Monitoring within a Healthcare System

The Sanford PLEDGE Study

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pledge
A SIMPLE SCREENING FOR TYPE 1 DIABETES AND CELIAC

6th Childhood Diabetes Prevention Symposium
Barbara Davis Center
9 November 2023

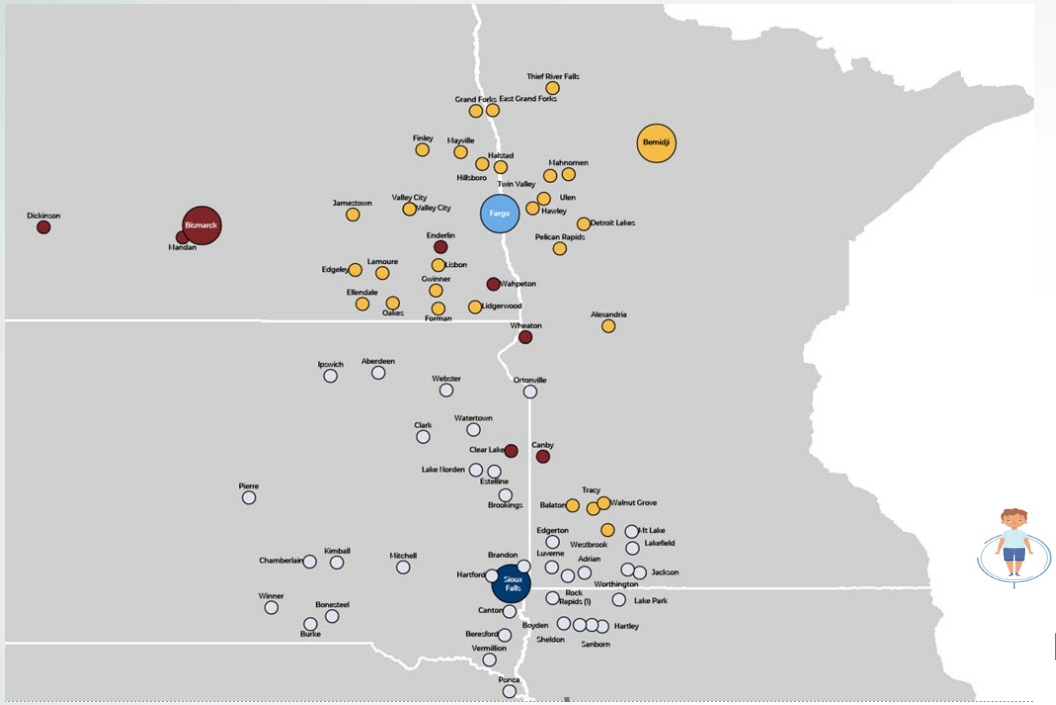
In Partnership with

THE LEONA M. AND HARRY B. HELMSLEY CHARITABLE TRUST

SANFORD RESEARCH

PLEDGE Overview

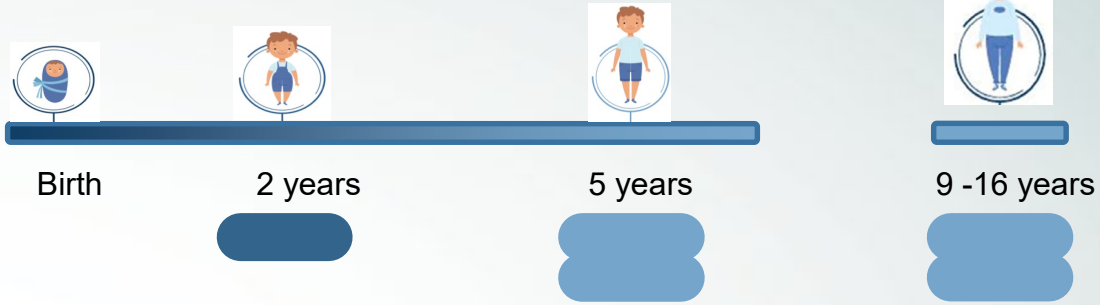
Enrolling at every primary care clinic across Sanford footprint

