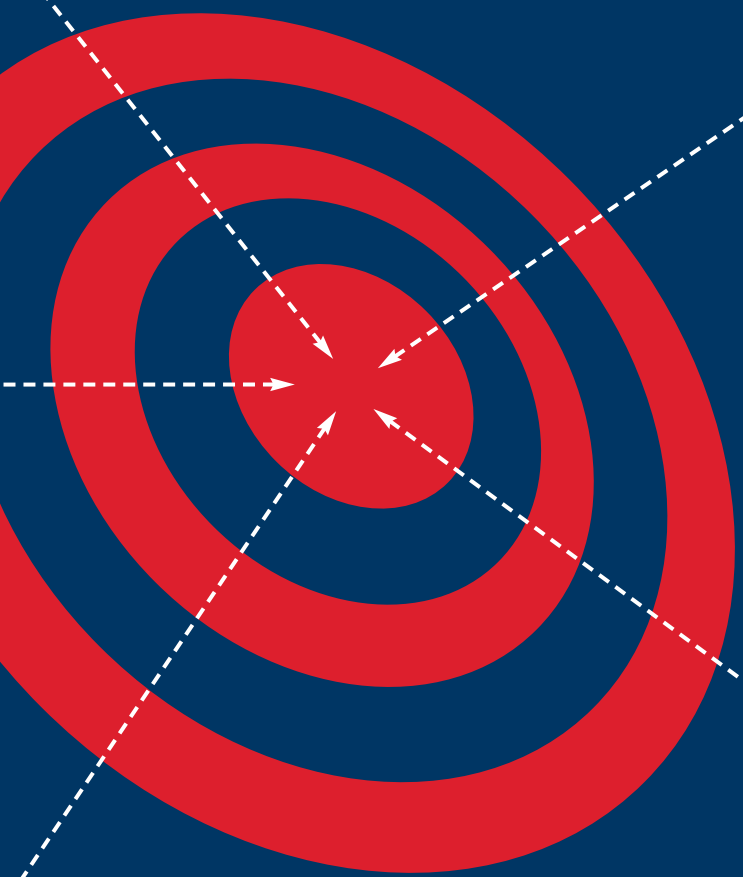
FDA/NIH Joint Symposium on Diabetes

Targeting Safe and Effective Prevention and Treatment



MAY 13-14, 2004

NATCHER CONFERENCE CENTER
MAIN AUDITORIUM
NIH CAMPUS, BETHESDA, MD

FDA/NIH Joint Symposium on Diabetes

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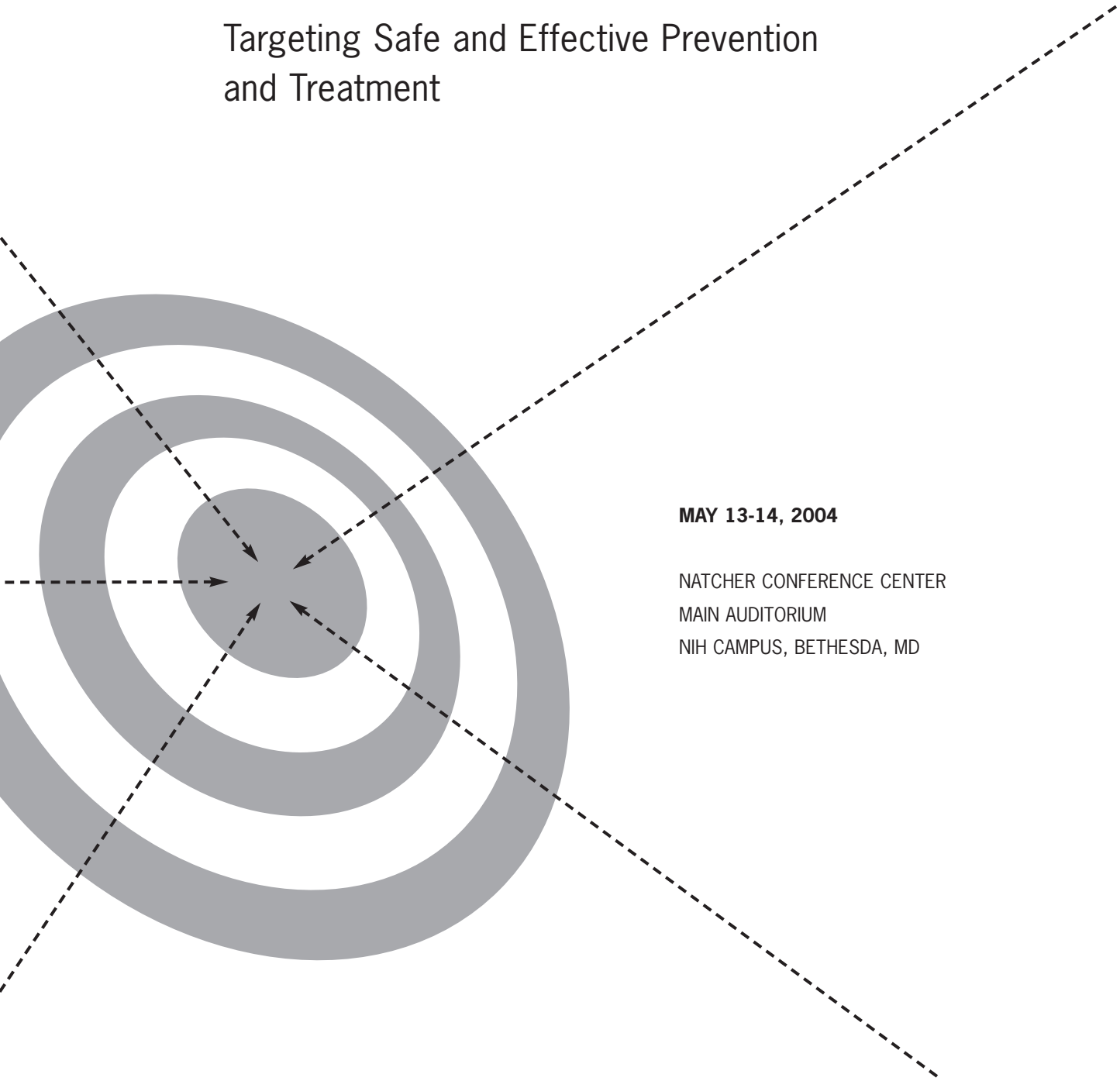

