

# **International Collaborations in Behavioral Medicine: The Environmental Determinants of Diabetes in the Young Study (TEDDY)**

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Global Approaches to Behavioral Medicine**

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AMERICAN PSYCHOLOGICAL ASSOCIATION



# Presentation Overview

- Why do international research
- Why do international research in type 1 diabetes
- The Environmental Determinants of Diabetes in the Young (TEDDY) study
- Role of Psychosocial Studies Committee in TEDDY







# Why do International Research

- NAS Report on International Collaborations in Behavioral and Social Sciences [http://www.nap.edu/catalog.php?record\\_id=12053](http://www.nap.edu/catalog.php?record_id=12053)
- Conceptual
- Pragmatic
- Simple Imperative





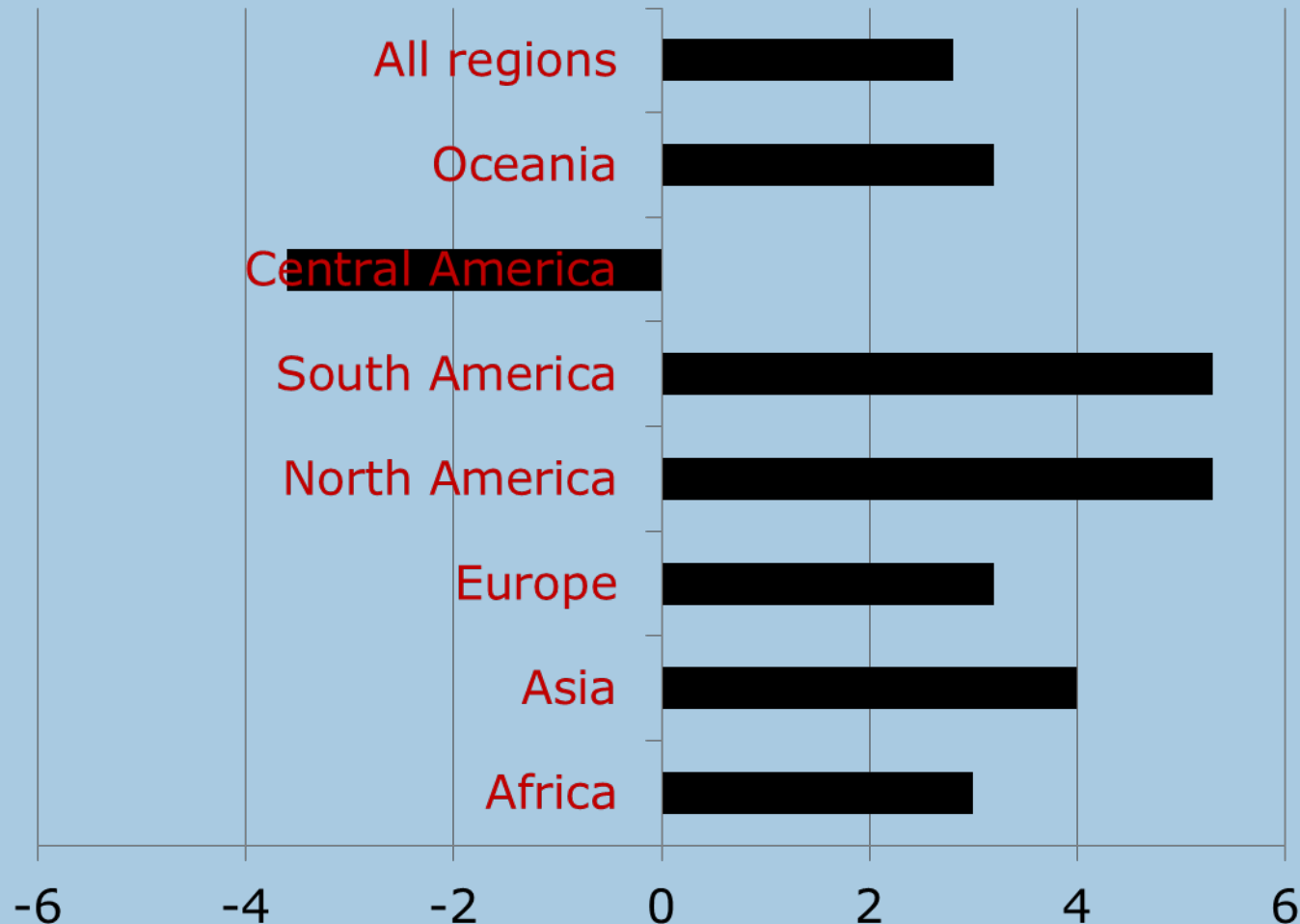
# Why Do International Research in Type 1 Diabetes (T1D)