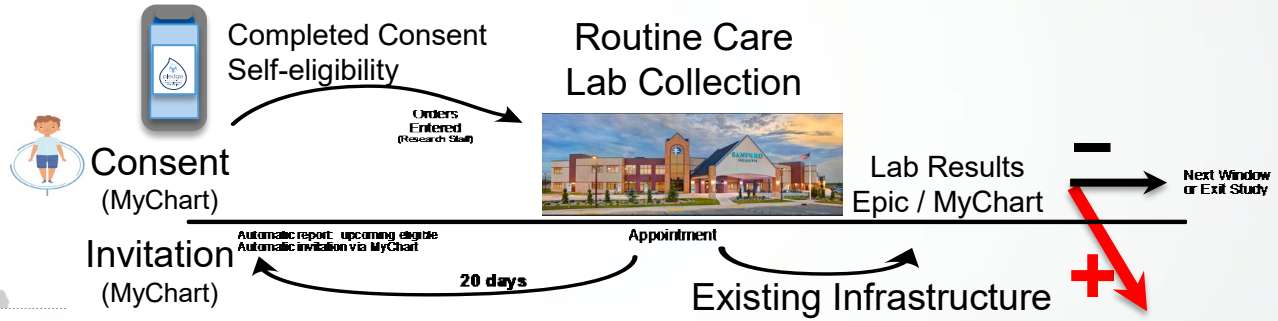


0 – 6 y OR once 9 -16 y.

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

T1D AutoAb
Celiac Testing





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

Research Staff will:
– Contact Family & Explain
– Retest
– Persistent Positives → Monitoring

Goals: Prevent DKA at diagnosis!
Offer early interventions/trials
Referral to clinical care at appropriate time

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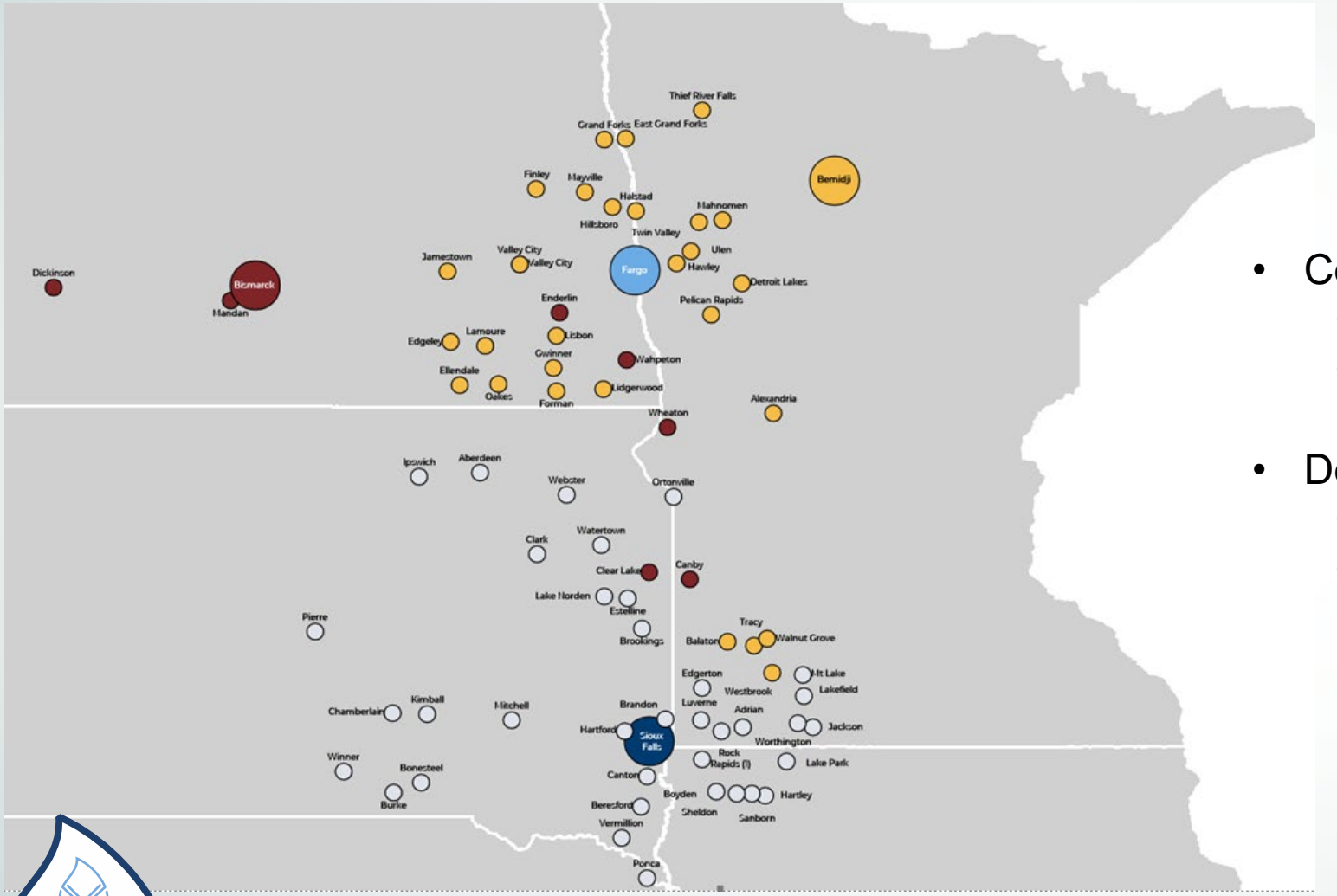
PLEDGE Monitoring