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FOREWORD

On January 31, 2003, the Food and Drug Administration launched the initiative *Improving Innovation in Medical Technology: Beyond 2002* to improve the development and availability of innovative medical products, in part by creating clearer guidance on clinical research for product development in priority therapeutic areas, including diabetes. The purpose of this symposium is to define the current state of the prevention and management of diabetes and to identify and discuss therapeutic gaps and hurdles to safe and effective prevention and treatment of type 1 and type 2 diabetes mellitus. The symposium is intended to provide assistance to FDA, NIDDK, clinical and basic scientists, and interested regulated industries in their efforts to reduce the burden of diabetes and improve the health of all people with diabetes.

The next two days will include eight sessions during which a discussion of diabetes and related issues associated with diabetes prevention and treatment will be presented. Each session will include time specifically allocated for discussion of issues between speakers and meeting attendees.

PLANNING COMMITTEE

US Food and Drug Administration	Patricia A. Bernhardt James T. Cross Jacquelyn Gianios Ilan Irony Vikki Kinsey Richard McFarland Robert J. Meyer David G. Orloff Cynthia Rask Marcia L. Trenter
National Institute of Diabetes and Digestive and Kidney Diseases	Judith Fradkin Sanford A. Garfield

AGENDA

DAY 1: **THURSDAY, MAY 13**
MAJOR CHALLENGES TO DEVELOPMENT
OF NEW THERAPEUTICS AND DIAGNOSTICS

7:30 am Registration
8:30 am Welcome FDA/NIH
– Allen Spiegel, Director, NIDDK
– Janet Woodcock, Acting Deputy Commissioner, FDA

Session I: **Overview/Setting the Stage** *(Moderator: David Orloff, FDA)*

8:50 am Diabetes 2004: Setting the Table
– David Nathan, Harvard Medical School
9:20 am Diabetes Mellitus and Vascular Disease Outcomes
– Peter Wilson, Medical University of South Carolina
9:50 am Discussion
10:15 am BREAK

Session II: **New Targets of Intervention** *(Moderator: Judith Fradkin, NIDDK)*

10:30 am New Molecular Targets in Type 2 Diabetes Mellitus
– Nancy Thornberry, Merck and Company
11:00 am Immunomodulation in Type 1 Diabetes
– George Eisenbarth, University of Colorado Health Sciences Center
11:30 am Discussion
11:55 am LUNCH (on your own)

