Pre-Symptomatic T1D Screening and Monitoring: A Quality Improvement Change Package

Prepared by T1D Exchange; Funded by Breakthrough T1D

Contents

Introduction

A change package is a document that describes the improvement methodology for a clinical or operational process. This change package is intended to be a pragmatic guide of best practices, ideas, tools, and strategies that can be adapted to a new setting, thereby accelerating implementation.

The pre-symptomatic T1D Screening and Monitoring pilot program presented here represents shared learning from two clinical T1D Exchange Quality Improvement Collaborative (T1DX-QI) centers. The project was funded by Breakthrough T1D and led by the Investigators below:

- **T1D Exchange** (Boston, MA) - Osagie Ebekozien, MD, MPH
- **University of Florida** (Gainesville, FL) –Laura Jacobsen, MD
- **Rady Children's Hospital** (San Diego, CA) – Carla Demeterco-Berggren, MD, PhD

Background

Annually about 64,000 new cases of type 1 diabetes (T1D) are diagnosed in the United States, almost half of which are in people younger than 18 years. (1) The risk of developing T1D is 15 times higher than those with a first-degree relative with T1D, however, 85% of people with T1D have no known family history of the disease. (2)

There are three stages of T1D progression (3):

- **Stage 1** autoantibodies (markers in the blood that indicate an increased risk of developing T1D) develop and beta cell function begins to decline.
- **Stage 2** beta cell function continues to decline, and dysglycemia is present; and
- **Stage 3** where symptoms of T1D and hyperglycemia are present.

Time of progression from stage 1 to stage 3 ranges from months to years.

Rationale

Type 1 diabetes autoantibodies (AA) can be detected months to years before clinical onset (stage 3) of T1D. T1D AA includes islet cell (ICA), insulin (IAA), glutamic acid decarboxylase (GADA), IA-2A, and zinc transporter 8 (ZnT8). Nearly 100% of children with multiple AA will ultimately progress to Stage 3 T1D, compared with 15% who have a single islet autoantibody. (4,5)

Screening and monitoring for T1D AA could inform individuals' risk of developing T1D before the onset of clinical symptoms, allowing the opportunity for early disease management and possible mitigation of the psychological distress that comes with an unexpected diagnosis, allowing people to be educated before diagnosis and preventing diabetes related ketoacidosis (DKA). (6) More than 50% of children experience DKA at the time of T1D diagnosis. (7,8) Although the mortality rate of DKA in children is low (9) but is associated with harmful long-term outcomes, including detrimental neurocognitive outcomes (10-12) and not meeting recommended glycemic target. (13-15)

Additionally screening for AA reduces the risk of DKA at clinical diagnosis. (16,17) Current American Diabetes Association (ADA) Standards of Care recommend AA screening and monitoring for pre-symptomatic T1D in the setting of a research study or considered an option for first-degree family members with T1D (18). New programs exploring general population Screening and Monitoring are expanding. (5)

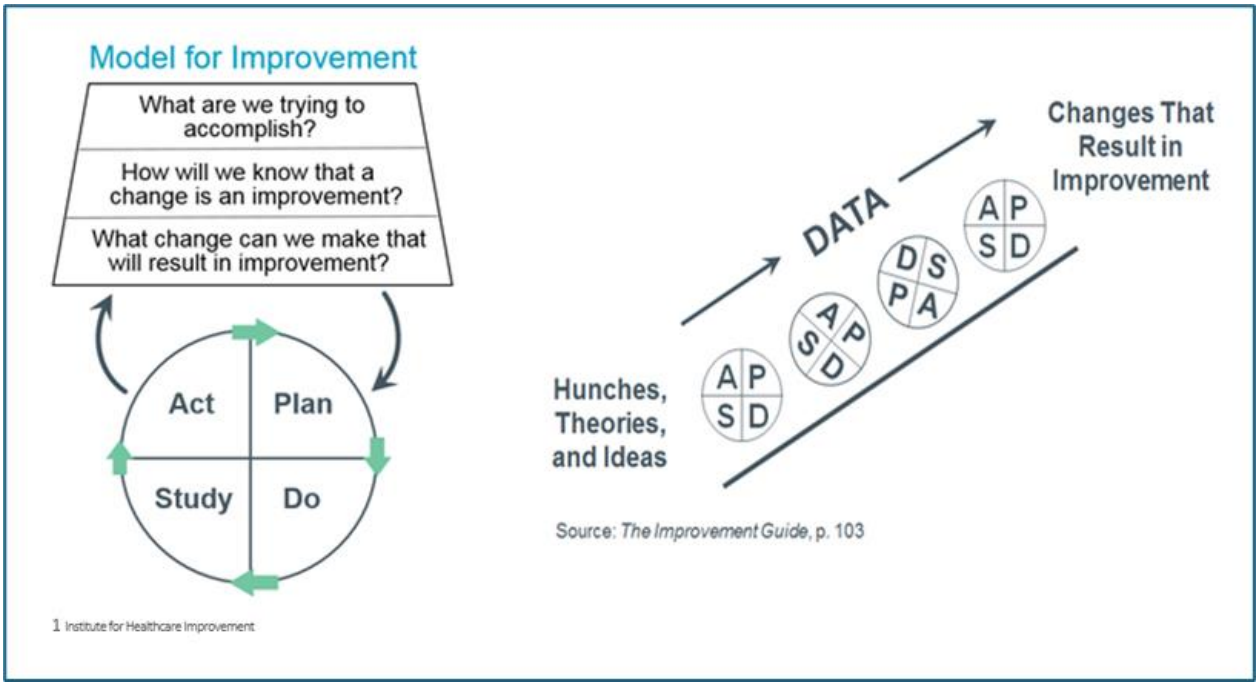
Project Objectives

The T1D Pre-symptomatic Screening and Monitoring pilot objective is to operationalize routine screening and monitoring for stage 1 and stage 2 T1D in a real-world setting.

Improvement Method

The centers utilized a modified *Model for Improvement* cycles and quality improvement tools (Figure 1) to map current process, understand contributing factors and test new practices.

Figure 1: Model for Improvement and Plan-Do-Study-Act cycles



The T1DX-QI coaching staff worked with each center on developing practical solutions for incorporating Screening and Monitoring for T1D. These solutions were tested for brief periods with successful approaches continuing and unsuccessful approaches modified until operationalization of Screening and Monitoring practice is achieved.

Map of Current Process

Process mapping is an early analysis tool used to either design a new workflow or map the current state for assessment of improvement opportunities (clinical care safety, quality, service delivery). Complexity (the number of hand-offs between process steps) is made visible and efforts to reduce the number of exchanges by co-locating the work and combining activity steps is desirable wherever possible.

