

Should Screening for Type 1 Diabetes Risk be Widely Disseminated?

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Presentation Overview

- Epidemiology of Type 1 Diabetes (T1D)
- Advances in understanding pathogenesis
- Advances in prediction
 - Genetic precursors
 - Autoimmune process
- Limitations of current knowledge
 - No known means of preventing T1D in those at-risk
- Concerns about widespread dissemination of screening for T1D risk

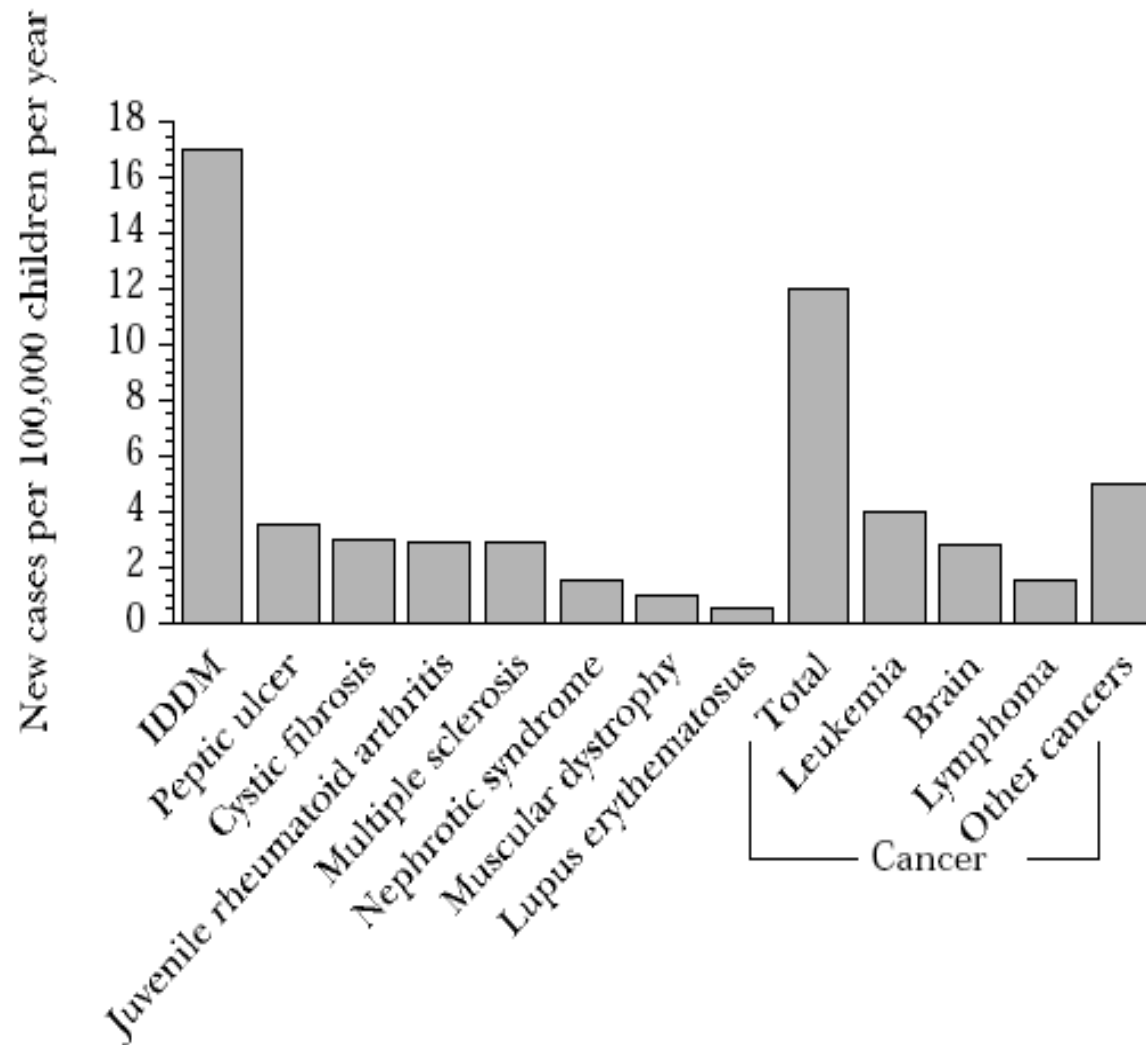


Epidemiology of T1D

- T1D is different from Type 2 Diabetes
 - T1D is typically diagnosed in childhood, not associated with obesity
 - T2D is far more common, usually diagnosed in older adulthood, associated with obesity
- T1D is a common serious disease of childhood
 - 1 in 300 US children; 177,000 US children
 - Varies geographically – highest in Scandinavia, lowest in China
- Increasing world-wide (3-5% annually)
- Requires life-long complex treatment regimen, including multiple daily insulin injections for survival

