

DIABETES RESEARCH IN CHILDREN NETWORK (DirecNet)

Description of Project

- The mission of DirecNet is to investigate the potential use of glucose monitoring technology and its impact on the management of type 1 diabetes (T1DM) in children.

Accomplishments

DirecNet has developed seven protocols and four ancillary studies

Completed Protocols

- 1) The Accuracy of Continuous Glucose Monitors in Children with Type 1 Diabetes; this protocol included three ancillary studies:
 - a. An assessment of the accuracy of the OneTouch Ultra home glucose meter
 - b. An evaluation of the alarm function of the GlucoWatch 2 Biographer
 - c. An evaluation of an accelerometer to assess exercise in children with T1DM
- 2) A Pilot Study to Assess the Accuracy of Continuous Glucose Monitors in Normal Children
- 3) A Pilot Study to Evaluate the GlucoWatch 2 Biographer in the Management of Type 1 Diabetes in Children
- 4) A Randomized Clinical Trial to Assess the Effectiveness of the GlucoWatch Biographer in the Management of Type 1 Diabetes in Children
- 5) The Effect of Exercise on the Development of Hypoglycemia in Children with Type 1 Diabetes

Protocols in Progress

- 1) A Pilot Study to Evaluate the Navigator Continuous Glucose Sensor in the Management of Type 1 Diabetes in Children
- 2) The Effect of Basal Insulin During Exercise on the Development of Hypoglycemia in Children with Type 1 Diabetes; this protocol includes the ancillary study:
 - a. Accuracy Assessment of the A1cNow

Manuscripts, Abstracts and Presentations

Manuscripts- Published

- 1) Diabetes Research in Children Network (DirecNet) Study Group: **The Accuracy of the CGMS in Children with Type 1 Diabetes: Results of the Diabetes Research in Children Network (DirecNet) Accuracy Study.** Diabetes Technol Ther 2003; 5(5):781-789.
- 2) Diabetes Research in Children Network (DirecNet) Study Group: **The Accuracy of the GlucoWatch G2 Biographer in Children with Type 1 Diabetes: Results of the Diabetes Research in Children Network (DirecNet) Accuracy Study.** Diabetes Technol Ther 2003; 5(5):791-800.

- 3) Diabetes Research in Children Network (DirecNet) Study Group: **A Multi-center Study of the Accuracy of the One Touch Ultra Home Glucose Meter in Children with Type 1 Diabetes.** *Diabetes Technol Ther* 2003; 5(6):933-941.
- 4) Diabetes Research in Children Network (DirecNet) Study Group: **Accuracy of the GlucoWatch G2 Biographer and the Continuous Glucose Monitoring System During Hypoglycemia. Experience of the Diabetes Research in Children Network (DirecNet).** *Diabetes Care* 2004; 27(3):722-726.
- 5) Diabetes Research in Children Network (DirecNet) Study Group: **Lack of Accuracy of Continuous Glucose Sensors in Healthy, Nondiabetic Children. Results of the Diabetes Research in Children Network (DirecNet) Accuracy Study.** *J Pediatr* 2004; 144(6):770-775.
- 6) Diabetes Research in Children Network (DirecNet) Study Group: **GlucoWatch G2 Biographer (GW2B) Alarm Reliability During Hypoglycemia in Children.** *Diabetes Technol Ther* 2004; 6(5):559-566.
- 7) Diabetes Research in Children Network (DirecNet) Study Group: **Accuracy of the Modified Continuous Glucose Monitoring System (CGMS) Sensor in an Outpatient Setting: Results from a Diabetes Research in Children Network (DirecNet) Study.** *Diabetes Technol Ther* 2005; 7(1):109-114.
- 8) Tsalikian E, Beck RW, Kalajian A, Janz JF, Tansey MJ for the Diabetes Research in Children Network (DirecNet) Study Group: **Function of the GlucoWatch G2 Biographer During Exercise (Letter to the Editor).** *Diabetes Technol Ther* 2005; 7(1):230.
- 9) Diabetes Research in Children Network (DirecNet) Study Group: **Comparison of Fingerstick Hemoglobin A_{1c} Levels Assayed by DCA 2000 with the DCCT/EDIC Central Laboratory Assay: Results of a Diabetes Research in Children Network (DirecNet) Study.** *Pediatr Diabetes* 2005; 6(1):13-16.
- 10) Diabetes Research in Children Network (DirecNet) Study Group: **A Randomized Multicenter Trial Comparing the GlucoWatch Biographer with Standard Glucose Monitoring in Children with Type 1 Diabetes.** *Diabetes Care* 2005; 28(5):1101-1106.

