	7 (10.8)	11 (7.5)
Other	6 (2.1)	4 (5.8)	1 (1.5)	1 (0.7)
Caregiver age, years	39.0 (34.0–43.0)	40 (35–44)	39 (36–45)	38 (33–43)
Caregiver education				
High school diploma or less than high school	102 (38.4)	21 (32.3)	18 (29.5)	63 (45.0)
Postsecondary	69 (25.9)	18 (27.7)	15 (24.6)	36 (25.7)
College or graduate degree	95 (35.7)	26 (40.0)	28 (46.0)	41 (29.3)
Child age, years	10.3 (6.9–13.5)	9 (5.6–12.2)	12 (8.1–14.7)	10 (7.2–13.3)
Child race/ethnicity*				
Non-Hispanic White	113 (40.4)	39 (56.5)	34 (52.3)	40 (27.4)
Hispanic, any race	140 (50.0)	25 (36.2)	27 (41.5)	88 (60.3)
Asian	6 (2.1)	1 (1.5)	0 (0)	5 (3.4)
African American	13 (4.6)	2 (2.9)	3 (4.6)	8 (5.5)
American Indian/Alaskan Native	2 (0.7)	1 (1.5)	0 (0)	1 (0.7)
More than one race	6 (2.1)	1 (1.5)	1 (1.5)	4 (2.7)
Child with first-degree relative with T1D†				
No	256 (91.4)	59 (85.5)	56 (86.2)	141 (96.6)
Yes	24 (8.6)	10 (14.5)	9 (13.8)	5 (3.4)
Mother	6 (2.1)	2 (2.9)	3 (4.6)	1 (0.7)
Father	8 (2.9)	3 (4.4)	3 (4.6)	2 (1.4)
Sibling	10 (3.6)	5 (7.2)	3 (4.6)	2 (1.4)
Mean (SD) anxiety score	46.1 (11.2)	47.0 (9.0)	44.7 (12.5)	46.3 (11.6)
Parent perception of child's T1D risk†				
Not at increased risk	143 (51.1)	23 (33.3)	29 (44.6)	91 (62.3)
At increased risk	137 (48.9)	46 (66.7)	36 (55.4)	55 (37.7)

Data are presented as n (%) or median (interquartile range) unless otherwise noted. *Indicates significant difference among groups at $P < 0.01$. †Indicates significant difference among groups at $P < 0.001$.



What do we know? Parent Anxiety

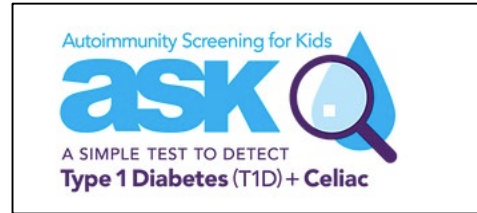
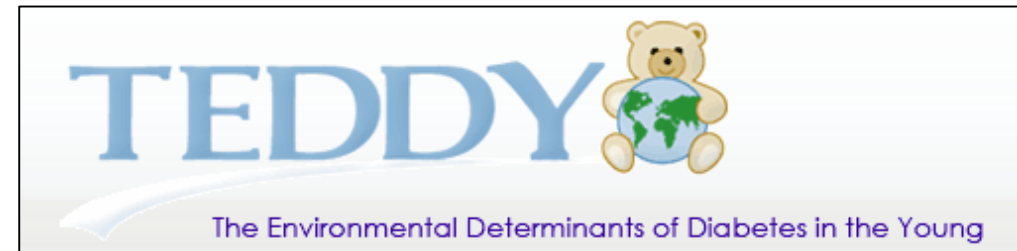


Table 2—Multivariate linear regression factors associated with parental anxiety at baseline (N = 280)

