6th Childhood Diabetes Prevention Symposium

General Population Screening for T1D
Reports from Ongoing Screening Programs

PrIMeD (Precision Individualized Medicine for Diabetes)

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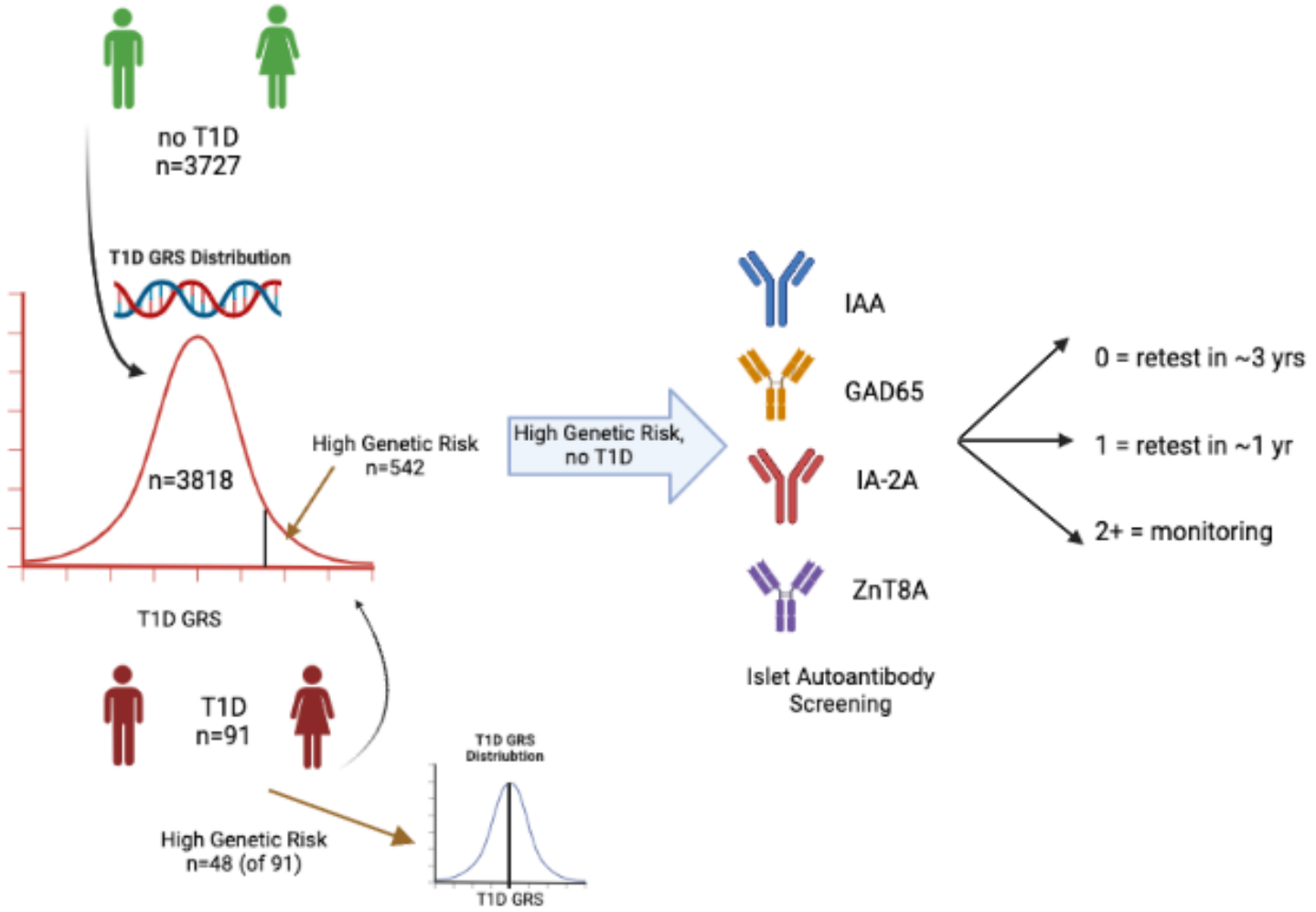
PrIMeD Study Design, Concept and Initial Results