Manuscripts- In Press

- 11) Buckingham BA, Block JM, Burdick J, Kalajian A, Kollman C, Choy M, Wilson DM, Chase HP for the Diabetes Research in Children Network: **Response to Nocturnal Alarms Using a Real-Time Glucose Sensor.** *Diabetes Technol Ther*, In Press.
- 12) Diabetes Research in Children Network (DirecNet) Study Group: **Eight-point Glucose Testing versus the Continuous Glucose Monitoring System (CGMS) in Evaluation of Glycemic Control in Type 1 Diabetes.** *JCEM*, In Press.
- 13) Diabetes Research in Children Network (DirecNet) Study Group: **Impact of Exercise on Overnight Glycemic Control in Children with Type 1 Diabetes.** *J Pediatr*, In Press.

- 14) Diabetes Research in Children Network (DirecNet) Study Group: **Youth and Parent Satisfaction with Clinical Use of the Gluowatch G2 Biographer in the Management of Pediatric Type 1 Diabetes.** Diabetes Care, In Press.

Manuscripts- Submitted

- 15) Kollman C, Wilson DM, Wysocki T, Tamborlane WV, and Beck RW for the Diabetes Research in Children Network (DirecNet) Study Group: **Limitations of Statistical Measures of Error in Assessing the Accuracy of Continuous Glucose Sensors.** Submitted March, 2005.
- 16) Diabetes Research in Children Network (DirecNet) Study Group: **Psychological Aspects of Continuous Glucose Monitoring in Pediatric Type 1 Diabetes.** Submitted March, 2005.
- 17) Diabetes Research in Children Network (DirecNet) Study Group: **Accuracy of Newer Generation Home Blood Glucose Meters in a Diabetes Research in Children Network (DirecNet) Inpatient Exercise Study.** Revision submitted April, 2005.
- 18) Diabetes Research in Children Network (DirecNet) Study Group: **Diabetes Self Management Profile for Flexible Insulin Regimens: Cross-Sectional and Longitudinal Analysis of Psychometric Properties in a Pediatric Sample.** Revision submitted May, 2005.

Published Abstracts

- 1) Nelly Mauras, Roy Beck, Katrina Ruedy, Andrea Booth, Stuart Weinzimer, and the Diabetes Research in Children Network (DirecNet) Study Group: **The Physiological Variations of Plasma Glucose Concentrations in Healthy, Non-Diabetic Children: Use of Continuous Glucose Sensors.** *Pediatr Res* 2003; 53(4 Pt 2):1A-669A (Oral).
- 2) Stuart Weinzimer, Roy Beck, Katrina Ruedy, Andrea Booth, Elizabeth Boland, and the Diabetes Research in Children Network (DirecNet) Study Group: **Mealtime Glycemic Excursions in Pediatric Subjects with Type 1 Diabetes Mellitus (T1DM): The DirecNet Experience.** *Pediatr Res* 2003; 53(4 Pt 2):1A-669A (Poster).
- 3) Eva Tsalikian, Roy Beck, Katrina Ruedy, Andrea Booth, Michael Tansey, and the Diabetes Research in Children Network (DirecNet) Study Group: **Glycemic Pattern of Insulin Induced Hypoglycemia in Pediatric Subjects with Type 1 Diabetes Mellitus (T1DM): The DirecNet Experience.** *Pediatr Res* 2003; 53(4 Pt 2):1A-669A (Poster).
- 4) Bruce Buckingham, Roy Beck, William Tamborlane, Katrina Ruedy, Elizabeth Boland, Peter Chase, Timothy Wysocki, Eva Tsalikian, Darrell Wilson, Nelly Mauras, Stuart Weinzimer, Michael Tansey, Rosanna Fiallo-Scharer, Andrea Booth, Craig Kollman and the Diabetes Research In Children Network (DirecNet) Study Group: **Diabetes Research in Children Network (DirecNet) Accuracy Study of the Continuous Glucose Monitoring System (CGMS) and GlucoWatch G2 Biographer (GWB) in Children with Type 1 Diabetes-A CRC-based Study.** *Diabetes* 2003; 52(Suppl 1):A36 (Oral).
- 5) Darrell Wilson, Bruce Buckingham, Roy Beck, Katrina Ruedy, Craig Kollman, Eva Tsalikian, Timothy Wysocki, Stuart Weinzimer, Peter Chase and the Diabetes Research in Children Network (DirecNet) Study Group: **A 5-center CRC-based Study of the Accuracy of the**

GlucoWatch G2 Biographer in Children and Adolescents with Type 1 Diabetes. Diabetes 2003; 52(Suppl 1):A101 (Poster).