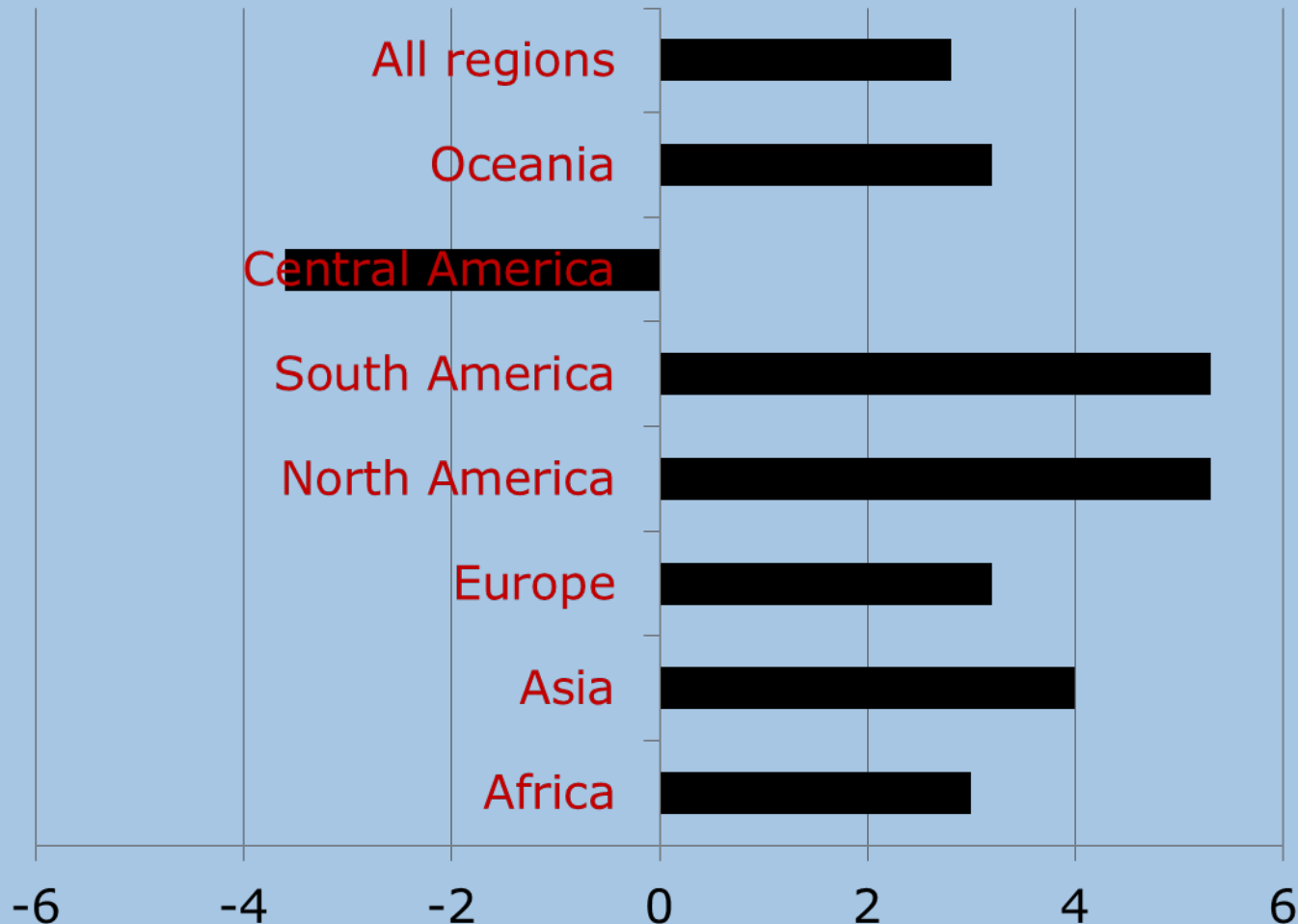


Incidence of IDDM Compared with Other Chronic Diseases of