The Sanford PLEDGE Study

Integrating Screening into Routine Pediatric Care Across a Health System

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6th Childhood Diabetes Prevention Symposium
Barbara Davis Center
10 November 2023
Past Screening Efforts
Miss Most People at Risk

Diabetes TrialNet
• Screen for autoantibodies in family members of people with T1D
• ~250,000 people screened over 18 years

BUT:
• 92% who will get T1D have no family history
• Not eligible for TrialNet screening
• Expect 1 in 200 people
Sanford PLEDGE: General Population Screening

Novel, Pragmatic Design:
– Minimize burden on:
  Providers & Staff
  Families
  Research Coordinators
– Integrated into routine clinic visits
– Leverage existing Epic electronic record system and
– MyChart patient messaging for enrollment & questionnaires
– Economic analyses and modeling
– No cost to families
Goals

• Prevent initial diabetic ketoacidosis

• Identify patients for possible intervention:
  – Teplizumab when appropriate
  – Stage 1 / 2 intervention trials

• Generate evidence to support including T1D screening
  – Demonstrate feasibility of integration into routine pediatric care
  – Prospective validation of GRS and assessment of utility to focus screening
  – Assess cost effectiveness of general population screening
PLEDGE Overview of Procedures

- **Entry before 6th birthday** OR once 9 - 16 y.
- **Genetic Risk Score**
  - GRS2 Once at study entry
  - (blood spot; can be with Newborn Screening)
- **Anxiety Survey**
  - Entry & Annually
- **T1D AutoAb**
- **Celiac Testing**

**Birth**

**2 years**

**5 years**

**9 - 16 years**
PLEDGE Overview of Procedures

Entry before 6th birthday
OR once 11-16 y.

Genetic Risk Score
GRS2 Once at study entry
(blood spot; can be with Newborn Screening)

Anxiety Survey
Entry & Annually

T1D AutoAb
Celiac Testing

Antibody Screening at ~2, ~5, and 9-16 years of age
PLEDGE Overview of Procedures

- Entry before 6th birthday OR once 11-16 y.
- Genetic Risk Score (GRS2) Once at study entry (blood spot; can be with Newborn Screening)
- Celiac Testing
- T1D AutoAb
- Anxiety Survey

GRS2 at study entry
- SNP-based risk score for T1D and Celiac autoimmunity
  - Can enroll before birth and collect with newborn screens
Integration into routine care
Leverage existing processes and infrastructure
Automation of invitation, enrollment, and messaging

Research Staff will:
- Contact Family & Explain
- Retest
- If persistent:
  - Monitoring Protocol for T1D
  - Clinical referral to pediatrics GI for celiac

Investigator Enters Result Note
- Library of "Dotphrases"
- Routed to PCP
- Attached to result detail

Existing Infrastructure
- Collection
- Processing
- Shipping (PNRI)
- Results

Lab Results
Epic / MyChart
Next Window or Exit Study

Orders Entered (Research Staff)
Completed Consent
Self-eligibility

Consent (MyChart)
Invitation (MyChart)

Routine Care
Lab Collection

Automatic report: upcoming eligible
Automatic invitation via MyChart

20 days
Epic Notifications

“BPA” [light] in Storyboard

“Patient Chart Advisory”
- Appears on opening chart
- Reminder to consider T1D
- Provides guidance
- Does not slow work
- Less intrusive than BPA
Expansion and Enrollment

Now Open at every primary care clinic in Sioux Falls and Fargo

Still ahead of planned enrollment and budget
Expansion and Enrollment

Race
- Caucasian: 2344
- African American: 75
- Native American: 64
- Asian: 31
- HI/Pacific Island: 1

Ethnicity
- Not Hispanic: 2390
- Hispanic: 117
- Unknown: 22

Sex
- Male: 1262
- Female: 1273

Age at Entry (with collection)
Screening Results

Celiac Disease:
- Positive Screens: 92
- Previously known CD: 11
- Repeat Testing Pending: 3
- Persistent positives (to GI): 45

T1D:
- Positive Screens: 124
- Repeat Testing Pending: 2
- **Persistent positive**: 36
  - Single Antibody: 25
    - RBA-only: 6
    - “High Affinity” RBA & ECL: 11
  - Multiple Antibodies: 11
    - 2 Antibodies: 5
    - 3 Antibodies: 2
    - 4 Antibodies: 4

Clinical Care: 3

DKA at Diagnosis: 0 … so far
PLEDGE Screening
PLEDGE Screening

PLEDGE Monitoring

- Separate Protocol and Consent after confirmation of persistent antibody.
- Tailor extent and frequency to expected risk
- 48 Children in enrolled
Thank you

All the families who participate

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