SUMMARY OF SIXTH ANNUAL DIABETES TECHNOLOGY MEETING
NOVEMBER 2-4, 2006
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The sixth annual Diabetes Technology Meeting was held in Atlanta from November 2 - 4, 2006. In attendance were over 500 scientists, engineers, and doctors from government, industry, academia, and clinical practice. The attendees hailed from 25 countries. The meeting was presented by Diabetes Technology Society in cooperation with Centers for Disease Control and Prevention (CDC), the US Army Technologies for Metabolic Monitoring Research Program, National Space Biomedical Research Institute, University of California at Berkeley Bioengineering Department, Georgia Tech/Emory Center for the Engineering of Living Tissues, and Mills-Peninsula Health Services. During the three half-day workshops and two days of general sessions, speakers shared information on topics related to applications of bioengineered technologies to diabetes such as continuous glucose monitoring, non-invasive glucose monitoring, the physiology of interstitial fluid, closed loop control of blood glucose, alternate needle-free routes of insulin delivery, and software for describing and managing multiple blood glucose measurements.

Workshop A, entitled "Reimbursement Strategies for Diabetes Technologies" was comprised of four panels where: (1) reimbursement strategies (2) continuous glucose monitoring, (3) insulin pumps and (4) drugs for diabetes and obesity were discussed. The speakers concluded that new advanced technologies for patient monitoring must go through a scientific, regulatory, and political process in order to be eligible for reimbursement from Centers for Medicare & Medicaid Services and from private insurance companies. There was also a consensus among the speakers that creation of a repository of outcomes evidence from randomized controlled trials published in peer-reviewed journals will accelerate the approval process for new technologies.

Workshop B entitled "Physiology of Interstitial Fluid" was comprised of both an academic panel and an industry panel where discussions on lag time of glucose measurement, the relevance of the AST-Phenomenon to interstitial fluid glucose, open-flow microperfusion and microdialysis, and recent advances in the evaluation of microvascular function in the epidermis of man took place. The industry panel discussed how putative delays in interstitial fluid (ISF) glucose kinetics can be attributed to the glucose sensing systems used to measure them rather than to a delay in equilibration of glucose levels between blood and ISF glucose levels. Hypoglycemia and hyperglycemia alarm detection accuracy of a continuous glucose monitoring system, interstitial fluid sampling by reverse iontophoresis and the meaning of lag time was also discussed. The consensus of the speakers was that a lag between rapidly fluctuating blood glucose levels and ISF glucose levels is no more than ten minutes in most cases.

Workshop C entitled "Databases and Diabetes" covered the relationships between information technology and diabetes as well as telemedicine and Diabetes. The workshops addressed the question of how to establish a diabetes database and case management program and how to properly utilize database for successful healthcare delivery. Robert Vigersky, M.D. (Walter Reed Army Medical Center) discussed a comprehensive telemedicine program being developed by the US Army. John Oxendine, Insurance Commissioner of the State of Georgia provided insight into how Georgia's statewide diabetes tele-health program was created and became accepted by the medical community. The consensus of the speakers was that the use of databases in diabetes offers great promise for delivery of patient care and performance of large population research studies.

The first general session of the Meeting entitled "Technologies for Metabolic Monitoring", was moderated by Carl Hover, Ph.D. (US Army, Fort Detrick). Welcoming remarks were made by Eric Sampson, Ph.D., Director of Laboratory services at CDC. The keynote address on the first day of the meeting was delivered by Roderic Pettigrew, M.D., Ph.D., the Director of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) He discussed how the mission of promoting bioengineered solutions to diabetes is being carried out by NIBIB. This session covered new advances in measuring glucose noninvasively with near-infrared spectroscopy. The session also covered the accurate use of point-of-care monitors for measuring glucose accurately both in the inpatient and outpatient settings. Limitations in the use of current blood glucose monitors and solutions to these problems were discussed. Advances in Hemoglobin A1c testing to assess longterm control of diabetes, utilizing various point of care technologies were presented during this session. The consensus of the attendees was that new technologies for measuring analytes of interest in diabetes will continue to develop and affect the practice of diabetes medicine.

The second session entitled "Formulas for Expressing Continuous Blood Glucose Data" was moderated by Karl Friedl, Ph.D. (US Army, Fort Detrick). Topics relating to glucose variability, relation to risk analysis, use of ROC curves for determining optimal set points for alarms, and the temporal structure of continuous monitoring data were addressed. Novel approaches to continuous glucose analysis incorporating glycemic variation were presented. Accuracy requirements for a continuously monitored glucose monitor providing a hypoglycemia detector were presented and analytical models to evaluate the effects of bias, precision, and rate of glucose change on monitor accuracy were discussed. Mathematical modeling methods for on-line prediction of blood glucose were also addressed. The consensus was that better methods for expressing continuous glucose data are needed for clinicians to best utilize continuous glucose sensors and newly developed statistical methods will create useful algorithms for this purpose.

