

Diabetes Research Concerning Children

By Alfonso Vargas, MD

For a person with diabetes, participation in a research study is an invaluable way to help advance knowledge and understanding about the causes and treatment of the disease. Recruitment of children depends on the willingness of parents and healthcare providers, including school nurses, to spread the word and support, and even encourage, participation in recognized and properly designed research efforts.

How many children and adolescents have diabetes?

Diabetes is a common chronic disease among children. In the United States, about 176,500 people under 20 years of age have diabetes. Type 1 diabetes accounts for 5 to 10 percent of all diagnosed cases of diabetes, and is the leading cause of diabetes in children (NIDDK, 2005). Type 2 diabetes used to occur mainly in adults who were overweight and aged 40 and above, but as more children and adolescents in the United States become overweight and inactive, type 2 diabetes is being diagnosed more often in young people.

There are numerous research endeavors trying to advance the prevention and treatment of diabetes in pediatric populations. This article focuses on the importance of studying diabetes in children and describes current diabetes research efforts.

Why are studies with children important?

The last few decades have shown advances in the understanding of type 1 diabetes. Certain individuals are more prone than others to develop type 1 diabetes. Individuals at risk can be iden-

tified before diabetes manifests itself clinically. Research has shown that the progression of type 1 diabetes can be slowed down with medical interventions if it is caught early. However, many of these interventions remain experimental and safety concerns have not been fully addressed. Research studies, including clinical trials with children, are important in the quest to answer questions that remain about the prevention, treatment, and control of diabetes.

What is a clinical trial?

Clinical trials are research studies designed to answer scientific questions. They aim to find better ways to prevent, diagnose, and treat patients. A clinical trial is typically the final stage of a long research process. Studies are often done with patients to find out whether promising approaches to prevent, diagnose, and treat various health conditions are safe and effective for the greater population.

There are several different types of clinical trials:

- **Treatment trials** test treatments like a new medicine, new approaches to surgery or therapy, new combinations of treatments, or new methods.
- **Prevention trials** test new approaches, such as medicines, vitamins, minerals, or other supplements that doctors believe might lower the risk of developing a certain condition or disease.
- **Screening trials** test the best way to screen for or find a condition or disease, especially in its early stages.
- **Quality of Life trials** (also called Supportive Care trials) explore ways to improve comfort and quality of life for patients.

How is participant safety assured?

Research studies that involve children pose important questions regarding the ethical boundaries and issues related to privacy and safety. Federal and state regulations provide a framework that allows these types of studies to be implemented while guarding the privacy and safety of study participants.

All biomedical institutions that do research with human subjects in the United States follow federal regulations. These legislative measures provide boundaries to safeguard individuals who engage in research studies.

Some of the requirements are:

- the evaluation and review by an Institutional Review Board, which is composed of biomedical experts and lay people who assess the rationale of a project
- involving the parents or legal guardians as well as the children who are candidates for these studies in a discussion about the clinical trial
- study participants' signatures on documents that describe the benefits and risks involved in the study and the assurances of the voluntary nature of the participation.

Investigators are bound by law to disclose any new information that is learned during a study that might affect the study participants. In some cases a data safety monitoring board will supervise to ensure a study is being managed properly. This board can impose changes in the original study protocols and even terminate a study early if participants are exposed to undue risk or if the intervention being studied is shown to be beneficial and

could positively affect study participants who are not receiving the intervention.

Current diabetes research in children

The National Institutes of Health (NIH) is the largest supporter of biomedical research in the United States. NIH provides guidance and leadership on many projects involving research in children. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) conducts and supports a wide range of research aimed at investigating ways to prevent and treat diabetes and its health complications. Below are some examples of such research.

The Diabetes Research in Children Network (DirecNet)

DirecNet is a network of clinical centers working to determine the potential use of glucose monitoring technology and its impact on the management of type 1 diabetes in children (<http://public.direc.net/>).

The Environmental Determinants of Diabetes in the Young (TEDDY)

The TEDDY consortium organizes international efforts to identify infectious agents, dietary factors, or other environmental factors that trigger type 1 diabetes in genetically susceptible individuals (<http://www.teddystudy.org>).

The SEARCH for Diabetes in Youth Study (SEARCH)

The SEARCH study is co-funded by CDC and NIDDK to determine the incidence and prevalence of diabetes in children in six areas of the U.S. and to help clarify trends in the development of diabetes in youth (www.searchfordiabetes.org).

TrialNet

TrialNet is a network of 18 clinical centers working in cooperation with screening sites throughout the United States, Canada, Finland, United Kingdom, Italy, Germany, Australia, and New Zealand. This network is dedicated to the study, prevention, and early treatment of type 1 diabetes. TrialNet is supported by the U.S. Department of Health & Human Services and NIH, the Juvenile Diabe-

tes Research Foundation International, and the American Diabetes Association (www.diabetestrialnet.org).

The Natural History Study is one of the studies TrialNet will perform. The goal of this study is to learn more about how type 1 diabetes develops in at-risk individuals. Relatives of people with type 1 diabetes are being studied because they are at 10 to 15 times the risk of developing the disease than are people with no such family history.

The MMF/DZB study is another study that TrialNet will perform. The goal of the study is to find out if two immunosuppressive medicines are able to stop the immune system from destroying beta cells in new-onset type 1 diabetes patients (within 3 months of diagnosis). The two medicines are called Mycophenolate mofetil (MMF/CellCept®) and Daclizumab (DZB/Zenapax®). These medicines work by decreasing the immune system's activity.

Treatment Options for type 2 Diabetes in Adolescents and Youth Study (TODAY)

The TODAY trial seeks to identify the best treatment of type 2 diabetes in children and teens (<http://www.niddk.nih.gov/patient/today/today.htm>).

Studies to Treat or Prevent Pediatric Type 2 Diabetes (STOPP-T2D)

The STOPP-T2D study will test a program to lower risk factors for type 2 diabetes in middle-school students. Investigators from seven field centers are designing and developing this primary prevention trial of a middle school-based intervention that will target nutrition, physical activity, and behavior modification.

For more information about any of the research studies listed, visit the websites. For information about diabetes, visit the National Diabetes Education Program's website at www.ndep.nih.gov, or call 1-800-438-5383.

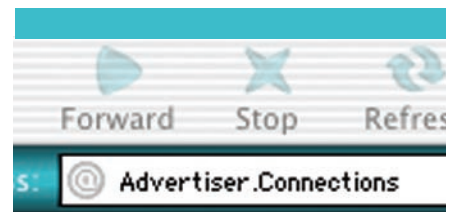
The U.S. Department of Health and Human Services' National Diabetes Education Program is jointly sponsored by the National Institutes of Health and the Centers for Disease Control and Prevention with the support of more than 200 partner organizations. 🐾

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