Each site mapped the design of their screening and monitoring flows, improving as process steps were implemented using the PDSA process.

Figure 2: University of Florida Process Map

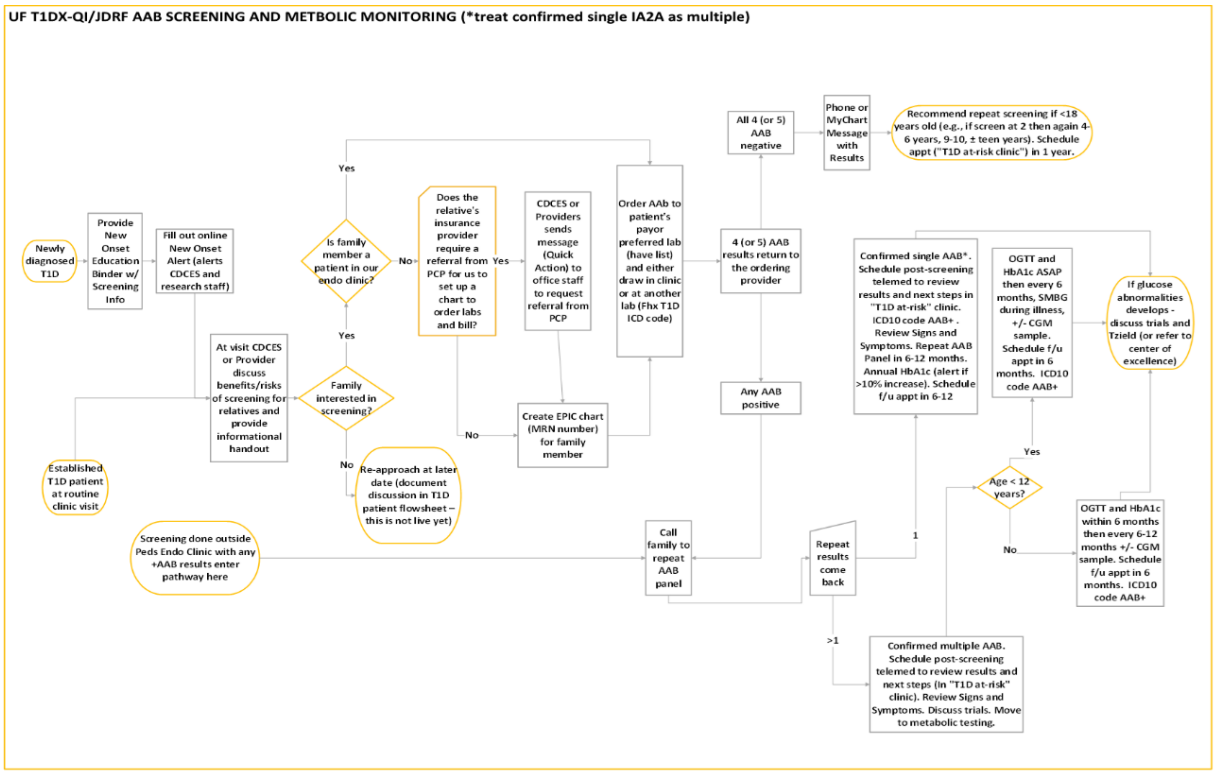
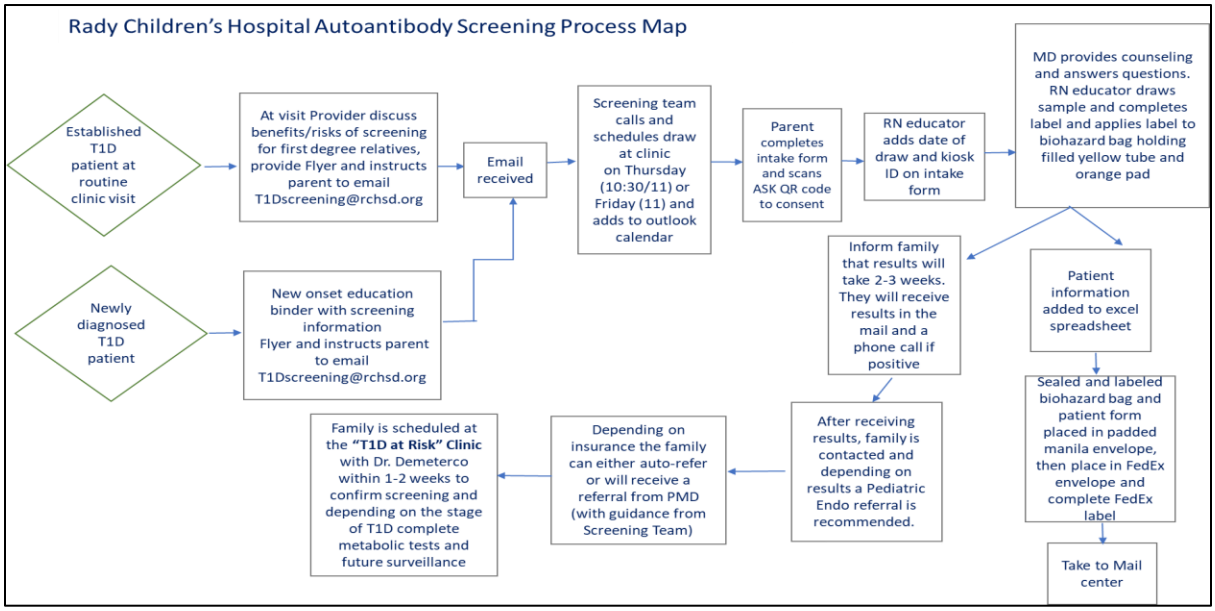


Figure 3: Rady Children's Hospital Process Map



Contributing Factors to successful AA Screening and Monitoring

Guided by the project aim, each site categorized the resources involved in their screening and monitoring process, drawn on a “fishbone” diagram, listing current problems in each category and then brainstorming possible solutions to test in addressing that constraint during the PDSA process.