AGENDA

Session III:	**Beta Cell Preservation** *(Moderator: Ilan Irony, FDA)*
1:10 pm	Assessment of Beta Cell Preservation in Type 1 Diabetes *– Jerry Palmer, Seattle VA Puget Sound Health Care System*
1:40 pm	ß-Cell Preservation in Type 2 Diabetes Mellitus *– Steven Kahn, VA Puget Sound Health Care System*
2:10 pm	Discussion
Session IV:	**Islet Transplantation** *(Moderator: Cynthia Rask and Richard McFarland, FDA)*
2:30 pm	Islet Transplants: Past, Present, and Future *– Bernhard Hering, University of Minnesota*
3:00 pm	Hurdles in the Clinical Application of Islet Transplantation *– Robert Sherwin, Yale University School of Medicine*
3:30 pm	Discussion
4:00 pm	BREAK
Session V:	**Devices** *(Moderator: Pat Bernhardt, FDA)*
4:20 pm	Devices Issues: Glucose Monitoring *– William Tamborlane, Yale University School of Medicine*
4:45 pm	Pumps: Hopes and Expectations *– Christopher Saudek, The Johns Hopkins Medical Institutions*
5:10 pm	Discussion
5:30 pm	ADJOURN

AGENDA

DAY 2: **FRIDAY, MAY 14**
PERSPECTIVES ON THE FUTURE OF PREVENTION AND THERAPY

7:00 am Registration

Session VI: **Prevention of Type 2 Diabetes** *(Moderator: Sanford Garfield, NIDDK)*

8:00 am Metabolic Syndrome: An Overview
– Barbara Howard, MedStar Research Institute
8:25 am Metabolic Syndrome: A Potential Target for
Prevention of Type 2 Diabetes Mellitus
– Robert Eckel, University of Colorado Health Sciences Center
8:50 am The Diabetes Prevention Program and
New Perspectives on the Metabolic Syndrome
– Harry Shamoon, The Albert Einstein College of Medicine
9:15 am Discussion
9:35 am BREAK

Session VII: **Industry and Advocacy Perspectives** *(Moderator: Robert Meyer, FDA)*

9:55 am Drugs
– Simeon Taylor, Bristol-Myers Squibb Pharmaceutical Research Institute
10:10 am Biologics
10:25 am IVD Industry Perspective
– David Horwitz, LifeScan, Inc.
10:40 am American Diabetes Association
– Nathaniel Clark
10:55 am Juvenile Diabetes Research Foundation International
– Robert Goldstein
11:10 am Discussion

Session VIII: **Targeting Safe and Effective Prevention and Treatment: Steps Forward by FDA and NIH**
(Moderator: David Orloff, FDA and Judith Fradkin, NIDDK)

11:35 am Panel Discussion
12:30 pm Closing

Speaker Abstracts

DIABETES 2004: SETTING THE TABLE

David M. Nathan, MD

Massachusetts General Hospital
Harvard Medical School
Boston, MA

Type 1 and Type 2 diabetes mellitus are chronic degenerative diseases that, despite their different pathogeneses, result in a similar spectrum of long-term microvascular and macrovascular complications. Basic and clinical research have advanced our understanding of the pathogenesis of Type 1 and Type 2 diabetes including an appreciation of their pre-clinical states, the development of long-term complications, and the treatments that prevent or delay the development of the disease (primary prevention), and the development (secondary intervention) or progression (tertiary intervention) of complications. The clinical trials that have established effective, new therapies have relied on an understanding of the course of diabetes, from pre-disease to disease to complications, and used "biological markers", "surrogate" measures, and "predictors", as well as "hard" clinical endpoints, to determine the effects of those interventions.

This introductory presentation will examine the current state of evidence-based diabetes therapy, identifying the gaps in our knowledge and the potential for progress. The productive use of biological markers as study endpoints in previous clinical trials will be highlighted and the potential to advance discovery of new therapies through the use of clinically relevant markers will be discussed.

