

Current Clinical Research on Type 2 Diabetes and Its Prevention in Youth

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The childhood obesity epidemic and the increase in type 2 diabetes in youth in the United States threaten the health and future of our nation's children. This article discusses:

- three clinical research trials sponsored by the National Institutes of Health (NIH) — SEARCH, TODAY and HEALTHY — that are designed to determine how many children have type 2 diabetes, and what are the best ways to treat and prevent this disease in the pediatric population, and
- an intervention by the National Association of School Nurses to address obesity with students and families.

The goal of the SEARCH trial is to estimate the prevalence of diabetes in youth less than 20 years of age and to determine what type of diabetes youth have by age, sex and race/ethnicity. The SEARCH study involves six centers in the U.S. Two approaches find children with diabetes:

1. In 4 geographic areas census-based data are used.
2. In 2 large health plans enrollment of youth with diabetes is used.

Using these methods, the SEARCH study group identified 6,379 young people with diabetes in 2001 and published their findings in *Pediatrics* in 2006 (SEARCH Study Group: The Burden of Diabetes Mellitus Among U.S. Youth: Prevalence Estimates from the SEARCH for Diabetes in Youth Study, *Pediatrics* Vol. 118, pp. 1510-1518). The estimated population base was about 3.5 million people for a case rate of approximately 1.82 cases per 1,000 youth overall. Results showed that:

- By age breakdown, there were fewer individuals in the young age group.
- For ages 0–9 years, the rate was 0.79

cases per 1,000 compared to ages 10–19, with a rate of 2.80 cases per 1,000.

- Non-Hispanic white youth had the highest prevalence, 1.06 cases per 1,000 in the younger group.
- In the older age group, African-American (3.22 cases per 1,000) and non-Hispanic white youth (3.18 cases per 1000 youth) had the highest rates, followed by Native American (2.28 cases per 1000 youth) and Hispanic youth (2.18 cases per 1000 youth).
- In the younger age range, more than 80% of diabetes was type 1.
- Among older children, type 2 accounted for 6% in non-Hispanic whites and 76% in Native Americans.
- It was estimated from these data that in 2001 there were 154,369 individuals aged under 19 in the U.S. with physician-diagnosed diabetes, and approximately 39,000 had type 2 diabetes.

The TODAY trial is attempting to determine the best ways to treat youth who have new-onset type 2 diabetes. The trial involves 15 clinical centers in 13 cities across the country. It is enrolling children between the ages of 10 and 17 years who have type 2 diabetes of less than 2 years' duration and whose BMI (body mass index, kg/m²) is greater than the 85th percentile for sex and age. The goal is to enroll 750 subjects who will be randomized to one of three treatment arms:

1. Metformin alone
2. Metformin plus a thiazolidinedione
3. Metformin plus intensive lifestyle change

The primary outcome of the trial is treatment failure or deterioration of glucose control. There also are a number of secondary outcomes that will examine the effects of

the three treatment arms on cardiovascular disease risk, co-morbidities, body composition, preservation of beta-cell function, and insulin resistance. In addition, cost and quality of life will be examined across the three treatment arms.

The lifestyle component of the TODAY study is very intensive. Young people randomized to this arm receive a lifestyle coach. They and their family support person — who is most often a parent — meet weekly for 26 weeks and then continue with frequent meetings for the duration of the trial. They follow a behavior change curriculum that is designed to improve nutrition and increase physical activity.

Data from the TODAY trial that as of May 2006 the study group had screened almost 600 youth for entry into the trial. All had been clinically diagnosed with type 2 diabetes. Of those youth screened for the trial, about 20% were white, about a third were African-American, and about a third were Hispanic. Of interest were their medication regimens:

- Almost 90% were on medications, and about 10% were treated with life style alone;
- Almost half were taking metformin as the only medication;
- A quarter were taking metformin plus insulin; and
- About 12% were taking only insulin.

While these findings are compatible with other reports of the treatment regimens for youth with type 2 diabetes, they are in marked contrast to the regimens for adults with diabetes. Most adults take oral medication as monotherapy, or in combination with other oral anti-diabetes medications, and insulin is used much less often early in the disease process.

Interestingly, these young people had a high rate of high blood pressure and abnormal lipid profile. About a quarter had a blood pressure value above the 95th percentile for sex, age, and height, which is considered hypertension in youth. Almost 60% had one abnormal lipid value.

The TODAY trial will be critically important to define how best to treat this emerging problem in the pediatric population to optimize long-term outcomes. Findings of cardiovascular risk factors, hypertension, and dyslipidemia early in the course of this disease underscore that those of us involved in caring for youth will need to focus on what were formerly considered adult disorders. For schools, providing appropriate nutrition and opportunities for physical activity will need to be a top priority. The TODAY trial will be completed in 2010.