The third session entitled the "Artificial Pancreas" discussed the accuracy of existing and future hypoglycemia and hyperglycemia alarms, used by of a continuous glucose monitoring systems, for detection of outlier glucose levels that can affect closed loop control. Data on glycemic profiles in healthy controls were presented. A feasibility study of closed loop control in a set of pediatric patients with Type 1 diabetes was presented. An on-chip microdialysis system with flow-through glucose sensing capabilities

was discussed. This session also included presentation of the Peterson Student Research Awards to the three students conducting research in diabetes technology, who first-authored the highest rated abstracts that were submitted to the meeting. The winners were from Pennsylvania State University (Gold), Univerzita Pavla Josefa Safarika, Kosice, Slovakia (Silver), and University of California at Irvine (Bronze). The consensus of attendees was that closed loop control of glucose is advancing closer to becoming a reality each year.

The fourth session entitled "Must Automatic Glucagon Delivery Be Part of an Artificial Pancreas?" addressed the importance of glucagon in metabolic regulation. Closed-loop blood-glucose control using dual subcutaneous infusions of both insulin and glucagon in vivo and closed-loop glycemic control in a model of Type 1 diabetes was addressed. Physiological aspects and pharmacological properties of commercial glucagon preparations were discussed. A barrier to the use of continuously delivered glucagon in solution was described to be the development of protein fibrils. The consensus of attendees was that if problems can be solved in formulating a stable glucagon preparation for continuous longterm administration of glucagon, then the use of this hormone as a rescue from insulin-induced hypoglycemia would be an attractive component of an artificial pancreas.

The fifth session entitled "Novel Technologies to Deliver Insulin and Other Metabolic Peptides" addressed the challenges and opportunities in tissue engineering of a pancreatic substitute. The keynote address on the second day of the meeting was delivered by Robert Nerem, Ph.D., the Director of the Georgia Tech/Emory Center for the Engineering of Living Tissues. He discussed how new sources of islet cells could lead to a tissue engineering solution to the problem of islet cell failure in diabetes. This session also discussed the relationships between various insulin formulations and their pharmacodynamics and pharmacokinetics. A very rapidly acting novel formulation of recombinant human insulin, called Viaject™, was discussed. Variations in insulin analog pharmacodynamics in pediatric patients using insulin pumps were discussed. The consensus of attendees was that new insulin formulations with unique properties will be developed in the near future.

The sixth session entitled "Inhaled Insulin" presented a clinical overview of the history of inhaled insulin as well as the clinical and safety issues associated with the use of this type of preparation. Advances in insulin delivery using Technosphere Insulin as well as a comparison of standard versus intensive training on usage of the AIR® Inhaled Insulin System in patients with Type 2 diabetes was presented. Pulmonary function in patients with diabetes receiving inhaled insulin was discussed. The consensus of speakers was that inhaled insulin has not been demonstrated to cause serious longterm pulmonary complications in diabetes, but because this product is relatively new, that additional scrutiny will nonetheless be needed in the future to exclude late complication s of chronic use. The annual Diabetes Technology Leadership Award was awarded to the person who has done the most to further the development of diabetes technology. The recipient this year was John Patton, Ph.D. from Nektar Therapeutics.

The seventh session entitled "Microelectrical Mechanical Systems (MEMS) and Diabetes" addressed the use of microneedles for interstitial fluid sampling and drug delivery. A presentation was made on the Debiotech Insulin Nanopump™ which can use MEMS technology to deliver minute pulses of insulin. The consensus of speakers was that on a MEMS scale, it is possible to perform ISF measurements and deliver insulin in a more controlled and accurate way than on a macro scale.

The eighth session entitled "Hospital Management Technology" addressed the use of the Glucommander-based glycemic protocol for cardiovascular surgery as well as an inpatient glycemic control protocol utilizing basal-bolus insulin therapy by way of a computerized order entry. The consensus of attendees was that intensive management of diabetes in hospitalized patients will be significantly aided by improved software for automatic insulin dosing.

The ninth session entitled "Survey and Demonstration" utilized an audience response system to ask the audience multiple-choice questions whose response could be displayed in real-time and discussed during this session. A panel of technology experts from the US, Europe, and New Zealand led the discussion. This session concluded with a demonstration by a team from the US Army of Physiological Monitoring of the Warfighter. In this demonstration an integrated Warfighter-worn health-and-performance monitoring system demonstrated vital-sign detection based on measurements of heart rate, respiration rate, body position orientation, actigraphy, skin temperature, and core temperature. A live feed to the audience in Atlanta from London, England utilized GPS technology to demonstrate, in real time, the vital signs and exact location of a volunteer who was wearing this multimodal monitor. The map was continuously refreshed to display the volunteer's real-time location. The consensus of meeting attendees was that physiological monitoring with remote transmission will become increasingly utilized for medical, and military purposes and that the US Army system represents one of the first examples of how this approach to telemedicine can provide important information to a home station responsible for wearers, who are a great distance away.