- 6) Rosanna Fiallo-Scharer, Peter Chase, Roy Beck, Katrina Ruedy, Andrea Booth, Timothy Wysocki, Elizabeth Boland, Bruce Buckingham, Eva Tsalikian and the Diabetes Research In Children Network (DirecNet) Study Group: **Performance of the One Touch Ultra at Different Glucose Levels in Three Age Groups of Children with T1DM in the CRC-DirecNet Accuracy Study.** Diabetes 2003; 52(Suppl 1):A562 (Poster).
- 7) Elizabeth Boland, Stuart Weinzimer, Roy Beck, Katrina Ruedy, Craig Kollman, Bruce Buckingham, Peter Chase, Michael Tansey, Nelly Mauras and the Diabetes Research In Children Network (DirecNet) Study Group: **Performance of the Medtronic MiniMed Continuous Glucose Monitoring System (CGMS) in Children with T1DM in the DirecNet Accuracy Study.** Diabetes 2003; 52(Suppl 1):A90 (Poster).
- 8) Michael Tansey, Roy Beck, Bruce Buckingham, Nelly Mauras, Rosanna Fiallo-Scharer, Dongyuan Xing, William Tamborlane, Katrina Ruedy, and the Diabetes Research in Children Network (DirecNet) Study Group. **A Comparison of the Original vs. Modified Continuous Glucose Monitoring System (CGMS) Sensor During Hypoglycemia in the Diabetes Research in Children Network (DirecNet) Accuracy Study.** Diabetes Technol Ther 2004; 6(2):275 (Poster).
- 9) Craig Kollman, Darrell Wilson, Tim Wysocki, Rosanna Fiallo-Scharer, Eva Tsalikian, William Tamborlane, Roy Beck, Katrina Ruedy, and the Diabetes Research In Children Network (DirecNet) Study Group. **Limitations of Statistical Measures of Error in Assessing the Accuracy of Glucose Sensors.** Diabetes Technol Ther 2004; 6(2):254 (Oral and Poster).
- 10) Eva Tsalikian, Craig Kollman, Rosanna Fiallo-Scharer, Roy Beck, Bruce Buckingham, Nelly Mauras, Stuart Weinzimer, William Tamborlane, Katrina Ruedy, and the Diabetes Research In Children Network (DirecNet) Study Group. **Down Alert Function of the GlucoWatch G2 Biographer (GW2B) During Insulin-induced Hypoglycemia in Children.** Diabetes Technol Ther 2004; 6(2):276 (Poster).
- 11) Stuart Weinzimer, Katrina Ruedy, Jennifer Fisher, Linda Larson, Jennifer Block, Elizabeth Boland, Keisha Bird, and the Diabetes Research in Children Network (DirecNet) Study Group. **Diabetes Research in Children Network (DirecNet) Outpatient Pilot Study to Evaluate the GlucoWatch G2 Biographer (GW2B) in the Management of Type 1 Diabetes (T1DM) in Children.** Diabetes Technol Ther 2004; 6(2):280 (Poster).
- 12) William Tamborlane, Dongyuan Xing, Michael Steffes, Craig Kollman, Katrina Ruedy, Roy Beck, Rosanna Fiallo-Scharer, Larry Fox, Darrell Wilson, Eva Tsalikian, and the Diabetes Research In Children Network (DirecNet) Study Group. **Performance of the DCA2000 for Measurement of Hemoglobin A1c Levels in Children with T1DM in a DirecNet Outpatient Clinical Trial.** Pediatr Res 2004; 55(4 Pt 2):138A (Poster).
- 13) Stuart Weinzimer, Katrina Ruedy, Linda Larson, Jennifer Block, Jennifer Fisher, Elizabeth Doyle, Keisha Bird, and the Diabetes Research in Children Network (DirecNet) Study Group. **Diabetes Research in Children Network (DirecNet) Outpatient Pilot Study to Evaluate the**

Feasibility of Computer-Based Data Acquisition and Transmission. *Pediatr Res* 2004; 55(4 Pt 2):138A (Poster).