The HEALTHY trial will look at school-based diabetes prevention programs. This study will follow a cohort of middle school students from sixth through eighth grade. It will be conducted at seven sites and each site will work with six schools in its area. Half of the schools will be intervention schools and half will be comparison schools. The study group will work with school staff in intervention schools to help change cafeteria offerings, as well as competitive food offerings. They will also work with physical education staff to enhance lesson plans and teaching methods to increase moderate to vigorous physical activity during physical education classes. A 10-week classroom curriculum offered each year to enhance behavior change will focus on intake of water, active versus sedentary behavior, food quality and, ultimately, energy balance. A social marketing campaign will employ a number of devices to get students, parents, and teachers to “buy in.”

This comprehensive school approach will aim to reduce risk factors for diabetes. Evaluation will compare at-risk levels of BMI between the intervention and comparison schools, as well as elevated fasting plasma glucose and insulin levels. In anticipation of the full trial, which was launched at the beginning of 2007, data were collected in a cohort of eighth graders in predominantly minority schools and the results were published in

Diabetes Care in 2006 (TODAY Study Group, Presence of Diabetes Risk Factors in a Large Cohort of U.S. Eighth-Grade Students, Vol. 29, pp. 212-217). The goal was to determine how many eighth grade students had diabetes, or abnormalities of glucose or insulin levels sampled after an overnight fast and during an oral glucose tolerance test. Data collected at school in over 1,700 students in 12 middle schools in three clinical centers in the U.S. revealed that:

- almost 50% of students had a BMI above the 85th percentile;
- 49% had a fasting glucose level in the abnormal range, compatible with impaired fasting glucose (between 100 and 126 mg/dL);
- 36% had a high fasting insulin level (greater than 30 μ /mL);
- very few (less than 1%) were found to have undiagnosed diabetes; and
- insulin and glucose levels increased with increasing BMI percentile, and fasting glucose was highest in Hispanic and Native American students.

This study shows that there is a high prevalence of risk factors for diabetes in middle school students in minority schools. The HEALTHY trial will be completed in 2009.

The National Association of School Nurses (NASN), funded through the Centers for Disease Control and Prevention and the National Diabetes Education Program, is developing a school model to address childhood overweight. The NASN-developed program, called School Nurses Childhood Obesity Prevention Education (SCOPE), provides school nurses with evidenced-based knowledge, skills and resources to identify, assess, counsel, and refer obese children to primary care providers. This program helps the school nurse communicate with primary care providers and provide culturally sensitive letters to parents and guardians regarding the BMI results for their child. The letters to parents are translated into many languages, including Spanish, Hmong, Somali, and Chinese. This program is in effect in four school districts: Saint Paul, MN, Oakland, CA, Albuquerque, NM, and Columbus, OH.

Although SCOPE has many facets, two primary components are:

- communication with parents/guardians and
- referrals to healthcare providers.

Information sent to parents from the school nurse is the key to parent support and cooperation. The introductory letter identifies the program and gives parents the opportunity to have their child “opt out.” Although health assistants may assist with the heights and weights after training, school nurses graph the BMIs based on the Body Mass Index: Child and Teen Calculator (<http://apps.nccd.cdc.gov/dnpabmi/Calculator.aspx>).

The BMI results letter sent to the parents from the school nurse after the screening is crucial to the program’s success. No judgments are made. The letter includes the height, weight, and BMI with explanations, and an opportunity to discuss the results with the school nurse (see Figure 1). In addition, information to guide families to follow up with a healthcare provider is included. Letters to parents were reviewed for cultural sensitivity and reading level by national experts in these areas. To date, more than one thousand students have been screened through this program and neither the school district nor school nurse has received negative comments. On the contrary, several parents have indicated that they are grateful for the information.

If a student is at the 95th percentile or above for BMI, with two or more risk factors, there is a follow-up phone assessment of the child with the parent/guardian. Those determined to be at risk of developing type 2 diabetes or other health problems are referred to their primary care providers. The school nurse sends a Diabetes Medical Request to Providers form to the parents to be taken to their healthcare provider (see Figure 2). This form is translated into Spanish on the reverse so that Hispanic/Latino parents can understand what they are taking to their primary care provider. (Plans have been made to translate this form into other languages.) The school nurse follows up with the parents to determine if the child has seen his or her healthcare provider. Follow-up information is sought from the healthcare provider.

Height and weight assessment by the school nurse, with additional physical

FIGURE 1. SAMPLE LETTER: RESULTS OF BODY MASS INDEX (BMI) SCREENING

Dear Parent/Guardian,

Your child, _____, was measured for height and weight. This was done for the Managing and Preventing Diabetes and Weight Gain (MAP) program. I sent a letter about that program on (_____ date). A body mass index (BMI) was figured from the height and weight. Your child's results showed:

Height: _____

Weight: _____

BMI-for-age percentile: _____

Doctors and nurses use guidelines to identify underweight, normal weight, at risk of overweight, and overweight in children. These guidelines are based on the BMI.

