6th Childhood Diabetes Prevention Symposium

General Population Screening for T1D
Reports from Ongoing Screening Programs

PrIMeD (Precision Individualized Medicine for Diabetes)

Stephen S Rich, PhD, FAHA
University of Virginia

November 10, 2023
Frequency of PrIMeD Participants by T1D GRS

Not High (n=3276, 85.8%)  High (n=542, 14.2%)
Follow-up of Participants

Starting one year after study entry

- Follow-up survey developed for all participants
  - Review of contact information
  - Update on participant health history
  - Update health history of family members of autoimmune diseases
- Initial telephone contact
- Email contact after 3 failed telephone contacts
  - Email included individualized link to the follow-up survey
  - Survey used HIPAA-compliant web-based survey platform
Results

• T1D community screening for genetic risk at
  • UVA Health (3 sites in Charlottesville)
  • UVA Health Orange clinic (30 mi, rural)
  • UVA Health Culpeper clinic (50 mi N, suburban)
  • UVA Health Augusta clinic (50 mi W, rural)
  • 3 non-UVA affiliated private clinics (Charlottesville)
  • 3 non-UVA affiliated private clinics (remote)

• Clinical Research Coordinators in pediatric waiting rooms
  • Collect consent, medical history, saliva (DNA)
  • Screening for islet autoantibodies (5.7%) due to COVID-19 restrictions

• Follow-up completed in 2,096 (55%) of parents/guardians of participants
Follow-up Results

• With Follow-up
  • 0.1% (2 participants) reported development of type 1 diabetes
    • One participant at “high genetic risk”, also had an affected sibling
    • One participant at “not high genetic risk”
  • No evidence of other family members developing autoimmune diseases

• Nearly one-third of participants were lost to follow-up
  • Failure to respond to both telephone and email contact
  • Mail returned due to contact address no longer active and returned to sender
  • With participant age range (2-16 years), IRB restricted contact once beyond study age
  • ~20% of participants lost to follow-up were “high genetic risk”
Thoughts on Implementation of Screening

• Use of Clinical Research Coordinators in Pediatric Clinics not Feasible
• Provide cost-effective, scalable screening
  • Information on type 1 diabetes, screening, and interventions, testing
    • Patient-facing information
    • Waiting room posters, handouts
    • Check-in nurse to ask if screened previously
  • Nurse to perform finger-stick blood spot collection (e.g., Enable Biosciences)
    • Batch each collection day to central site (e.g., Enable Biosciences)
    • List of coded IDs for each sample to central coordinating site
  • Results of islet autoantibody screening to coordinating site
  • Define process for communication from autoantibody screening to parent/guardian
    (including referral for medical follow-up, Diabetes Clinic)
  • For those with 2+ islet autoantibodies, determine if stage 1 or stage 2
    • Surveillance and monitoring
    • Initiation of potential entry into immune intervention (access to Infusion Clinic)
Thanks and Questions

• Population Screening – is it time? (yes, why not? In whom?)
• Follow-up of Screening Results (difficult in the USA, a mobile and typically un-trusting society)
• Establishing the logistics of screening (health systems? Insurers? Statewide governmental/public health regulators? Congressional?)
• Scalable, cost-effective, minimally invasive islet autoantibody testing
• Communication of risk and follow-up protocols (and compliance)?
• Approach to optimal monitoring
• Continuation of advances in immune interventions
Acknowledgements

- Stephen Rich, PhD, FAHA
- Kristin Guertin, PhD
- David Repaske, MD
- Julia Taylor, MD
- Suna Onengut-Gumuscu, PhD
- Wei-Min Chen, PhD
- Emily Farber, MS
- Sarah Boggs, MD
- Eli Williams, MD
- Katherine Keating, MS, CGC
- Liping Yu, MD

Supported by UVA Strategic Investment Fund

PrIMeD
Precision Individualized Medicine for Diabetes

Lucas Allen
Lacey Botteon
Louis Daniel
Mika Labergerie
Tyler Lienhart
Jorge Gonzalez-Mejia
Matt Starnowski