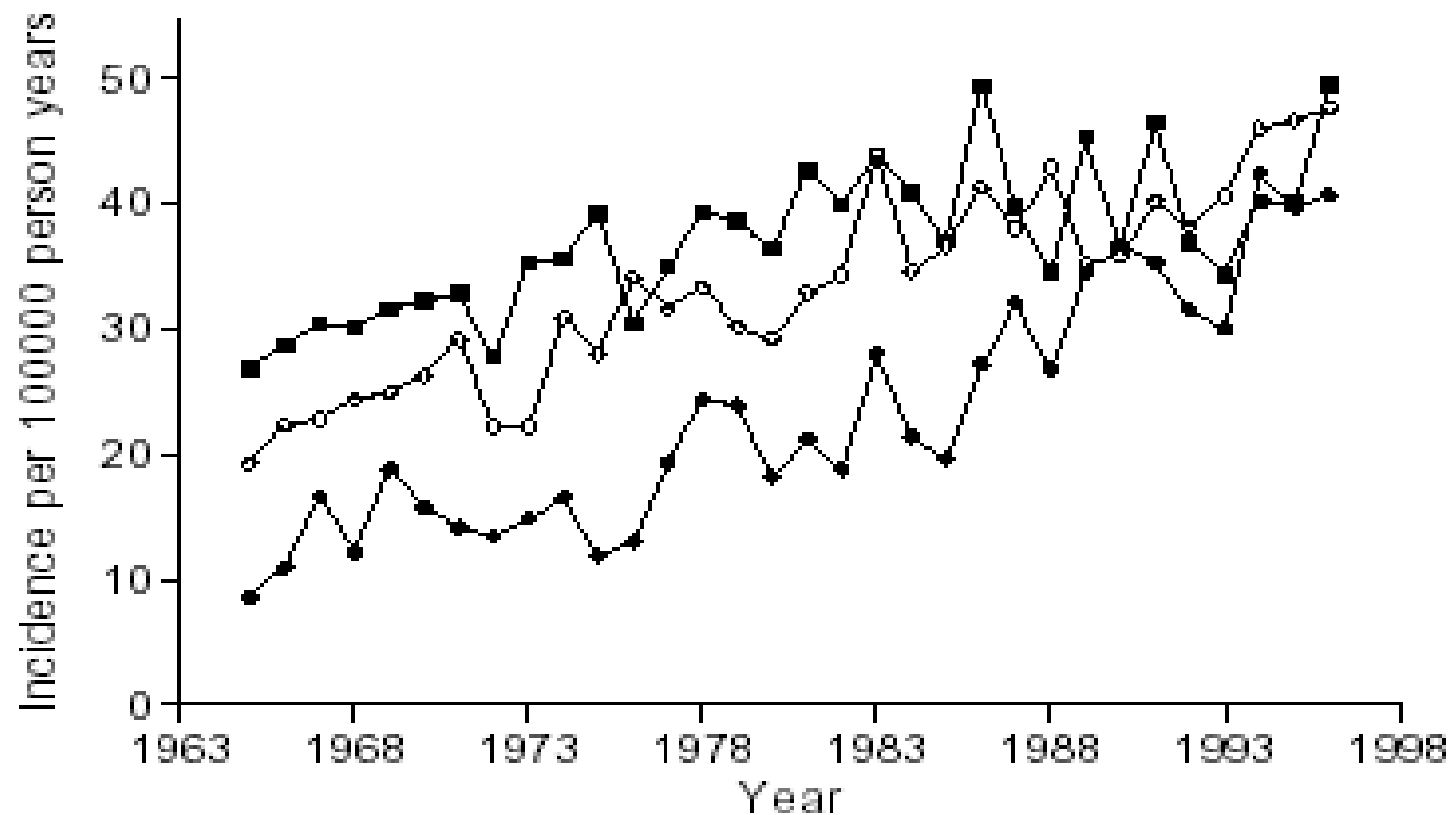
- T1D is a serious disease of childhood requiring a life-long complex treatment regimen, including multiple daily insulin injections for survival
- Increasing world-wide (3-5% annually)
- Varies geographically – highest in Scandinavia, lowest in China
- If the environmental trigger(s) of T1D in genetically at-risk children could be identified, prevention is possible