- Centralized management in Sioux Falls, SD
  - 1 program manager
  - 1 clinical coordinator

- Decentralized Procedures
  - 157 clinics screening
  - Monitoring visits performed in local clinics
    - Use in-clinic labs for OGTT
    - Local staff start CGM

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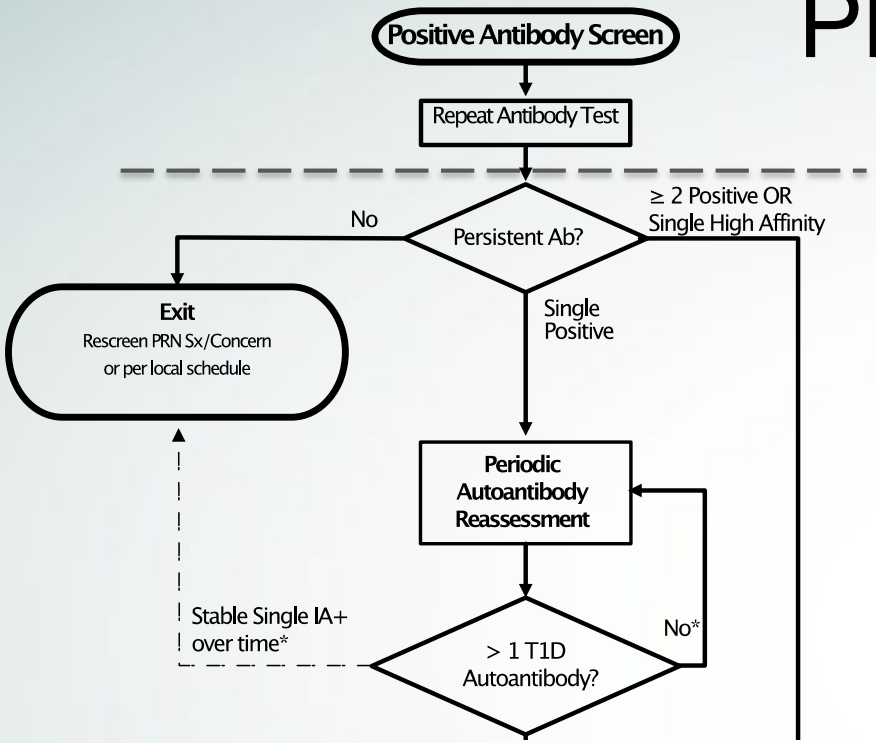

- Separate Protocol and Consent after confirmation of persistent antibody.
- Tailor extent and frequency to expected risk

- Single Islet antibodies:
  - Periodic reassessment of antibodies, Hemoglobin A1c
  - Home ketone testing PRN symptoms or illness