Figure 4: University of Florida Fishbone Diagram

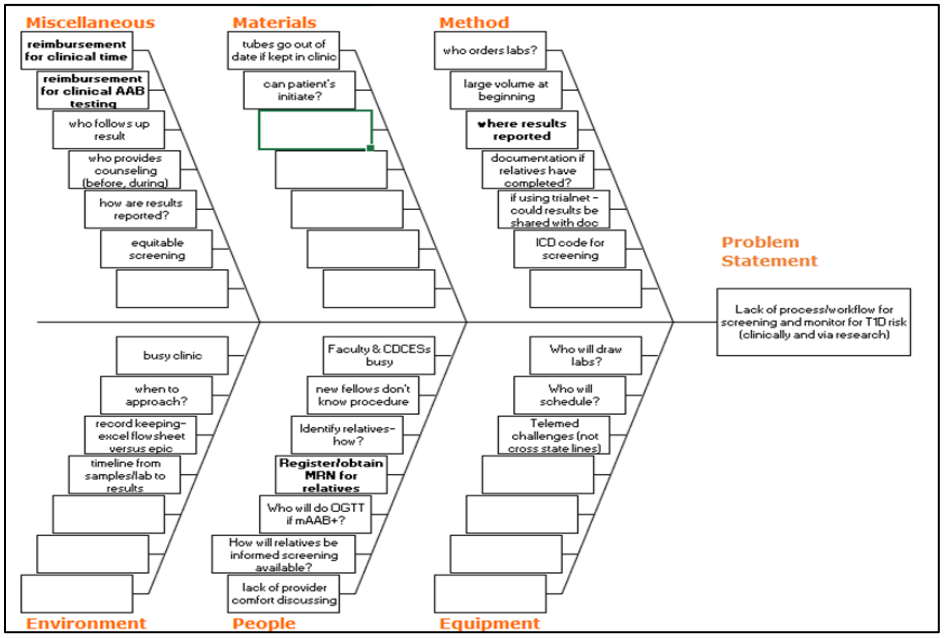


Figure 5: Rady Children’s Hospital **Fishbone Diagram**

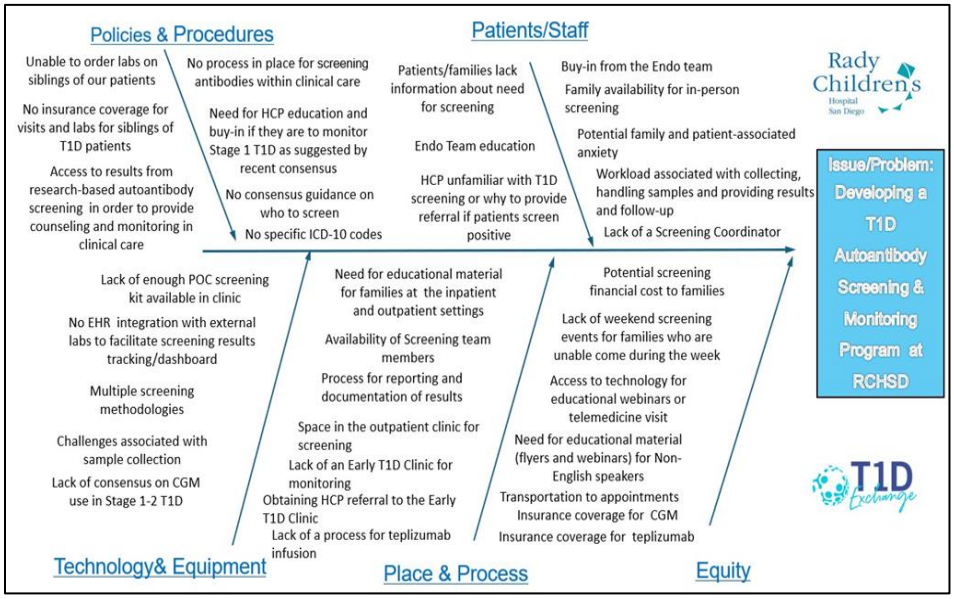
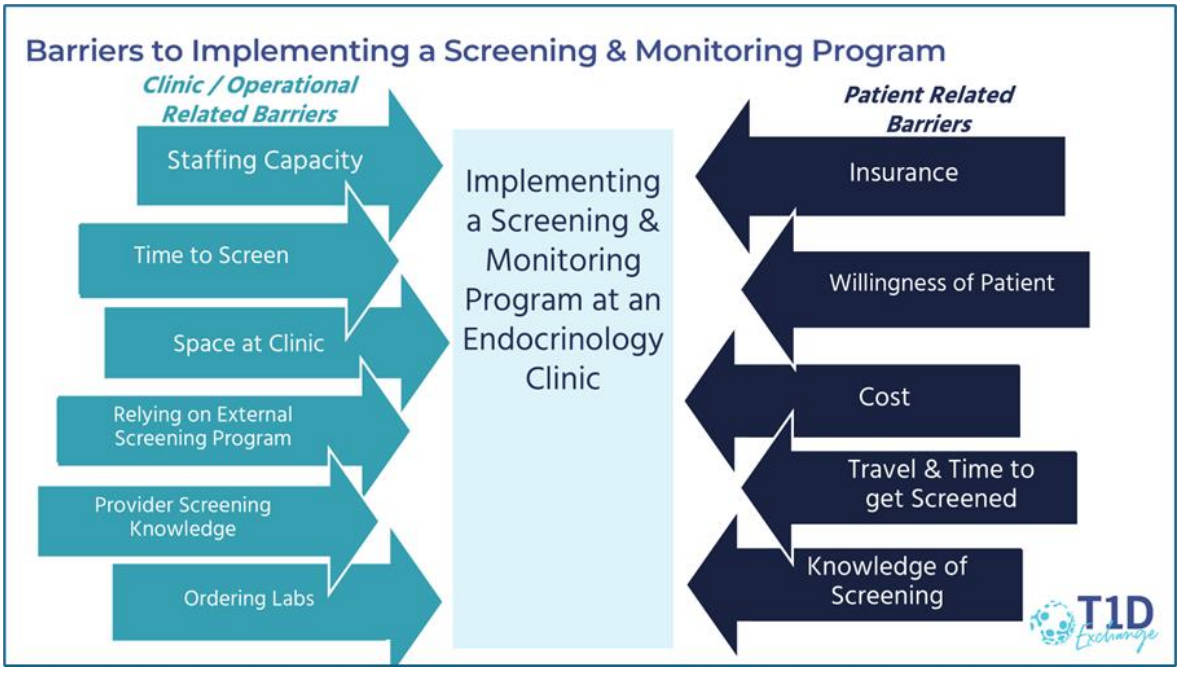


Figure 6. Summary Clinic, Operational, and Patient-Related Barriers to Implementing a Screening Program