Children Age <16 Years



Diabetes in Children is Increasing Worldwide

Annual % Increase in Type 1 Diabetes 1990-1999



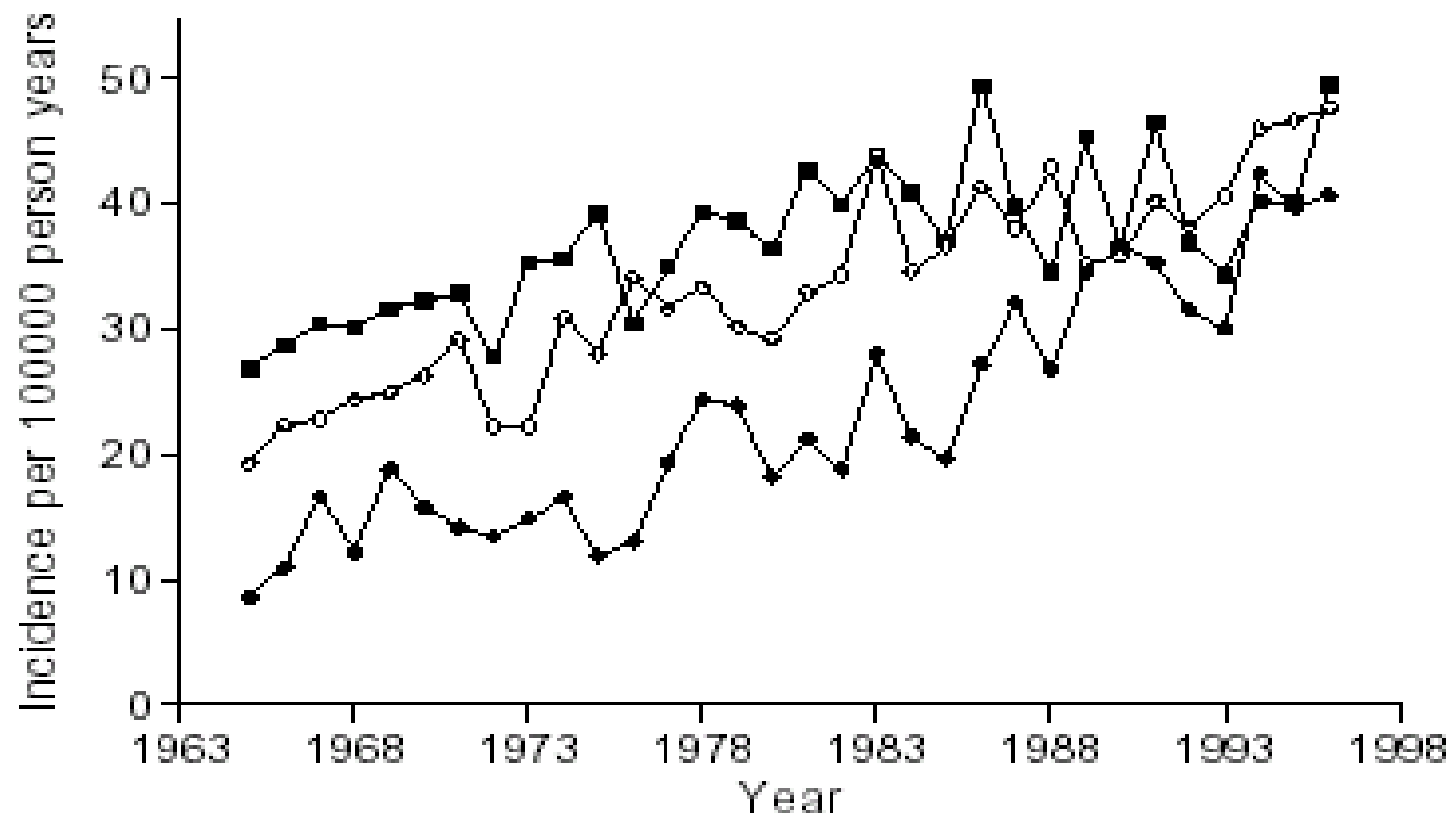
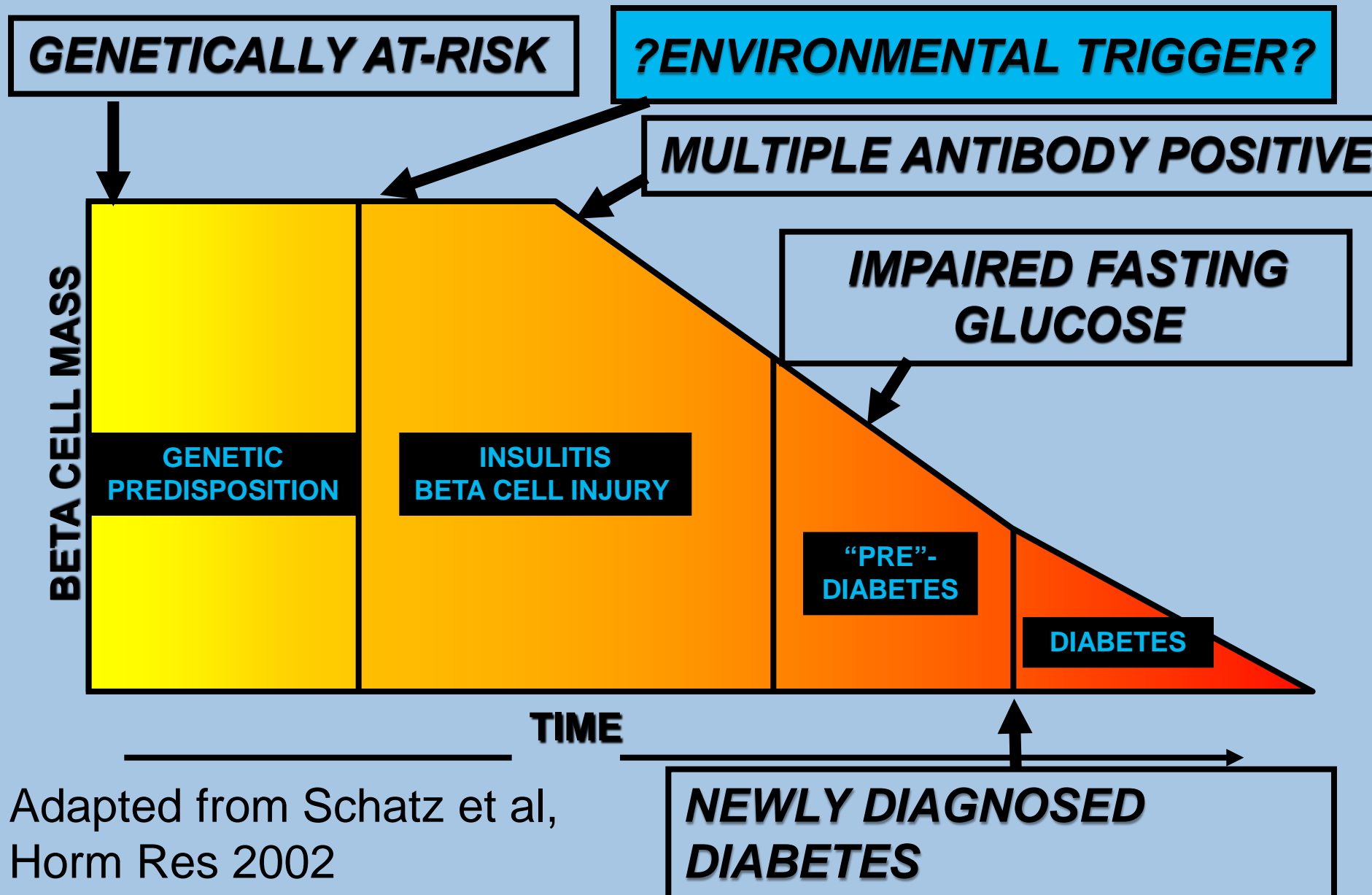