# Diabetes in Children is Increasing Worldwide

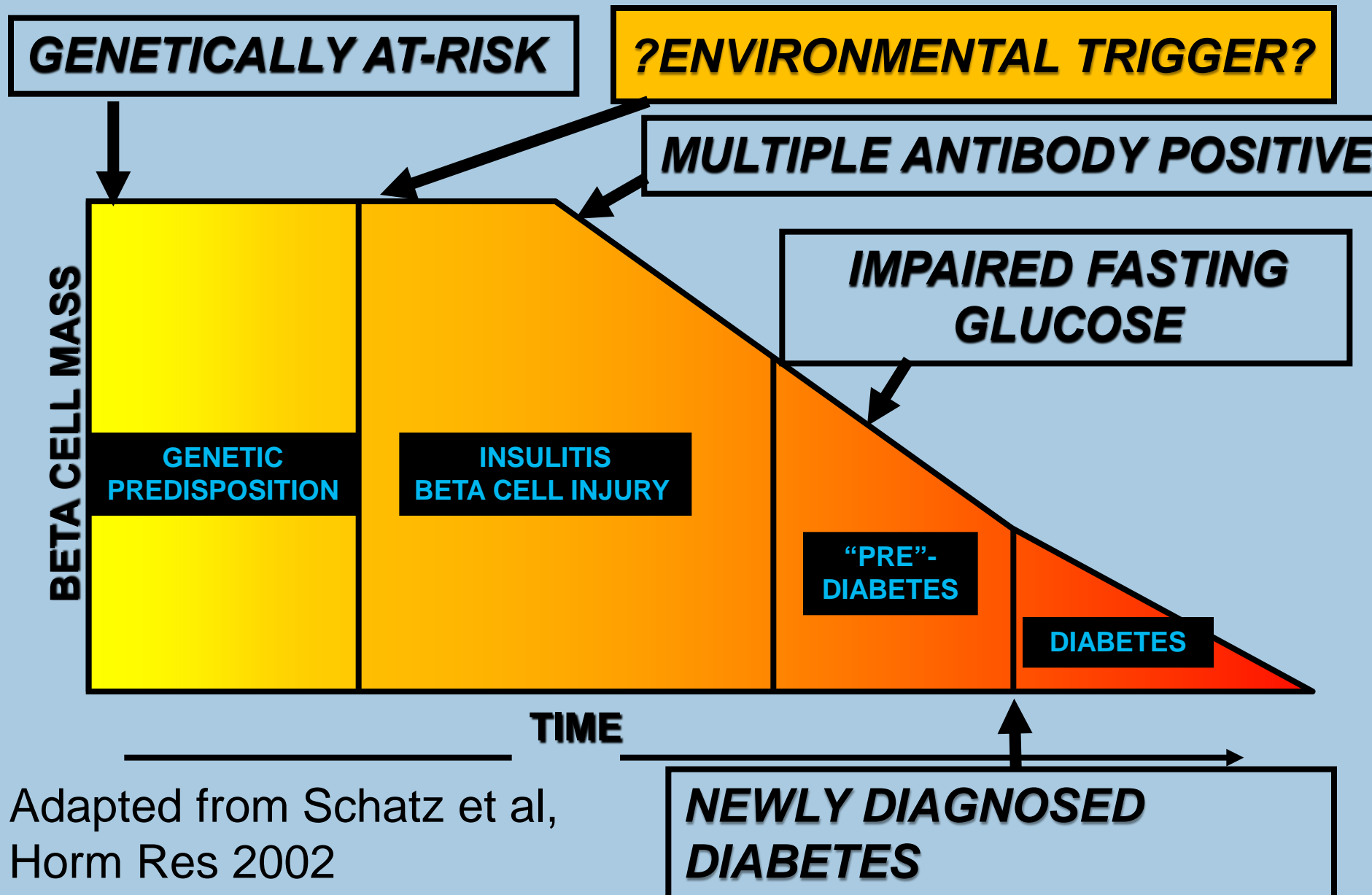
## Annual % Increase in Type 1 Diabetes 1990-1999