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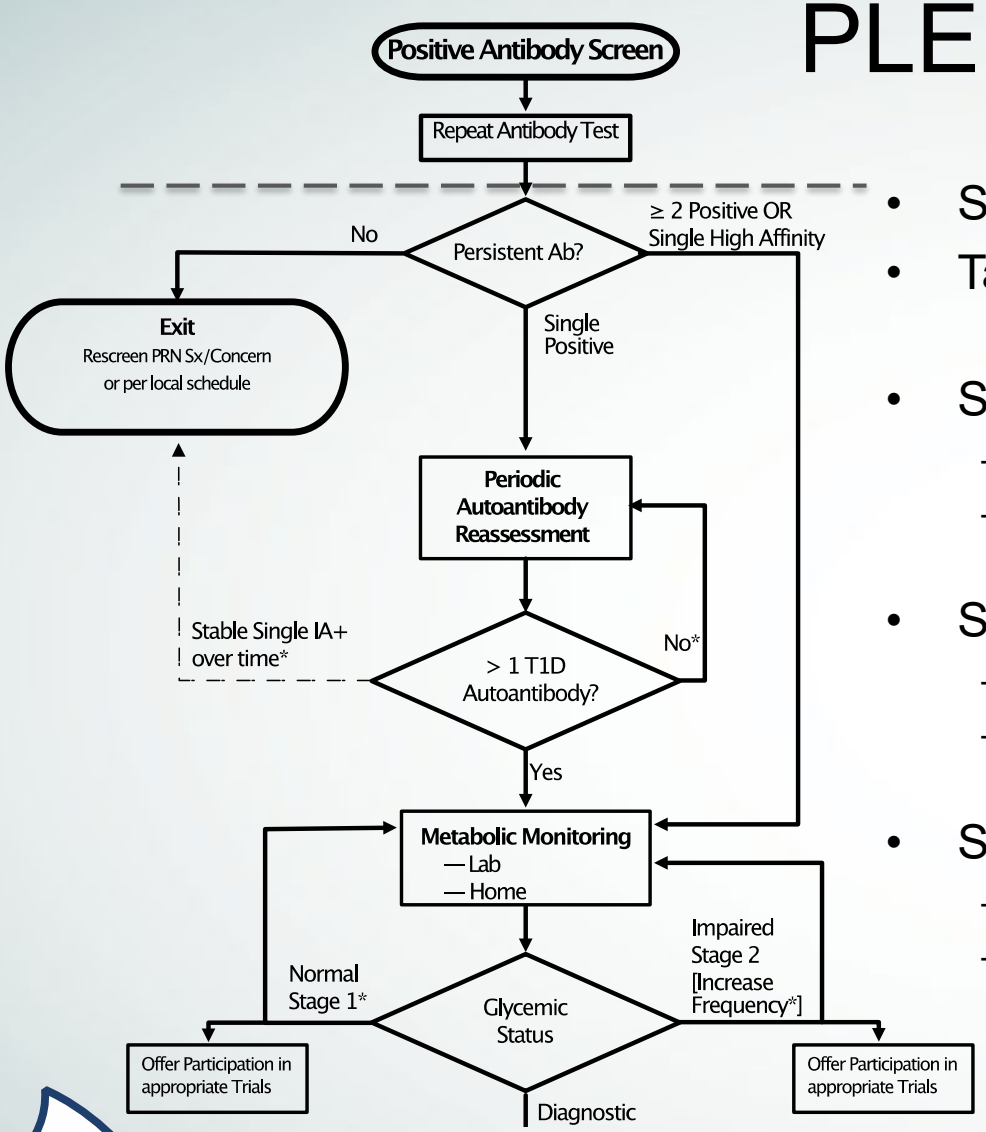

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- Stage 1: Multiple Islet Antibodies with *Normal* Glucose Regulation
  - Metabolic monitoring: Add OGTT, Hemoglobin A1c, Proinsulin:C-peptide ratio
  - Home testing: Ketones and Blood Glucose PRN Symptoms or illness