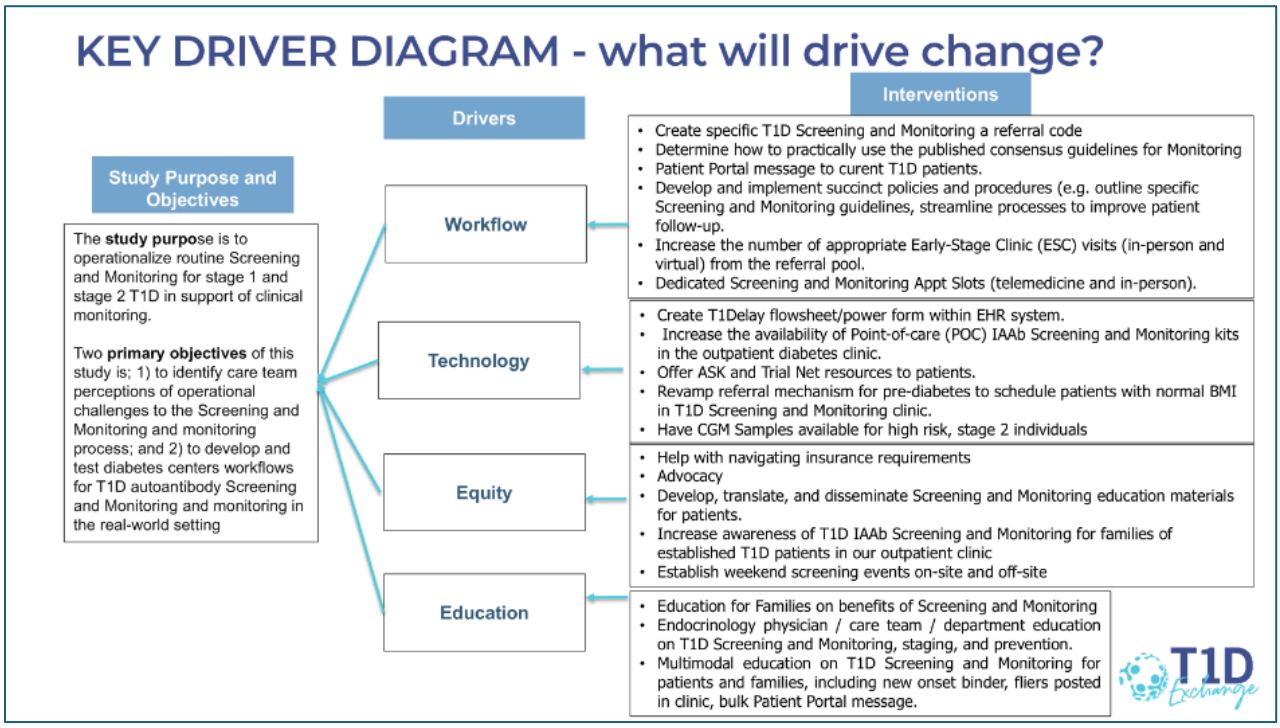


Interventions Tested

Quality process interventions were implemented to develop and test diabetes centers' workflows for AA screening and monitoring in both centers. Quality improvement methodologies were used, as well as the initial development of consensus materials for both *patient counseling* and *provider education* regarding patients screened positive for T1D autoantibodies. T1D screening and monitoring protocols were developed, educational coaching on operational changes was conducted, and iteration *PDSA process* took place to incorporate successful approaches and refine unsuccessful approaches with the goal of operationalizing a screening and monitoring program in each center.

The four focus areas of these PDSA processes identified to target change were education, workflow, technology, and equity (Figure 7).

Figure 7. Key Driver Diagram for Pilot Project



Providing **education on screening and monitoring** for both patients and providers is crucial to the success of this project. Education was provided to families benefits of T1D AA screening and monitoring and health care professionals on T1D screening and monitoring, staging and prevention and various delivery modes were tested and modified based on feedback through tests of change. Physician education was offered to both primary care and endocrinology physicians. For primary care, project leads informed them why they may be reaching out and asking for referrals for siblings who screened positive. Teams developed standard operating procedures for creating new charts in the EHR and ordering labs to train new staff and tracked insurance denials of laboratory testing and clinic visit reimbursement. Centers met with insurers and developed a letter of medical necessity for autoantibody testing. Additionally, centers created multimodal education on T1D AA screening and monitoring for patients and families, including new onset binder, flyers posted in clinic, and bulk electronic Patient Portal messages

Integrating screening and monitoring into an existing workflow was another important target area. Workflow related tests of change included developing and

implementing policies and procedures that outlined specific screening and monitoring guidelines and streamlined processes to improve patient follow-up. Other examples include creating a new referral code for T1D screening and monitoring to avoid longer waitlists than a typical diabetes clinic, increasing the number of appropriate Early-Stage Clinic (ESC) visits (in-person and virtual) form the referral pool, and creating dedicated screening and monitoring appointment visits. Periodic Patient Portal messages were sent to current patients with T1D to inform them of screening for relatives.

Technology related tests of change targeted ways to improve the efficiency of using technology in clinic (such as using the EHR system itself) related to screening and monitoring, and patient-related technology. Examples of these included creating T1D delay flowsheet and power forms within electronic health record systems, revamping referral mechanisms for pre-diabetes to schedule patients with normal BMI in T1D screening and monitoring clinic, and modifying the clinic note template based on feedback. Other modifications included increasing the availability of point-of-care islet autoantibody (IAAb) screening and monitoring kits in the outpatient diabetes clinic, switching from obtaining 2 lab tubes (rather than 5) for the IAAb tests and color coding these (1 gold, 1 red), and having CGM samples available for high risk, stage 2 individuals. Centers made sure to have care team members offer ASK and Trial Net resources to patients.

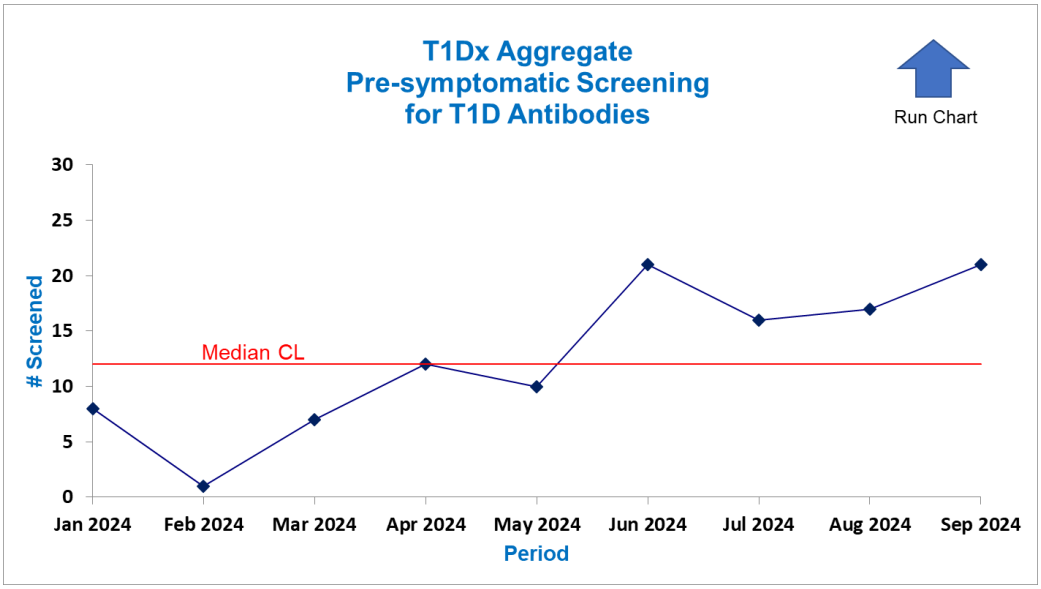
Lastly, **equity related tests of change t**argeted advocacy for equal access, treatment and patient care. This was addressed initially by increasing awareness of screening and monitoring for all families of established T1D patients in outpatient clinics. Centers advocated for enhanced assistance with navigating insurance requirements, including provision of letter of medical necessity and developing, translating and disseminating screening and monitoring materials for patients, and including this in languages other than English. Additionally, weekend screening events were established both on and off site to offer more times for families to be screened.