	β estimate	95% CI	P
Intercept	37.0	27.6–46.5	<0.0001
Diabetes risk by autoantibodies (ref = single IA+)			
Single IA+ by two methods	0.0	–3.7 to 3.7	0.83
Multiple IAs+	1.4	–2.3 to 5.1	0.45
Age of child (per year)	0.0	–0.4 to 0.4	0.92
Age of parent (per year)	0.0	–0.2 to 0.2	0.98
Parent education (ref = college or graduate degree)			
Postsecondary	4.1	0.0–8.1	0.05
High school diploma or less	8.1	3.9–12.3	<0.001
Child race/ethnicity (ref = non-Hispanic White)			
Hispanic, any race	4.2	0.4–8.0	0.03
All others	4.9	–0.6 to 10.3	0.08
Child has first-degree relative with T1D (Ref = No)			
Yes	3.3	–1.7 to 8.4	0.20
Parent’s perception of child’s T1D risk (ref = not at increased risk)			
At increased risk for T1D	3.7	0.6–6.9	0.02

Ref, reference.

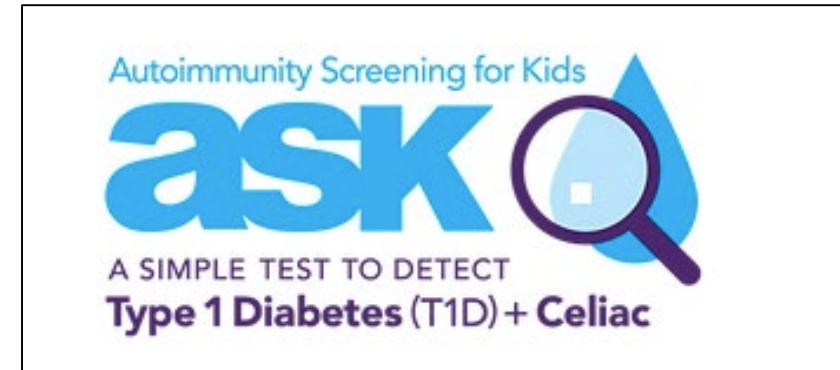
TEDDY Child SAI-C in Response to Risk of Getting Diabetes