- Stage 2: Multiple Islet Antibodies with *Impaired* Glucose Regulation
  - Monitoring visits at least q 6 months.
  - Home testing:
    - Blood glucose 2 points monthly
    - Ketones and Blood Glucose PRN Symptoms or illness

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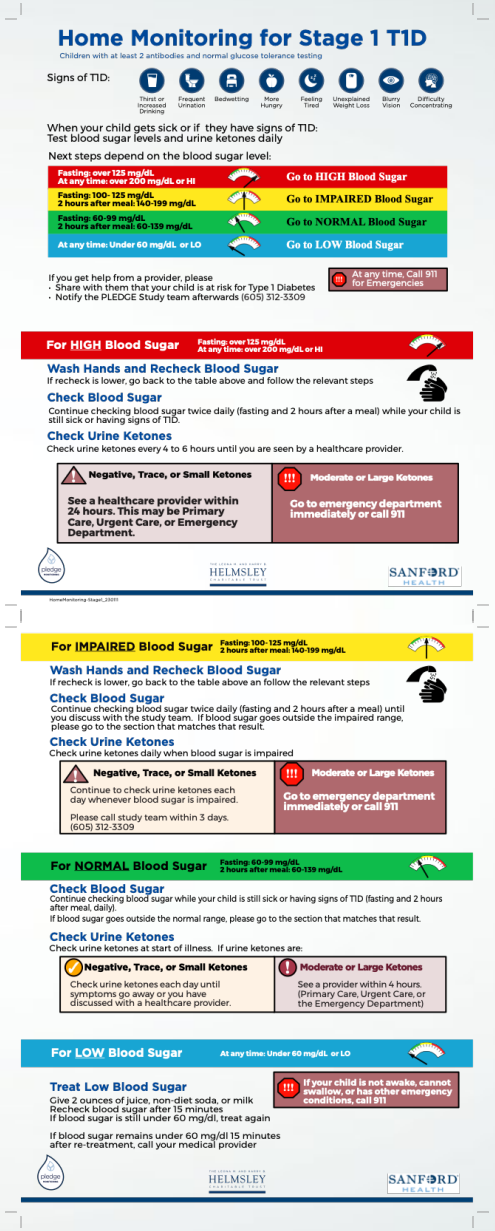
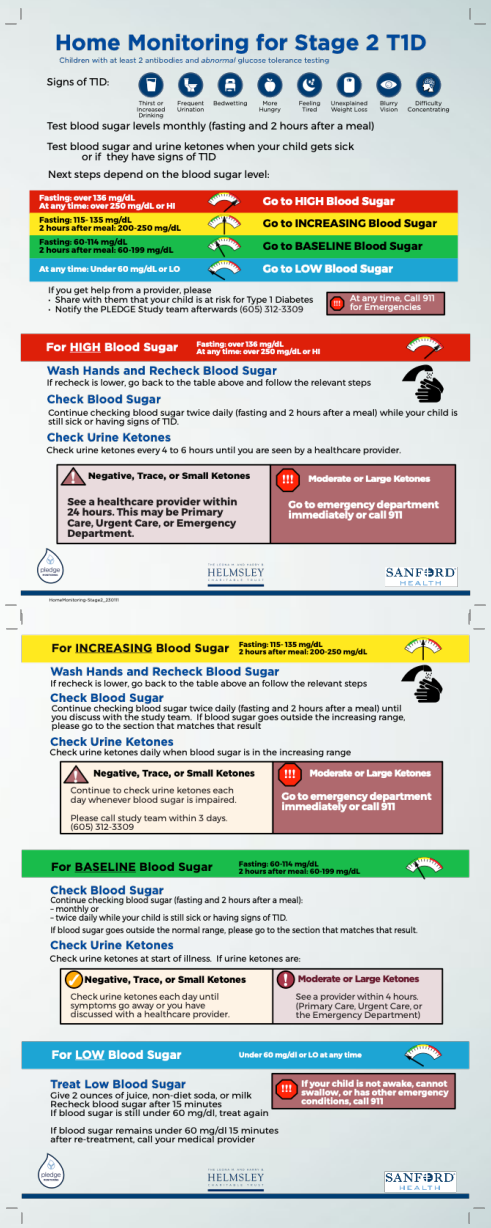
Education