Data Collection and Analysis

Data was shared monthly with the T1DX-QI coordinating center. Run and statistical process control charts were plotted to observe trends and shifts.

Over the course of the project, a total of **110 individuals** aged 1-25 years were screened at the two pilot centers. The number screened per month increased at each center month by month, starting with a combined total of 8 individuals screened in January, and more than doubling the amount screened to 21 individuals per month by the end of the project. (Figure 7)

Figure 8. Number of Individuals Screened Over Time During Project from Both Centers



Additionally, the number of individuals that had a scheduled monitoring appointment after receiving their screening results per the consensus guidelines was tracked over time. These individuals were the ones that received confirmed positive test results. The figure below (Figure 8) outlines monitoring over time. The number per month fluctuates from January to September and is tied to the results of the individuals screened.

Demographic information was collected and aggregated among the total screened population (Table 1). Most individuals screened were White (72%), Non-Hispanic or Latino (67%), and have private insurance (59%). This population was made up of mostly family members of patients with type 1 diabetes who were existing patients at each center. More detailed metrics were collected and aggregated for those who received positive results for multiple autoantibodies including which autoantibodies they were positive for, the stage they presented in, their A1c, and interventions offered to them based on eligibility criteria.

Table 1**:** Demographic Information for All Screened Individuals

Demographic Variables	**N = 110 (%)**
Race	
White	79(72)
Black or African American	7(6)
American Indian or Alaska	1(1)
Native	4(4)
Asian	6(5)
Other	13(12)
Unknown	
Ethnicity	
Hispanic or Latino	25(23)
Non-Hispanic or Latino	67(61)
Unknown	18(16)
Insurance Type	
Private	65(59)
Medicaid	26(24)
Military	5(5)
Medicare	3(3)
Other	2(2)
Unknown	9(8)

Of the total population screened, 22.7% received initial positive results, and after repeat testing, 11.8% received confirmed positive results with multiple autoantibodies. The most common autoantibodies present were GADA (85%) and ZnT8A (77%) for those with confirmed positive results. Table 2 below shows a full breakdown of autoantibody

types for individuals in the study population with confirmed positive results for multiple autoantibodies.

Table 2**:** Type of Autoantibody for Screened Individuals with Confirmed Positive Results

Type of Autoantibody	Percent of Screened Individuals
GADA	85%
ZNT8A	77%
IA2A	54%
IAA	31%
ICA	31%

GADA- glutamine acid decarboxylase; IA2A- insulinoma-associated-2 autoantibodies; IAA-insulin autoantibodies; ZNT8A- Zinc Transporter 8 antibodies; ICA- islet cell cytoplasmic autoantibodies

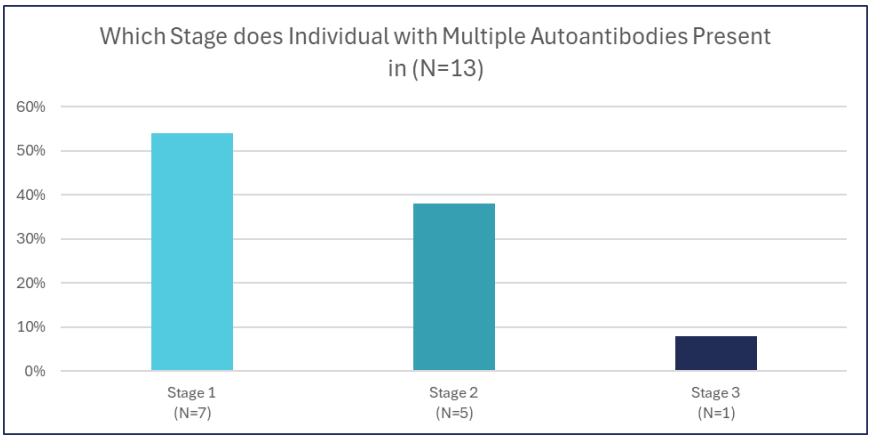
Demographic information was collected and aggregated among this population as well. Like the entire population screened, most individuals with confirmed positive results were White (77%) and Non-Hispanic or Latino (62%), with private insurance (54%). The full breakdown of demographic information is shown below in Table 3.

Table 3. Confirmed Positive Multiple Autoantibody Individuals Demographics

Demographic Variables	**N = 13 (%)**
Race	
White	10(77)
Black or African American	1(8)
Asian	0(0)
Unknown	2(15)
Ethnicity	
Hispanic or Latino	2(15)
Non-Hispanic or Latino	8(62)
Unknown	3(23)
Insurance Type	
Private	7(54)
Medicaid	3(23)
Military	1(8)
Unknown	2(15)

In addition, 100% of individuals with a confirmed positive test result had no documented DKA event in the last 12 months. During screening, more than half (54%) of individuals with multiple positive confirmed autoantibodies presented in stage 1 with normal blood glucose levels (Figure 9), and 8% presented in stage 3 with blood glucose levels above ADA diagnostic thresholds or a1c is greater than or equal to 6.4%.

Figure 9. Stage of T1D that Individuals with Confirmed Positive Results



All screened individuals that received confirmed positive results for multiple autoantibodies have a follow-up visit scheduled within the following year at a minimum. Following the new consensus guidelines, depending on the age of individual and antibody status, monitoring appointments are scheduled according to guidelines.