**Fig.2.** The age-specific annual incidence of Type I diabetes per 100 000 Finnish children aged 1–14 years between 1965 and 1996. ● 1–4 years, ○ 5–9 years, ■ 10–14 years

# Development of Type 1 Diabetes







# The Environmental Determinants of Diabetes in the Young (TEDDY) Study

- Multi-site NIDDK supported observational study involving 3 sites in the US and sites in Finland, Germany and Sweden
- 420,000 newborns screened for HLA conferred T1D risk
- 21,589 were HLA eligible – most have no family member with T1D
- 8668 joined the TEDDY study
- A host of possible triggers for T1D are monitored (diet, infections, stress)
- Children will be followed up to 15 years





# TEDDY Psychosocial Studies Committee Objectives

1. To determine if psychological variables are directly or indirectly associated with study outcomes: antibody positivity and T1D
  - a. Stress
  - b. Lifestyle behaviors (diet and exercise)
2. To determine the impact on child and family of participation in TEDDY
3. To determine factors associated with study recruitment, retention and compliance and to test/develop methods to improve study retention and compliance

# Objective 1:

## Measures of Psychological Stress

- Parent measures
  - Life stress
  - Postpartum depression & general depression (mother & father)
  - Anxiety about the child's T1D risk (mother & father)
- Child measures
  - Life stress (parent report )
  - Child Behavior Checklist (3 years -parent report)
  - Salivary cortisol (3 years)
  - To be developed as the child grows older



# Objective 1:

## Measures of Lifestyle Behaviors

### ➤ Parent

- Smoking
- Alcohol consumption (pregnancy only)
- Working outside the home

### ➤ Child

- diet from birth (parent report)
- Body mass index from birth
- activity level (5 years- accelerometer)



# Objective 2: Measures of Impact of TEDDY Participation

- Parent measures (mother and father)
  - Postpartum and general depression
  - Anxiety about the child's T1D risk
  - T1D risk perception
  - Hyper-vigilance (over-reporting of child illness)
  - Behaviors initiated to prevent T1D
- Child measures
  - Child Behavior Checklist (3 years -parent report)
  - To be developed as the child grows older



## Objective 3: Measures Associated with Recruitment, Retention and Study Compliance

- Sociodemographic: Maternal age & education & marital status, child gender & race/ethnicity, only child status
- Environmental: Life stress, crowding, country
- Emotional: parental depression, anxiety about the child's risk, study satisfaction; child internalizing subscale of the CBCL; other child measures to be added
- Cognitive: parental T1D risk perception and beliefs; child measures to be added
- Behavioral: parental behaviors to prevent T1D, hyper-vigilance; child externalizing subscale of the CBCL; child activity level; other child measures to be added





# Psychosocial Committee Accomplishments to Date

- Initial focus on recruitment and retention: able to identify those at risk for study withdrawal at study inception and develop an intervention strategy to improve retention
- Documented cognitive, emotional, and behavior impact of TEDDY on parents by country, role (mom vs dad), and family history of T1D
- Documented country differences in life stress and post-partum depression in the first year of TEDDY





# Selected TEDDY Psychosocial Committee Publications

- ◎ Johnson SB, Lee H-S, Baxter J, Lernmark B, Roth R, Simell T for the TEDDY Study Group. The Environmental Determinants of Diabetes in the Young (TEDDY) study: Predictors of early study withdrawal among participants with no family history of type 1 diabetes. *Pediatric Diabetes*, 2011,12:165-171.
- ◎ Lernmark B, Johnson SB, Vehik K, Smith L, Ballard L, Baxter J, Mcleod W, Roth R, Simell T for the TEDDY Study Group. Enrollment experiences in a pediatric longitudinal observational study: The Environmental Determinants of Diabetes in the Young (TEDDY) study. *Contemporary Clinical Trials*, 2011,32:517-523.
- ◎ Johnson S B. Psychological impact of screening and prediction in type 1 diabetes. *Current Diabetes Report*, 2011,11:454-459.
- ◎ Baxter J, Vehik K, Johnson SB, Lernmark B, Roth R, Simell T for the TEDDY Study Group. Differences in recruitment and early retention among ethnic minority participants in a large pediatric cohort: The TEDDY Study. *Contemporary Clinical Trials*, 2012,33:633-40