Follow-up

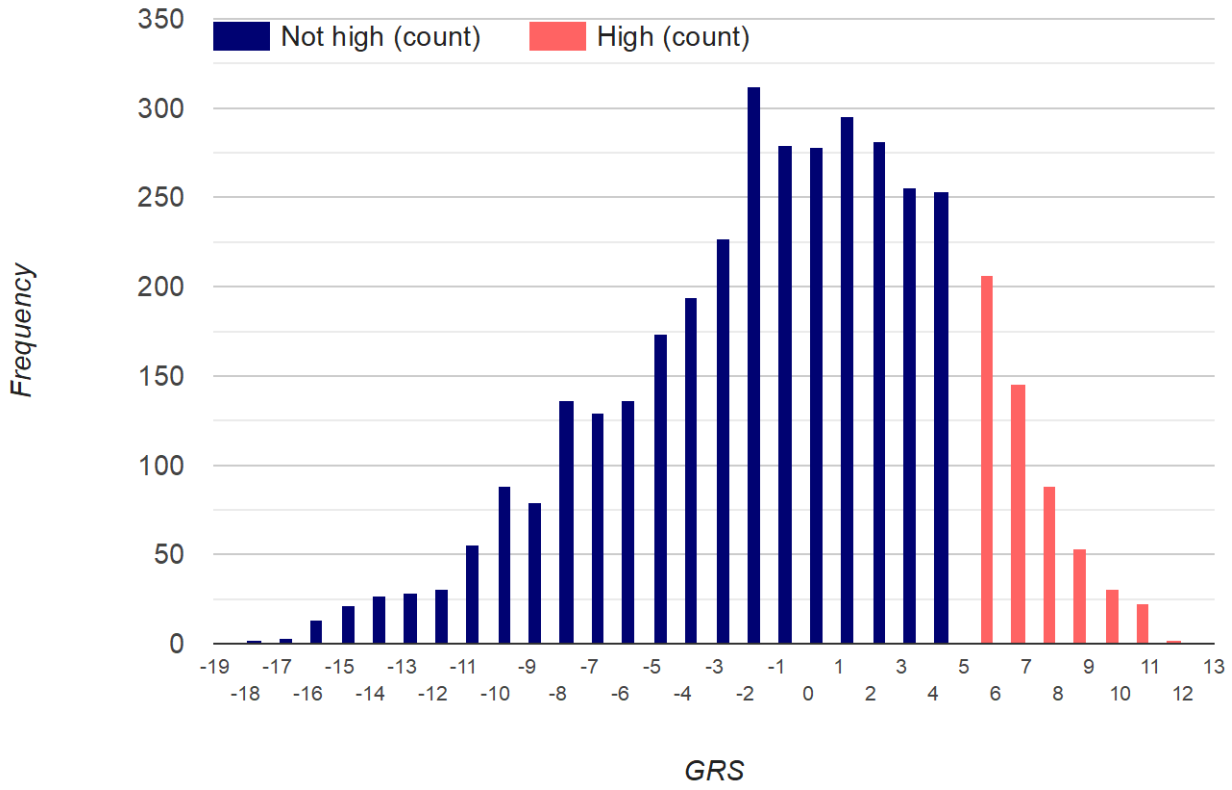
Email
Telephone

Standardized
Form

Case Report
Family Hx

Frequency of PrIMeD Participants by T1D GRS

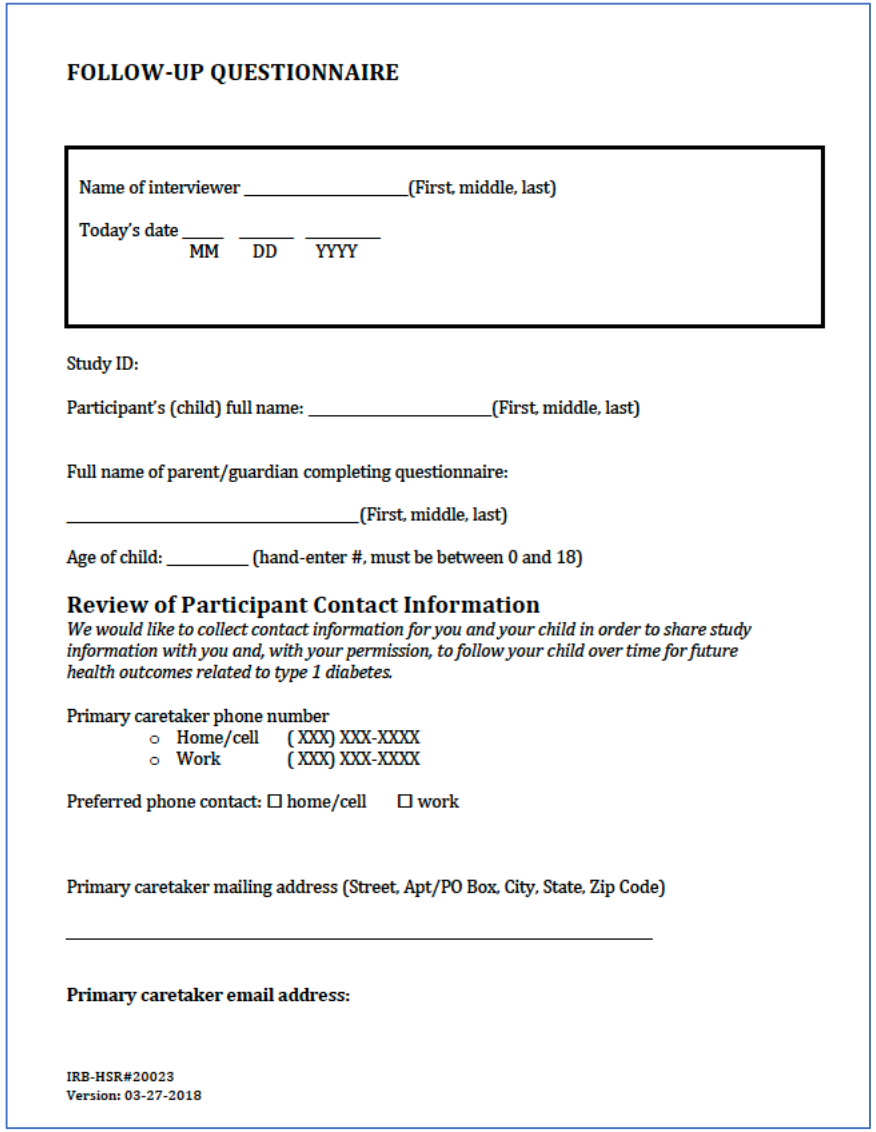
Not High (n=3276, 85.8%) High (n=542, 14.2%)



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



FOLLOW-UP QUESTIONNAIRE

Name of interviewer _____(First, middle, last)

Today's date ____ ____ _____
MM DD YYYY

Study ID:

Participant's (child) full name: _____(First, middle, last)

Full name of parent/guardian completing questionnaire:

_____(First, middle, last)

Age of child: _____ (hand-enter #, must be between 0 and 18)

Review of Participant Contact Information
We would like to collect contact information for you and your child in order to share study information with you and, with your permission, to follow your child over time for future health outcomes related to type 1 diabetes.

Primary caretaker phone number
- Home/cell (XXX) XXX-XXXX
- Work (XXX) XXX-XXXX

Preferred phone contact: ☐ home/cell ☐ work

Primary caretaker mailing address (Street, Apt/PO Box, City, State, Zip Code)

_____

Primary caretaker email address:

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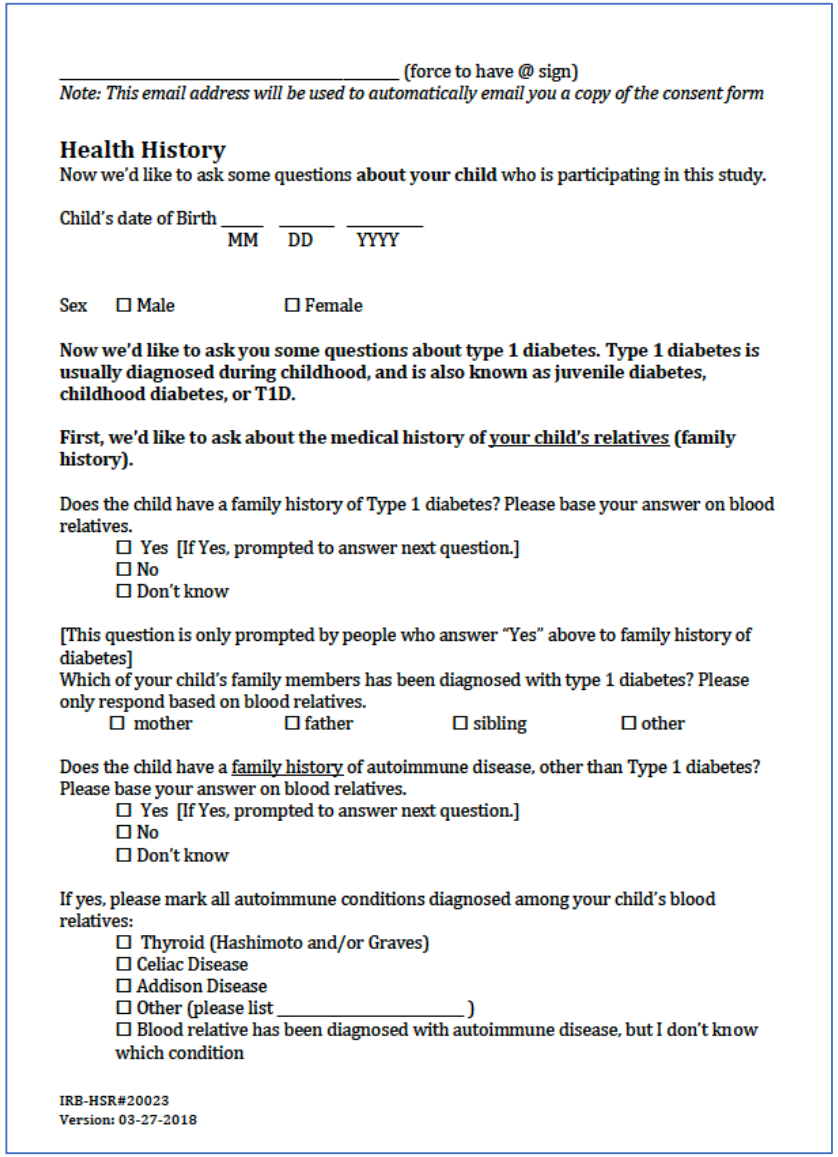
Results

- 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



_____ (force to have @ sign)
Note: This email address will be used to automatically email you a copy of the consent form

Health History
Now we'd like to ask some questions **about your child** who is participating in this study.

Child's date of Birth ____ ____ _____
MM DD YYYY

Sex ☐ Male ☐ Female

Now we'd like to ask you some questions about type 1 diabetes. Type 1 diabetes is usually diagnosed during childhood, and is also known as juvenile diabetes, childhood diabetes, or T1D.

First, we'd like to ask about the medical history of your child's relatives (family history).

Does the child have a family history of Type 1 diabetes? Please base your answer on blood relatives.
☐ Yes [If Yes, prompted to answer next question.]
☐ No
☐ Don't know

[This question is only prompted by people who answer "Yes" above to family history of diabetes]
Which of your child's family members has been diagnosed with type 1 diabetes? Please only respond based on blood relatives.
☐ mother ☐ father ☐ sibling ☐ other

Does the child have a family history of autoimmune disease, other than Type 1 diabetes? Please base your answer on blood relatives.
☐ Yes [If Yes, prompted to answer next question.]
☐ No
☐ Don't know

If yes, please mark all autoimmune conditions diagnosed among your child's blood relatives:
☐ Thyroid (Hashimoto and/or Graves)
☐ Celiac Disease
☐ Addison Disease
☐ Other (please list _____)
☐ Blood relative has been diagnosed with autoimmune disease, but I don't know which condition