Monitoring

Every individual who was screened and received confirmed positive results, regardless of single versus multiple antibody status, was offered monitoring as a form of intervention

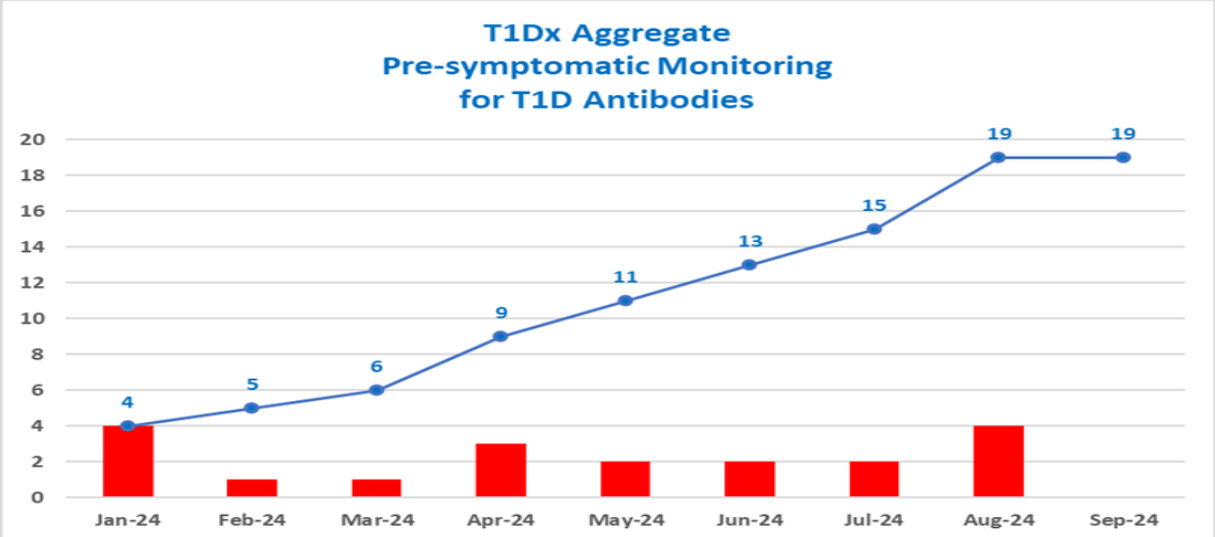
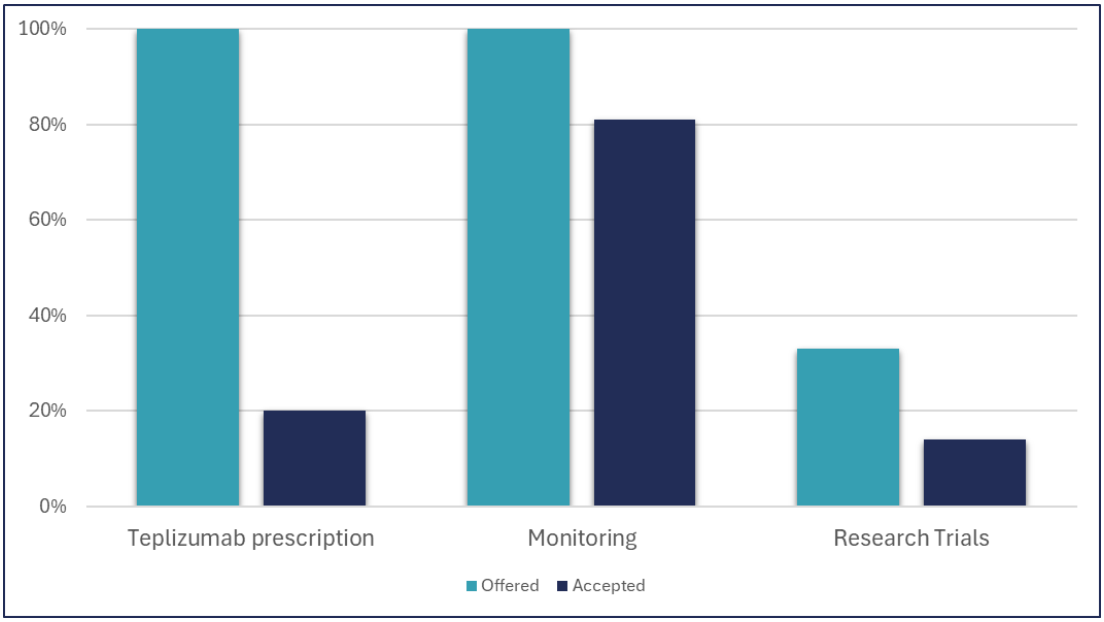


Figure 10 Number of Individuals monitored

Throughout this pilot project, three interventions were monitored and offered to screened individuals based on eligibility criteria including monitoring, participating in research trials, and offered a Teplizumab prescription (Figure 11). . Out of all individuals offered monitoring, 81% accepted it as an intervention, and had a follow-up visit scheduled with an endocrinologist. All individuals who were in stage 2 and 8 years of age or older were offered Teplizumab; of those individuals, 20% accepted it as a form of intervention. Lastly, 33% of individuals were offered to participate in a research trial as a form of intervention, and 14% elected to participate. The availability of clinical trials has been limited.

Figure 11. Interventions Offered to & Accepted by Screened Individuals with Confirmed Positive Results



Lessons Learned

Centers shared lessons learned over the course of this pilot project, highlighting things that worked well and helped facilitate growth within this project, and things that did not work as well and were barriers to success. These findings were echoed through focus group findings as well.

Things that worked well and were important for success in this project included proper communication with healthcare professionals and patient populations. Creating proper communication channels to inform both the healthcare and patient community about screening and monitoring was essential. This included creating informative flyers that were available at both outpatient and inpatient settings. One center created an email address dedicated to screening and monitoring questions which proved to be extremely useful. The screening team had access to this and were able to monitor and track referred patients.

EHR related successes included creating a unique referral code to the “T1D at-risk” clinic, creating a note template following the monitoring consensus guidelines, and once autoantibody positive, the ICD10 codes E10.AO, E10.A1, E10.A2 (T1D presymptomatic) applies and were effective as of October 1st 2024. These ICD 10

codes allow for tracking overtime of pre stage 3 clinical diabetes, including stages 1 and 2. Advocating for insurance coverage and no cost has been a facilitator in the success of this project. For one center, the ICD10 code Z83.3 (family history of type 1 diabetes) has been covered at local labs by insurers. Other facilitators included clinical coordinators seeing families at the end of visits for one center, informing them about screening for their family members, and the other centers partnership with the ASK program that provided screening kits to be available in clinic.

Things that did not work well or acted as barriers to the success of the project were identified during fishbone exercises and illustrated in diagrams included the need for provider education and buy in from people outside of the direct endocrinology team. This is essential for the continued expansion of screening and monitoring.

The biggest barriers were time, cost, and training. A significant amount of time is needed to screen and collect these screening samples, as well as for pre-screening counseling and waiting for reimbursements results. Additionally, for monitoring specifically, metabolic monitoring labs such as OGTT and materials such as Glucola and even CGM samples are needed in the clinic. Barriers related to the EHR included creating new MRN’s and obtaining referrals to pediatric endocrinology.