- 14) Michael Tansey, Roy Beck, Bruce Buckingham, Nelly Mauras, Rosanna Fiallo-Scharer, Dongyuan Xing, Craig Kollman, William Tamborlane, Katrina Ruedy, and the Diabetes Research in Children Network (DirecNet) Study Group. **A Comparison of the Original vs. Modified Continuous Glucose Monitoring System (CGMS) Sensor During Using Data from Two DirecNet Studies.** *Diabetes* 2004; 53 Suppl 2:A465.
- 15) Rosanna Fiallo-Scharer, Dongyuan Xing, Stuart Weinzimer, Bruce Buckingham, Nelly Mauras, Michael Tansey, Roy Beck, Katrina Ruedy, Craig Kollman, William Tamborlane, and the Diabetes Research in Children Network (DirecNet) Study Group. **Utility of CGMS as a Measure of Glycemic Control in Children with Type 1 Diabetes (T1DM).** *Diabetes* 2004; 53(Suppl 2):A67 (Oral).
- 16) Peter Chase, Dongyuan Xing, Stuart Weinzimer, Bruce Buckingham, Nelly Mauras, Michael Tansey, Roy Beck, Katrina Ruedy, Craig Kollman, William Tamborlane, and the Diabetes Research in Children Network (DirecNet) Study Group. **Comparison of 8-point Glucose Testing with Glycemic Control in Children with Type 1 Diabetes (T1DM).** *Diabetes* 2004; 53(Suppl 2):A600.
- 17) Tim Wysocki, Dongyuan Xing, Rosanna Fiallo-Scharer, Elizabeth Doyle, Jennifer Block, Eva Tsalikian, Roy Beck, Katrina Ruedy, Craig Kollman, William Tamborlane, and the Diabetes Research in Children Network (DirecNet) Study Group. **Diabetes Self-Management Profile-Revised for Conventional and Flexible Insulin Regimens.** *Diabetes* 2004; 53(Suppl 2):A436 (Poster).
- 18) H. Peter Chase, Roy Beck, William Tamborlane, Bruce Buckingham, Nelly Mauras, Eva Tsalikian, Tim Wysocki, Stuart Weinzimer, Katrina Ruedy, Dongyuan Xing, and the Diabetes Research in Children Network (DirecNet) Study Group. **Lack of Effectiveness of the GlucoWatch G2 Biographer in Altering Glycemic Control in Children with Type 1 Diabetes.** *Diabetes Technol Ther* 2005; 7(2):370 (Poster).

Submitted Abstracts

- 19) Eva Tsalikian, Roy Beck, Peter Chase, Tim Wysocki, Bruce Buckingham, Stuart Weinzimer, Nelly Mauras, Katrina Ruedy, Craig Kollman, Dongyuan Xing, Katrina Ruedy, William Tamborlane and the Diabetes Research in Children Network (DirecNet) Study Group. **Impact of Exercise on Overnight Glycemic Control in Children with Type 1 Diabetes (T1DM).** Accepted as Oral Presentation for 2005 ADA Meeting.
- 20) Darrell Wilson, Rosanna Fiallo-Scharer, Dongyuan Xing, Tim Wycoki, Jennifer Block, Stu Weinzimer, Craig Kollman, Roy Beck, Katrina Ruedy, William Tamborlane, and the Diabetes Research in Children Network (DirecNet) Study Group. **Reliability of Two Indices of the Biologic Variability in Glycosylation among Children and Adolescents with T1DM.** Accepted as Poster Presentation for 2005 ADA Meeting.
- 21) Michael Tansey, William Tamborlane, Nelly Mauras, Eva Tsalikian, Kathleen Janz, Elizabeth Doyle, Roy Beck, Dongyuan Xing, Craig Kollman, Katrina Ruedy and the Diabetes Research in Children Network (DirecNet) Study Group. **The Effects of Structured Exercise on Counter-**

Regulatory Hormones and Risk for Hypoglycemia in Children with Type 1 Diabetes Mellitus (T1DM). Submitted for 2005 LWPES Meeting.

- 22) Tim Wysocki, Roy W. Beck, Craig Kollman, Katrina Ruedy, Dongyuan Xing, William V. Tamborlane, Rosanna Fiallo-Scharer, Eva Tsalikian, Jennifer M. Block, and the Diabetes Research in Children Network (DirecNet) Study Group. **Psychological Aspects of Clinical Use of the GlucoWatch G2 Biographer Continuous Glucose Monitor in Children and Adolescents with Type 1 Diabetes Mellitus.** Submitted for 2005 LWPES Meeting.

Additional Accomplishments

- Development of methods for the use of personal computers in the home for the child and family to download continuous glucose monitoring devices and home glucose meters.
- Development of methods for the data management and analysis of continuous glucose monitoring data and for utilizing the data in the management of children with T1DM.
- Development of methods for use of tablet computers in the clinic for paperless case report form completion and for completion of quality of life questionnaires.
- Development of quality of life questionnaire related to use of continuous glucose monitors.
- Development of statistical methods for the analysis of continuous glucose monitoring data.
- Development of algorithms for the child and parents to use for incorporating continuous glucose data into diabetes self-management.

Future Directions

- Initiate a randomized trial to evaluate the Navigator (pending results of pilot study).
- Evaluate and develop distinct, age-appropriate treatment approaches to T1DM in children.
- Evaluate prevention of nocturnal hypoglycemia using varying types of bedtime snacks.
- Assess the use of continuous glucose monitors to detect and prevent hypoglycemia during seasons of activity in adolescents with T1DM.
- Assess possible changes in neurocognitive function and how it relates to frequency of hypoglycemia in young children with type 1 diabetes.

Participants

Sponsors: National Institute of Child Health and Human Development
National Institute of Diabetes and Digestive and Kidney Diseases

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