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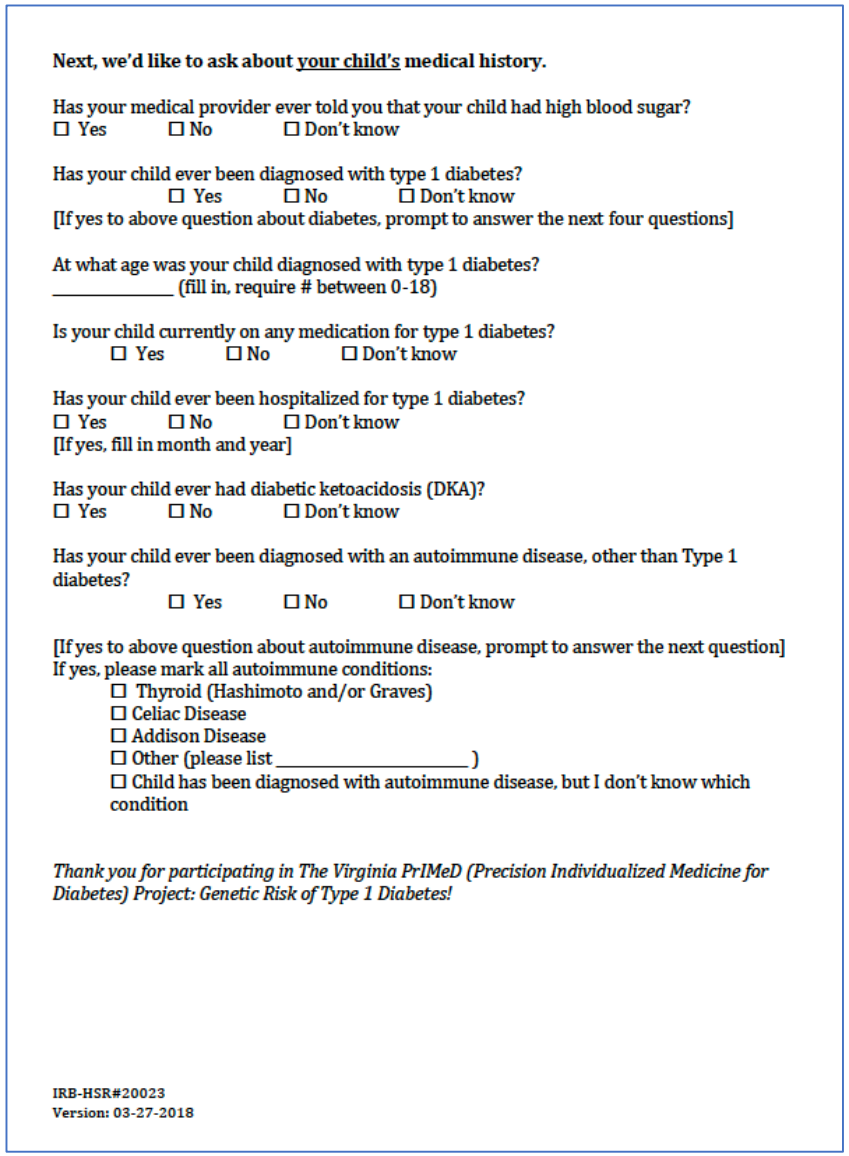
Follow-up Results

- 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”



Next, we'd like to ask about <u>your child's</u> medical history.

Has your medical provider ever told you that your child had high blood sugar?
☐ Yes ☐ No ☐ Don't know

Has your child ever been diagnosed with type 1 diabetes?
☐ Yes ☐ No ☐ Don't know
[If yes to above question about diabetes, prompt to answer the next four questions]

At what age was your child diagnosed with type 1 diabetes?
_____ (fill in, require # between 0-18)

Is your child currently on any medication for type 1 diabetes?
☐ Yes ☐ No ☐ Don't know

Has your child ever been hospitalized for type 1 diabetes?
☐ Yes ☐ No ☐ Don't know
[If yes, fill in month and year]

Has your child ever had diabetic ketoacidosis (DKA)?
☐ Yes ☐ No ☐ Don't know

Has your child ever been diagnosed with an autoimmune disease, other than Type 1 diabetes?
☐ Yes ☐ No ☐ Don't know

[If yes to above question about autoimmune disease, prompt to answer the next question]
If yes, please mark all autoimmune conditions:
☐ Thyroid (Hashimoto and/or Graves)
☐ Celiac Disease
☐ Addison Disease
☐ Other (please list _____)
☐ Child has been diagnosed with autoimmune disease, but I don't know which condition

Thank you for participating in The Virginia PrIMeD (Precision Individualized Medicine for Diabetes) Project: Genetic Risk of Type 1 Diabetes!

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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

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PrIMeD
Precision Individualized Medicine for Diabetes

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