Summary

Sites tested and scaled interventions using rapid PDSA cycles, and successful changes were scaled and sustained. Although pre-screening and monitoring for T1D is complicated, it is achievable with gradual and consistent changes to processes at all levels of care.

This study provided learning opportunities for the participating centers, and valuable insight was gained relating to facilitators and barriers to the implementation of a pre-screening and monitoring program.

Appendix

I. PDSA Tests of Change

Education

- Education for Families on benefits of T1D pre-symptomatic Screening and Monitoring – modified based on feedback
- Endocrinology physician / care team / department education on T1D pre-symptomatic Screening and Monitoring, staging, and prevention.
- Developed SOPs for creating new chart in the EHR and ordering labs to train new staff
- Multimodal education on T1D pre-symptom Screening and Monitoring for patients and families, including new onset binder, fliers posted in clinic, and bulk electronic Patient Portal messages
- Track insurance denials of laboratory testing and clinic visit reimbursement. Meet with insurers. Develop a letter of medical necessity for autoantibody testing.

Workflow

- Create specific T1D pre-symptomatic Screening and Monitoring as a new referral code to avoid long wait list in typical diabetes clinic.
- Determine how to practically use the published consensus guidelines for monitoring
- Periodic Patient Portal messages to current T1D patients.
- Develop and implement succinct policies and procedures guidelines (e.g. outline specific Screening and Monitoring guidelines and streamline processes to improve patient follow-up.
- Increase the number of appropriate Early-Stage Clinic visits (in-person and virtual) from the referral pool.
- Dedicated Screening and Monitoring appointment visits (telemedicine and in-person).

Technology

- Create T1D delay flowsheet/power form within Electronic Health Record system.
- Increase availability of point-of-care Islet Autoantibody (IAAb) Screening and Monitoring kits in the outpatient diabetes clinic.
- Pilot obtaining 2 lab tubes (rather than 5) for the IAAb tests (1 gold, 1 red)
- Offer ASK and Trial Net resources to patients.
- Revamp referral mechanism for pre-diabetes to schedule patients with normal BMI in T1D Screening and Monitoring clinic.
- Modification of clinic note template based on feedback

Equity

- Assistance with navigating insurance requirements, including provision of Letter of Medical Necessity
- Advocacy for equal access, treatment and patient care
- Develop, translate, and disseminate Screening and Monitoring education materials for patients. Later, expand to multiple languages.
- Increase awareness of T1D Islet Autoantibody (IAAb) Screening and Monitoring for families of established T1D patients in outpatient clinic
- Establish weekend screening events on-site and off-site

II. **Clinical Note T1D at risk monitoring** (Stage 1 or 2 T1D) – University of Florida

Diagnoses
@DIAGNOCANCELLED@
History of Present Illness
We had the pleasure of evaluating @NAMEPREFERREDFULL@ in our Pediatric Endocrinology clinic on @ED@. @FNAMEPREF@ is a @AGE@ @SEX@ with positive type 1 diabetes (T1D)-related autoantibody (AAB).
Referred by: ***PCP/Self/Endocrinologist
Indication for AAB testing: ***Family history of T1D/potential symptoms/other
Paste AAB lab results
Has metabolic testing been done: ***Yes/No
Type of metabolic testing: ***
Results: ***Normal/Abnormal
Paste Metabolic testing lab results

Are there T1D symptoms present? No nocturia, polyuria, polydipsia or weight loss.
@CMED@
@ALLERGY@
@PMH@
@PSH@
@FAMHX@
@SOCDOC@

Review of Systems
Constitutional:{UFPAMBPEDSENDONEG/POS:35544}
Eyes:{UFPAMBPEDSENDONEG/POS:35544}
ENT:{UFPAMBPEDSENDONEG/POS:35544}
Cardiovascular:{UFPAMBPEDSENDONEG/POS:35544}
Respiratory:{UFPAMBPEDSENDONEG/POS:35544}
Gastrointestinal:{UFPAMBPEDSENDONEG/POS:35544}
Musculoskeletal:{UFPAMBPEDSENDONEG/POS:35544}
Integumentary:{UFPAMBPEDSENDONEG/POS:35544}
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Psychiatric:{UFPAMBPEDSENDONEG/POS:35544}
Endocrine:{UFPAMBPEDSENDONEG/POS:35544}
Hematological/Lymphatic:{UFPAMBPEDSENDONEG/POS:35544}
Allergic/Immunological:{UFPAMBPEDSENDONEG/POS:35544}

Psychological Screening
@PHQ8@
@GAD7@

Physical Exam
@V@
@LASTWT(3)@
@LASTHT(3)@
@BMI@
@HFA@
@BPFALW95@

Physical Exam: well nourished, well developed, good affect, no acute distress, sclera clear, MMM, easy work of breathing, no focal neurologic deficits.
ASSESSMENT / PLAN
@NAMEBYAGE@ is a @AGE@ @SEX@ with ***1,2,3,4,5 ***confirmed T1D-realted AAB ***with/without glucose abnormalities. Per references (Phillip et al. Consensus guidance for monitoring individuals with islet autoantibody-positive pre-stage 3 type 1 diabetes. Diabetologia (2024). doi.org/10.1007/s00125-024-06205-5 & Simmons et al. Historical Insights and Current Perspectives on the Diagnosis and Management of Presymptomatic Type 1 Diabetes. Diabetes Technol Ther (2023). doi:

10.1089/dia.2023.0276) we will perform AAB and glycemic monitoring (see below) as @FNAMEPREF@ has an increased risk of developing symptomatic T1D. We reviewed signs and symptoms of T1D, discussed psychosocial aspects of T1D risk monitoring, provided our contact information, and detailed instructions (below). Return to clinic in *** months.