- Ongoing education at every contact with families
  - Signs/Symptoms of clinical T1D
  - Whom to contact for questions
- Additional teaching & materials at specific events
  - First Antibodies
  - Entry to stage 1
  - Entry to stage 2
  - Stage 3 & transition to clinical care





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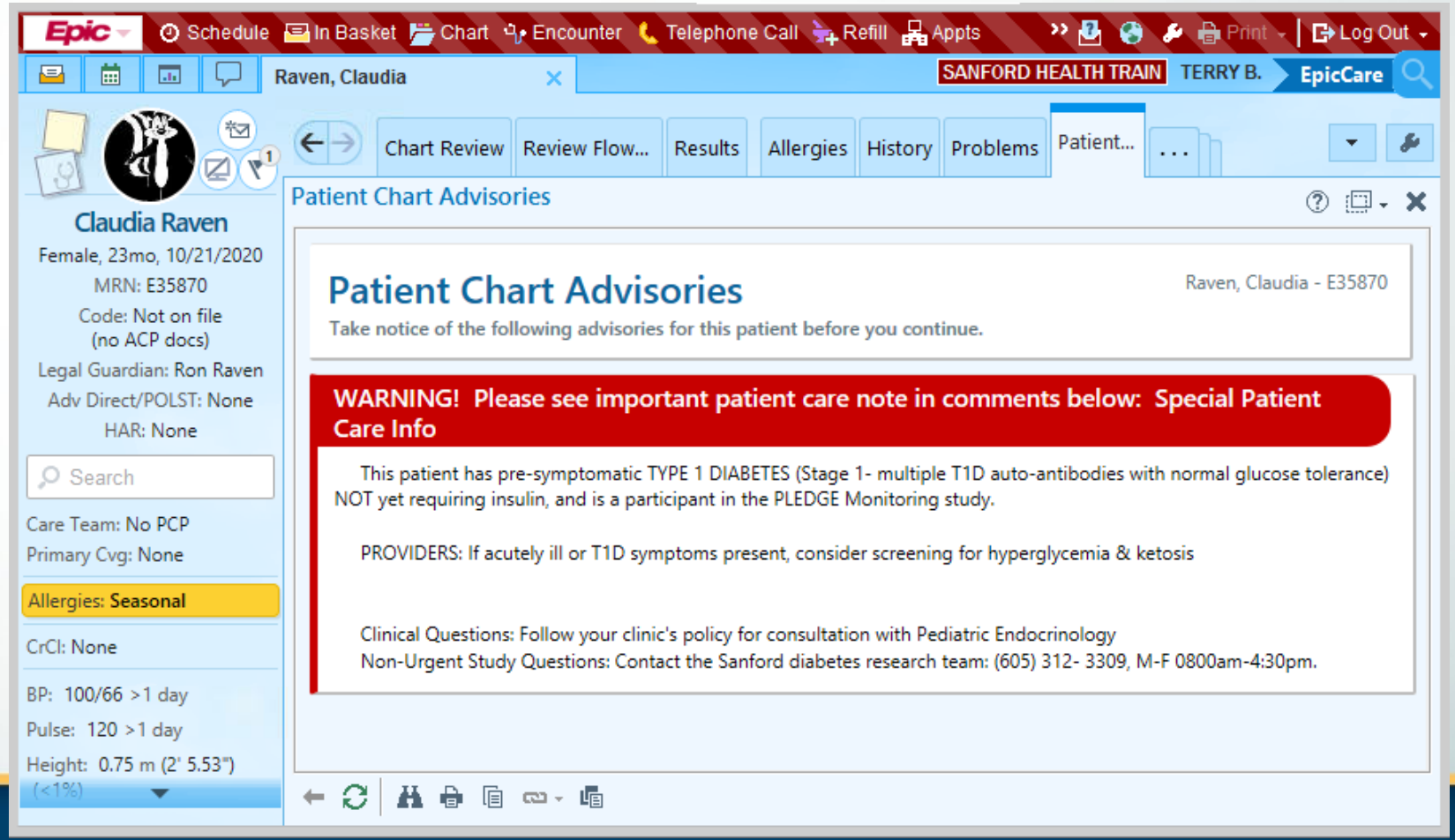
Alert for Clinicians