Underweight	BMI less than 5%
Within normal range	BMI 5% to 84%
At risk of overweight	BMI 85% to 94%
Overweight	BMI greater than or equal to 95%

BMI is not a final measure of overweight. Things like amount of activity in a day or history of illnesses in a family can influence height and weight in children and adolescents. Increased muscle from sports or physical activities can also increase BMI. Your child's healthcare provider is the best person to say whether his or her measurements are within a healthy range.

If your child is in the overweight area by BMI result, I will be contacting you soon. I will ask questions that help us to know if your child is at risk of diabetes. I will ask you to share the results with your child's healthcare provider. The healthcare provider may recommend changes in eating, physical activity, or other areas.

Classroom teaching about healthy eating and physical activity will start for all fourth graders in January. This is a part of the **Managing and Preventing Diabetes and Weight Gain (MAP) program**.

Please call me if you have any questions or concerns about the results of this BMI measurement.

Sincerely,

[School Nurse Name Here]

School Nurse

assessment for children at or above the 95th percentile for BMI, identifies those most at risk for developing diabetes. Preliminary accounts indicate that when this assessment and communication is done in a sensitive, caring manner – with the emphasis on the health of the child – parents are receptive to the information. School nurses can be the catalyst to encourage parents to address this health issue with their children and healthcare providers.

Summary

The SEARCH, TODAY, and HEALTHY studies, and NASN's SCOPE intervention, illustrate that collaboration between schools, school nurses, clinicians, students, and families can help treat and prevent

diabetes and obesity in youth. Findings will help identify the prevalence of diabetes in young people, the best ways to treat youth with new-onset type 2 diabetes, and healthful practices that can reduce risk factors for cardiovascular disease. Findings about diabetes prevention in the school setting can guide school nurses and school leadership to incorporate effective changes into food and physical activity offerings to students. Finally, school nurses can communicate with primary care providers and provide culturally sensitive letters to parents and guardians regarding the BMI results for the child. 🐦

RESOURCES

SEARCH trial: www.searchfordiabetes.org

TODAY trial: www.TODAYstudy.org.

National Diabetes Education Program: www.ndep.nih.gov/diabetes/youth/youth.htm or 1-800-438-5383 for free copies of tip sheets for kids with type 2 diabetes and other materials.

Weight-control Information Network: www.win.niddk.nih.gov/publications/child.htm. For nutrition, physical activity, and weight control information.

ABOUT THE AUTHORS

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FIGURE 2. DIABETES MEDICAL REQUEST TO PROVIDER

Presenting symptoms:

Date _____ Ht _____ Wt _____

BMI \geq 95th percentile for age/gender = _____

BP _____ BP percentile _____

- Increased thirst
- Exercise intolerance
- Acanthosis nigricans
- Fatigue
- Weight gain
- Unexplained weight loss
- Increased hunger
- Increased urination
- Blurred vision
- Other (please specify): _____

Diabetes risk factors:

- Parent or sibling diagnosed with diabetes
- Grandparent or aunt/uncle diagnosed with diabetes
- Mother diagnosed with diabetes

Higher-known risk groups:

- African American
- Pacific Islander
- Hispanic/Latino
- Asian American
- Native American
- < 60 minutes/day of physical activity or play
- > 2 hours of TV/computer/video game use/day
- Other (please specify): _____

To support this student's health, please address the following:

The American Diabetes Association (2006) Clinical Practice Recommendations and the American Heart Association (2005) Scientific Report recommends:

- 8+ hours *fasting venous blood glucose and lipoprotein profile*.
- If the FBG is \geq 126 mg/dl, confirm by repeating testing on a different day.
- The use of hemoglobin A1C for diabetes screening is *not* recommended at this time.
- Medical evaluation of the child and child/family diabetes education.
- Referral to a nutritionist/dietitian and an exercise program.

As noted below, ICD 9 codes are provided.

Healthcare Provider Response:

A diagnosis has been made (ICD 9):

- Overweight (278.92)
- Acanthosis nigricans (701.2)
- Hypertension (401.9)
- Hypercholesterolemia (272.0)
- Metabolic syndrome (277.7)
- Impaired fasting glucose (790.29) (FBG = 100–125 mg/dl)
- Impaired glucose tolerance (790.22) (2-hr post Oral Glucose Tolerance Test [OGTT]=140–199 mg/dl)
- Diabetes mellitus (250.0) (FBG \geq 126 mg/dl or 2-hr post OGTT \geq 200mg/dl)
- Other (please specify): _____

Treatment plan:

Healthcare Provider Name _____ Signature _____

Clinic Name _____ Phone _____ Date _____

Please fax this form to the school nurse. Thank you.

School Nurse _____ Fax: _____ Date _____

School Nurse Phone/Pager _____



The American Diabetes Association
congratulates School Nurse News for its
informative series of diabetes articles to help keep
children with diabetes **Safe at School.**

ADA is here to help with resources at
www.diabetes.org/schooltraining or by calling 1-800-DIABETES.