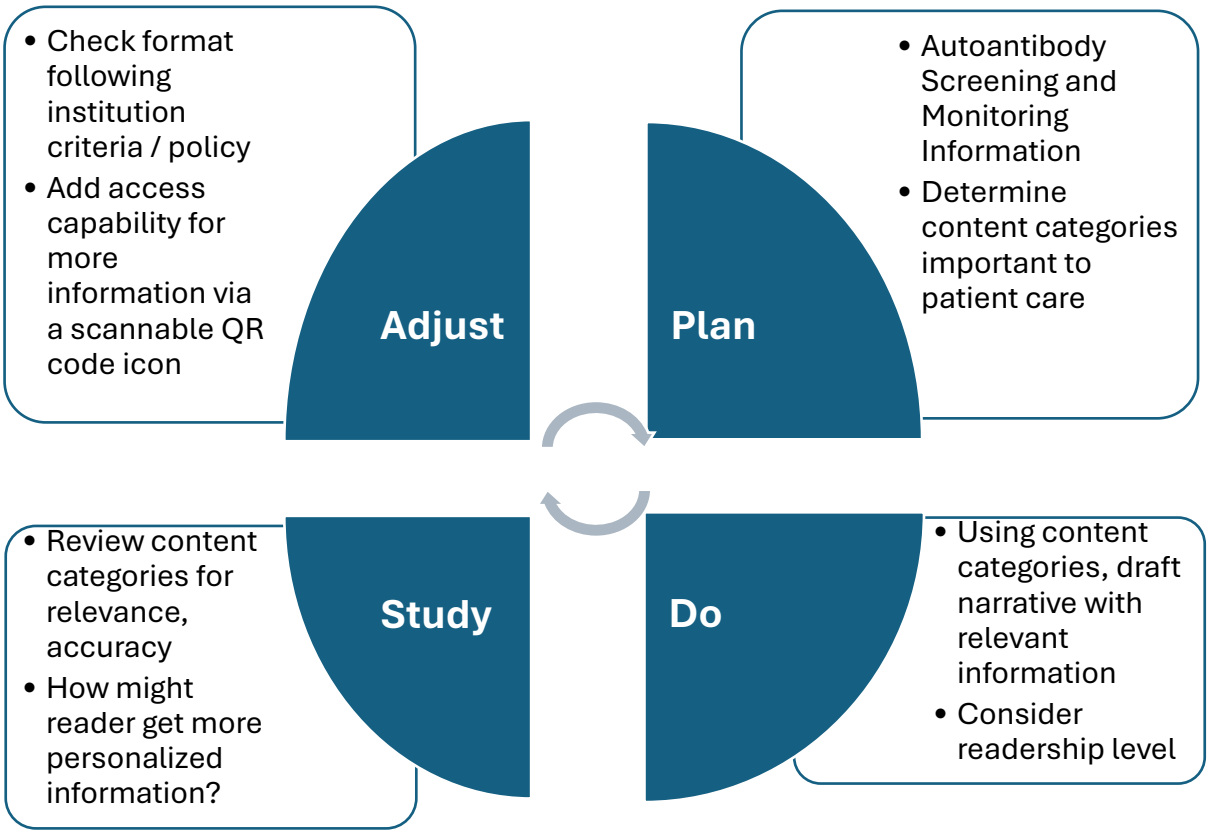
@ORDERSNMENC@

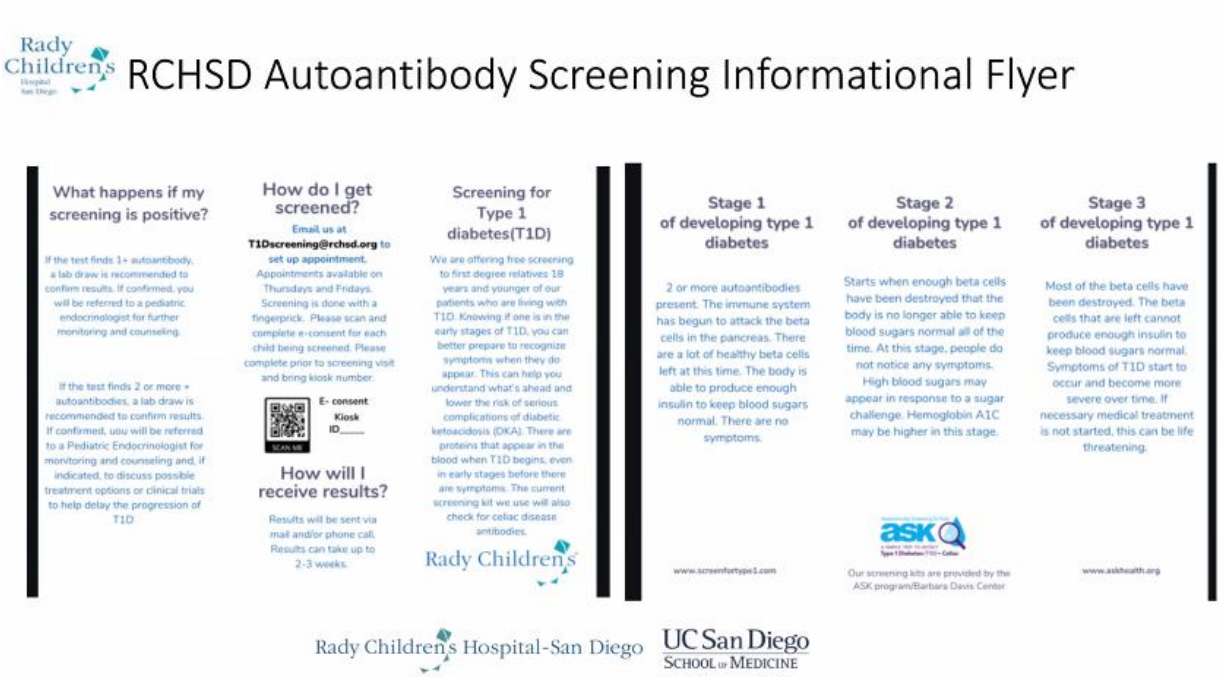
@PTINSTR@

III. Process for screening results and monitoring:

		Second sample (venous)		
		Any type of single AAB	**Any combination of multiple AABs**	**Negative**
First sample (capillary or venous)	**Negative (repeat AAB testing in pediatric patients)**	X	X	X
	Any type of single AAB	Single AAB confirmed	Follow as Multiple AAB	Negative (repeat AAB testing in pediatric patients)
	Any combination of multiple AABs	Follow as Single AAB	Multiple AAB confirmed	Negative (repeat AAB later in pediatrics; could consider repeating once in adults)

IV. PDSA Test of Change: Development Informational Flyer





V. Sample Clinic Visit

UF Health Pediatric Endocrinology @TD@

CLINIC VISIT INSTRUCTIONS

@NAME@, @BDAY@

Great meeting you all! @FNAME@ is being followed for ***. I recommend that @HE@:

***Check blood sugar when ill (fasting and 2-hours after dinner)

***Check blood sugar once a month (fasting and 2-hours after dinner)

***Check blood sugar once a week (fasting and 2-hours after dinner) Through MyChart or email, send me the log of glucoses every 3 months.

If glucose > 200 mg/dL, please wash hands and repeat. If still >200 mg/dL, call our on call provider for further instructions which may include testing urine for ketones or assessing if any symptoms are present.

Phone Numbers:

During the day (8am - 5pm): 352-265-7337

After 5pm, weekends or holidays: 352-265-0111 and ask for the "pediatric endocrinologist on call"

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