- How help providers recognize a child at risk for T1D when they present with relevant symptoms?
  - "Patient Chart Advisory"
    - Appears on opening chart
    - Reminder to consider T1D
    - Provides guidance
    - Does not slow work
    - Less intrusive than BPA



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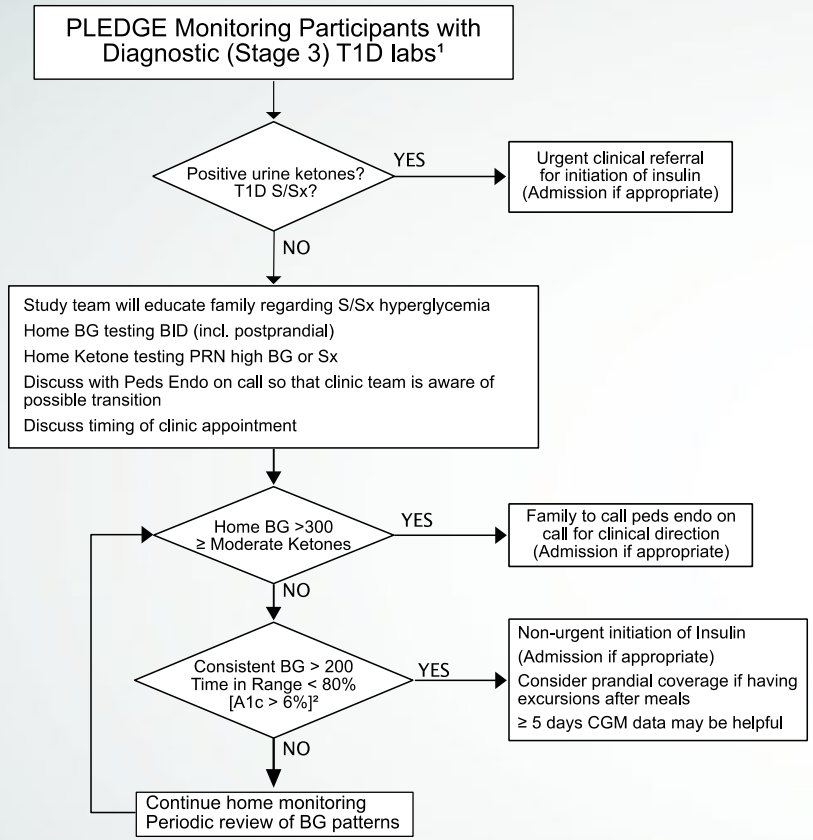
Transition to Clinical Care



- When meet standard ADA diagnostic criteria
- Close communication with pediatric endocrine clinic
- Assessment of urgency may be aided by CGM data
- Goal: start insulin when necessary to keep within treatment targets
  - Start with mealtime rapid insulin if there are postprandial spikes
  - Basal insulin if fasting blood glucose is elevated

[1]Child may have blinded CGM in place after PLEDGE monitoring visit
CGM may be downloaded at any interval

[2]Hemoglobin A1c is a lagging indicator and BG may be well above target before A1c becomes abnormal.

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A work in Progress

- Multiple refinements already implemented based on new information
  - “high affinity” antibodies
  - Frequency of monitoring
  - Educational materials
  - Timing of reminders

- Feedback has been very helpful
  - External advisors and collaborators
  - Participating providers and staff
  - Laboratory staff and leadership
  - Participating families

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Thank you!

All the families who participate

The Sanford Project Team
- Ann Mays
- Magdalena Skon
- Lana Baerenwald
- Vanessa Williams
- Mary Berg
- Connie Hoffman
- Staci Schwingler

Clinical Providers
- Luis Casas
- Stephanie Hanson
- John Shelso
- Rashmi Jain
- Benjamin Hoag
- Jennifer Richstmeier

Parent Representatives
- Kristin Little
- Holly McMahon

Sanford Health Plan
- Emily Griese

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Faculty Positions Available