Fig.2. The age-specific annual incidence of Type I diabetes per 100 000 Finnish children aged 1–14 years between 1965 and 1996. ● 1–4 years, ○ 5–9 years, ■ 10–14 years

Development of Type 1 Diabetes



Current state of our knowledge

- Screening for T1D risk is possible
- No means of preventing the disease currently exists
 - NIH Diabetes Prevention Trial – 1 (DPT-1) failed: tested subcutaneous and oral insulin in individuals in the insulinitis phase (screened autoantibody positive)
 - NIH TrialNet is testing potential interventions
<http://www.diabetestrialnet.org/public.html>
 - NIH TEDDY study is seeking to identify the environmental trigger
<http://teddy.epi.usf.edu/TEDDY/index.htm>



Screening for T1D Risk is Controversial

- Screening targets children who are unable to provide informed consent
- Positive genetic test results have poor predictive power and are poorly understood
- There is no known means of preventing the disease in those at risk
- Positive screening results may
 - increase psychological distress in child or parents
 - lead to behavior changes in an effort to prevent T1D
 - interfere with access to health insurance



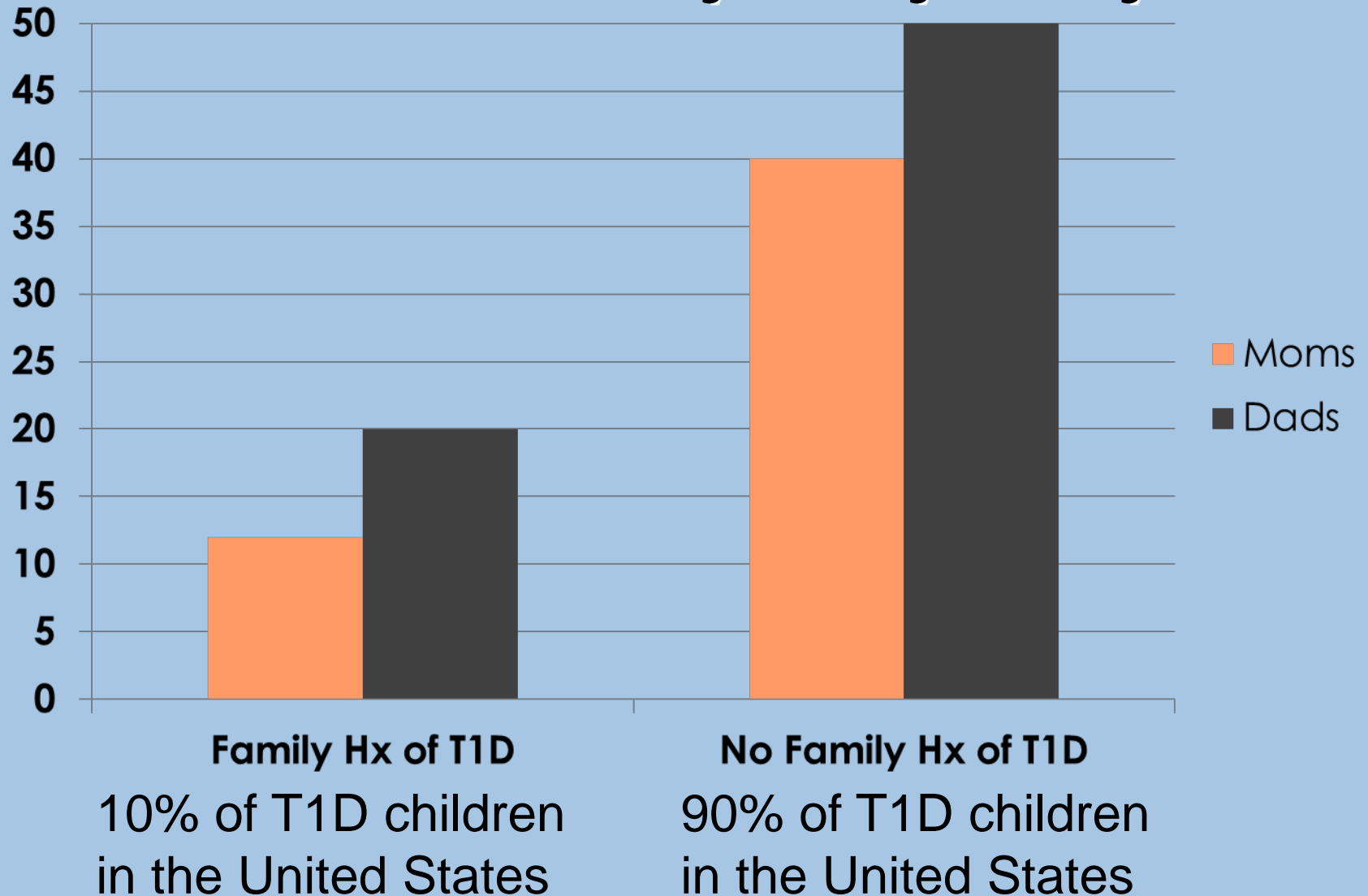
Predicting T1D

Screening Method	Absolute Risk by Relative Status	
	First Degree Relative with T1D?	
Genetic Marker	Yes	No
DR 3/4	22%	7%
DR 4/4	17%	5%
DR 3/3	10%	2%
Persistent Antibodies	5 Year Risk	
One	25%	
Two	45%	
Three	70%	
U.S. Comparison Sample	1-3% (T1D mom) 3-6% (T1D sib) 4-9% (T1D dad)	.003%

Schatz et al., Horm Res, 2002; Taplin et al., Autoimmunity, 2008; Diabetes in America, second edition)