Child Anxiety

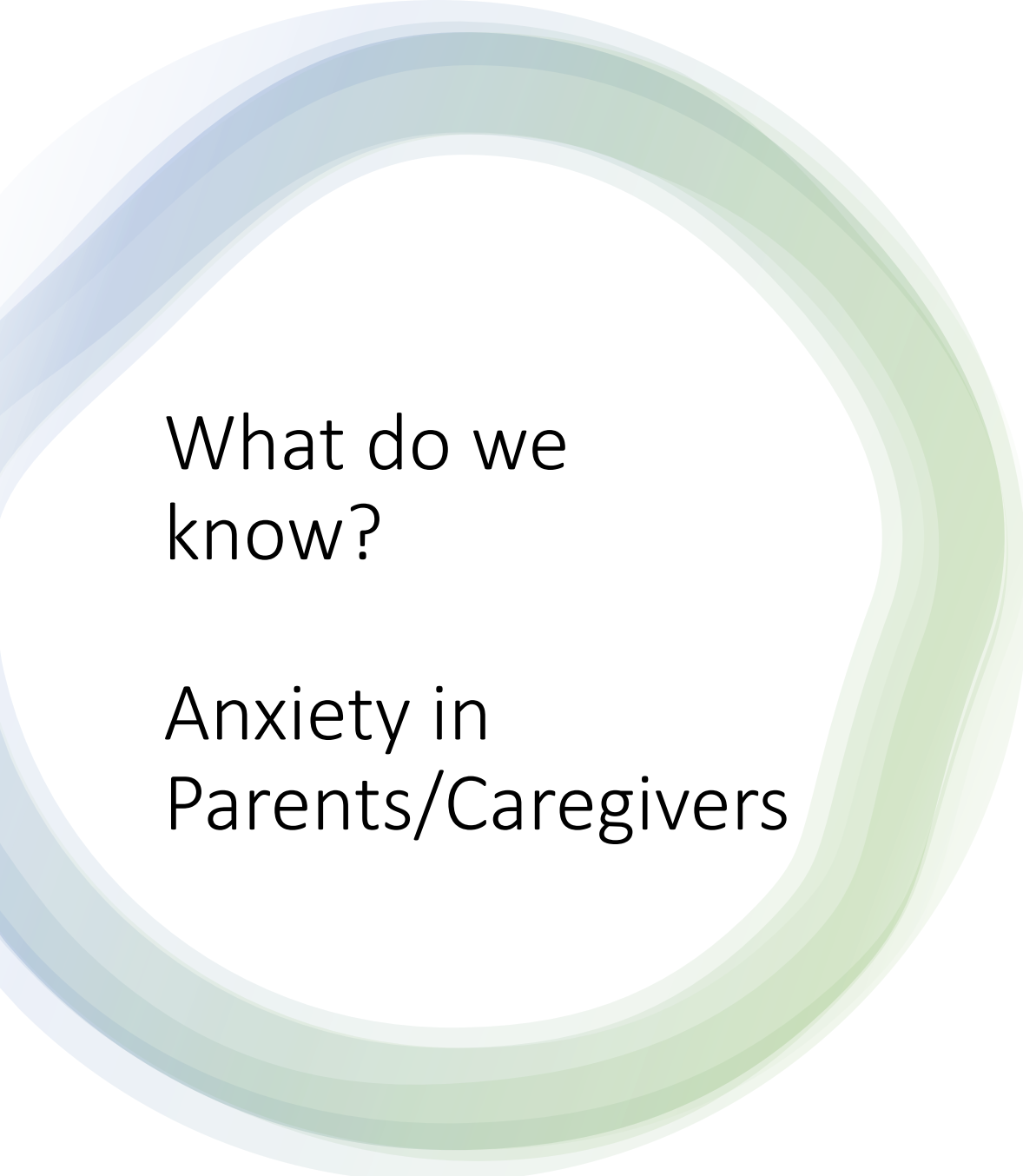
	10 (n=3749)	11 (n=3951)	12 (n=4002)	13 (n=3681)	14 (n=2925)	15 (n=2103)
Mean	35	35	35	35	35	35
% \geq 37	40%	39%	37%	37%	36%	37%

ASK Child SAI-C in Response to Risk of Getting Diabetes



Child Anxiety

	10 (n=27)	11 (n=23)	12 (n=23)	13 (n=20)	14 (n=20)	15 (n=12)
Mean	41	38	37	37	38	39
% \geq 37	78%	61%	57%	45%	60%	75%



What do we
know?

Anxiety in
Parents/Caregivers

- Most studies have been done with parents
- Mothers are more anxious than fathers
- Parents with a family history of T1D are more anxious than parents with no family history
- Repeated IA- test results is associated with a decline in anxiety over time
- IA+ test results increase anxiety
- Anxiety is greatest in those whose children have multiple IA+ test results; many have significant anxiety which can last for long periods of time



What do we know?

Anxiety in Youth

- A substantial number of children are anxious about their own T1D risk.
- Factors associated with that anxiety have yet to be determined.

Why is anxiety in response to T1D risk important?

- We are ethically obligated to monitor impact of studies like TEDDY, ASK on participant's emotional well-being.
- Anxiety about T1D risk is associated with
 - Study drop out
 - Study compliance
 - Behaviors to try and prevent T1D (e.g., changing diet)
 - Behavior change in both a natural history study (e.g., TEDDY) or a prevention trial (e.g., TRIALNET) could affect results



Increasing Stakeholder Engagement in Early T1D

- Data suggest that providers' concerns about anxiety are valid.
- Considering psychological impact of screening and *how* to address associated anxiety may increase stakeholder engagement.
- Anxiety is treatable! It is a modifiable barrier but must be considered to increase engagement.
- Truly informed consent (i.e., stating anxiety is a risk) may help screen out those for whom screening and monitoring is not a good fit.
- There are other concerns to be considered (i.e., costs). Will participants engage if they have to pay for screening or monitoring?



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