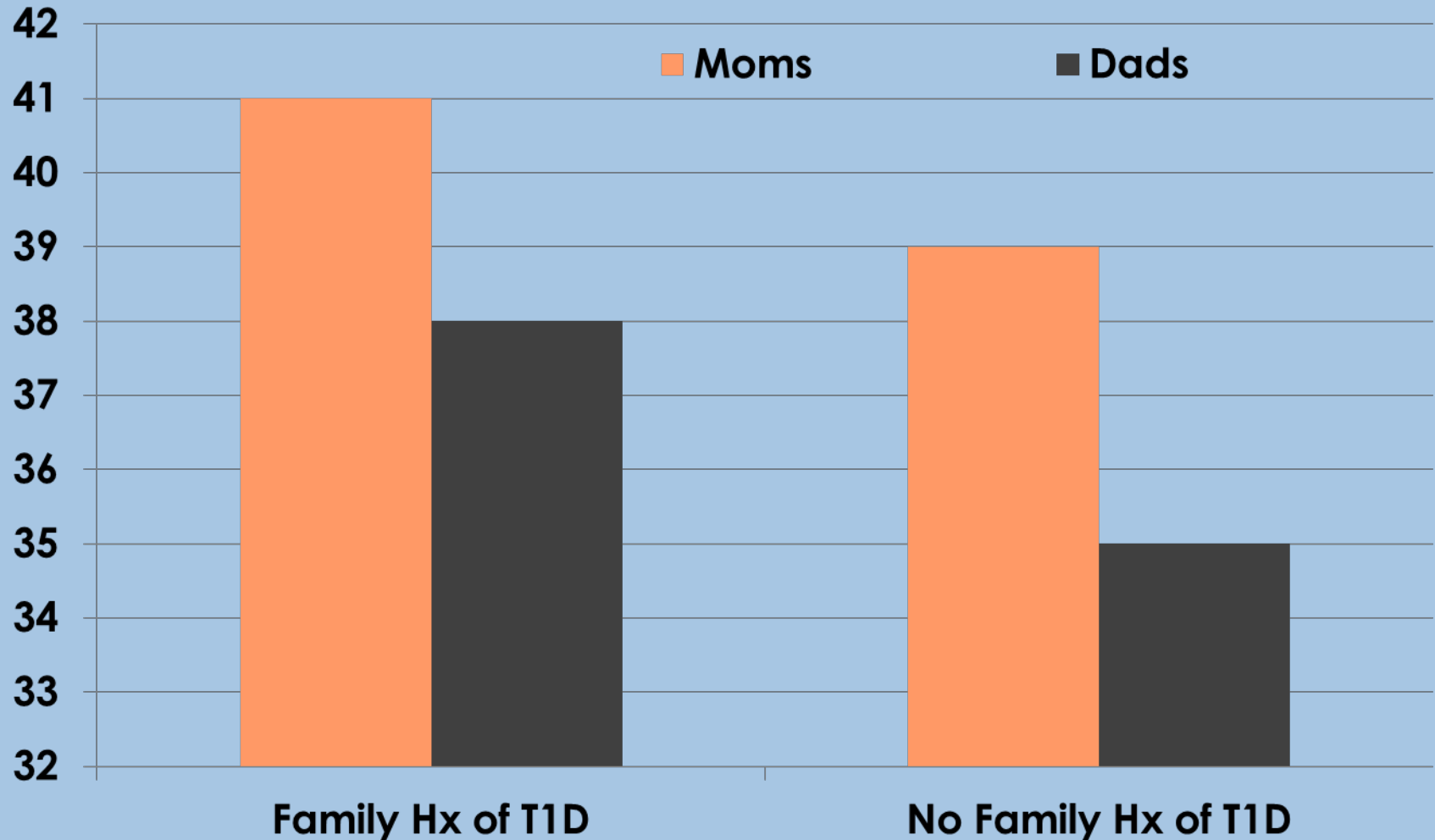


Percent of TEDDY Parents Who Underestimate Their Child's T1D Risk by Family History of T1D





TEDDY Parent State Anxiety Scores by Family History of T1D





Percent Reporting Efforts to Prevent T1D in Diabetes Prevention Trial (DPT-1) and TEDDY

Study/Respondent	Percent Reporting Behavior Change to Prevent T1DM
DPT-1 Oral Insulin Trial	
Parent	38
Participant	48
DPT-1 Parenteral Insulin Trial	
Parent	57
Participant	48
TEDDY year 1	
Parent (No Family Hx of T1D)	40
Parent (Family Hx of T1D)	51



Despite

- Poor predictive power
- Poor understanding of genetic test results
- Heightened anxiety associated with positive results
- Reported behavior changes associated with positive results
- Genetic testing is being marketed to families





Direct to Consumer (DTC) Genetic Testing: Multiple Concerns Raised

- Despite multiple reports and concerns raised by scientists, clinical geneticists, and other experts,
- DTC genetic testing is poorly regulated in US and Europe at all levels
 - Analytic validity-is the genetic variant present or absent?
 - Clinical validity –is a positive test result associated with a specific disease or condition in the patient (phenotype)
 - Clinical utility – does a test result provide helpful information
- DTC genetic testing is expected to increase due to lack of regulation and commercial allure (Hogarth et al, 2008)

Recommendations

- Wide-spread dissemination of screening for T1D risk is premature
- Screening for T1D risk should be limited to research centers where the psychosocial impact of screening can be monitored