DIABETES MELLITUS AND VASCULAR DISEASE OUTCOMES

Peter W.F. Wilson, MD

Medical University of South Carolina
Charleston, SC

Type 2 diabetes mellitus is associated with a greater risk for a large number of vascular disease outcomes. Large vessel disease (coronary artery disease, aortic disease) and small vessel disease (retina, kidney) have been the major disease areas studied, but other outcomes are involved and it is not always possible to separate small vessel disease processes from large vessel complications. Cardiovascular disease accounts for approximately 1/3 of the deaths in persons with type 1 diabetes mellitus and approximately 2/3 of the deaths in persons with type 2 diabetes mellitus. Using classic definitions of type 2 diabetes mellitus the relative risk for CVD outcomes is increased approximately threefold in women and twofold in men 35-64 years. At older ages, the relative risks are similar for each sex and a doubling of risk for most CVD outcomes is the norm. The relationship between the level of glycemia and cardiovascular disease (CVD) is only modest in diabetic subjects and the lack of a strong association between diabetes and cardiovascular disease may be partly attributable to the pre-diabetic state. Traditional risk factors operate relatively similarly in diabetic persons as in non-diabetics: total cholesterol (or LDL cholesterol), HDL-cholesterol, cigarette smoking, blood pressure are all highly related to the development of clinical disease. Glycemic control in persons with diabetes has been investigated thoroughly in observational studies and in clinical trials. In general, lower levels of glycosylated hemoglobin are associated with lower CHD risk in the observational data, but clinical trials have focused on blood pressure and glycemic interventions have corroborated the observational data. In addition, the criteria for "good" control is a changing landscape and aggressive practitioners are now achieving tighter control, with lower HbA1C levels, much more commonly than in the past. Two other factors that are of great interest for persons with diabetes mellitus are albuminuria and duration of diabetes. Each factor is generally related to greater risk of vascular disease in persons with diabetes, but the most comprehensive study to date, the UKPDS that was undertaken in the United Kingdom, found that microalbuminura was not predictive of CHD outcomes in their experience. Newer factors that are under investigation, such as markers of inflammation, appear to be important in the development of type 2 diabetes mellitus and in the progression to clinical vascular disease in all groups studied. The most compelling reduction in vascular disease risk in persons with diabetes has been reported for Danish adults with type 2 diabetes with aggressive treatments of lipoprotein, blood pressure, and blood glucose. Compared to the conventional treatment group in this trial, the diabetic individuals in the intensive treatment arm developed 47% of the CVD, 39% of the nephropathy, and 42% of the retinopathy–effects that were all statistically significant.

NEW MOLECULAR TARGETS IN TYPE 2 DIABETES MELLITUS

Nancy A. Thornberry

Department of Metabolic Disorders
Merck Research Laboratories
Rahway, NJ

The pathogenesis of T2DM involves a set of three primary defects: insulin resistance, insulin secretory dysfunction, and hepatic glucose overproduction. These defects are the principal targets of both current and future therapy. Currently available classes of oral antihyperglycemic agents include PPARγ agonists (insulin resistance), sulfonyureas/meglitinides (insulin secretion), and biquanides (hepatic glucose production). These agents are used either in monotherapy or, increasingly, in combinations to lower glucose levels. Despite the availability of a range of agents for T2DM, there remain critical unmet medical needs in the treatment of this disorder, including i) improved glycemic efficacy, ii) improved durability, iii) improved safety and tolerability, iv) treatment of earlier stages of disease, iv) treatment of hyperglycemia and comorbidities, v) treatment of diabetic complications. With an increasing understanding of the molecular pathways involved in glucose control, a range of new targets have emerged for treatment of the key areas of pathogenesis which address several of these unmet needs. For example, for treatment of insulin resistance, dual PPARγ/α agonists are being developed which retain the antihyperglycemic efficacy of commercial PPARγ agents while simultaneously providing improved control of dyslipidemia. In addition, partial agonists (SPPARγMs) are being pursued that have the potential to have improved safety and tolerability over current PPARγ agents. For insulin secretion, GLP-1 analogs and DP-IV inhibitors are new approaches that are anticipated to several advantages over currently marketed insulin secretagogues, including no weight gain, no hypoglycemia, and potential beneficial effects on _-cell function. Important features of next generation mediators of hepatic glucose production include superior efficacy and improved safety and tolerability relative to metformin. Glucokinase activators, glucagon antagonists, and fructose 1,6 bisphosphatase inhibitors are examples of new classes that are being pursued that target, in part, this aspect of pathology. The mechanisms of these new classes and their potential virtues and liabilities relatively to existing agents will be discussed.

IMMUNOMODULATION IN TYPE 1 DIABETES

George S. Eisenbarth, MD, PhD

Barbara Davis Center for Childhood Diabetes
University of Colorado Health Sciences Center
Denver, CO

Type 1A diabetes results from immune mediated destruction of the cells that produce insulin (beta cells of islets). Type 1A diabetes accounts for the great majority of European children developing diabetes and five to ten percent of adults with diabetes. Our understanding of the natural history of the disease has been revolutionized over the past three decades with the realization that there is a long prodrome preceding the onset of type 1 diabetes characterized by the presence of a series of anti-islet autoantibodies. In addition the genetic basis of the disorder is being defined with relatively simple assays for polymorphisms of HLA alleles determining the majority of the risk of type 1 diabetes and associated autoimmune disorders. Large studies are underway where genetic risk is defined at birth with typing of cord blood (e.g. DAISY study in Denver, BabyDiab study in Germany, DIPP study in Finland). The highest risk genotype for type 1 diabetes (DR3/4, DQ8/2) is present in 2.4% of newborns in Denver and such children have an absolute risk of 5% and comprise approximately 50% of children developing diabetes prior to age 5. As children progress to diabetes metabolic abnormalities are identified, and children in prospective followup rarely need to be hospitalized (due to ketoacidosis) at diabetes onset (<3%) compared to children from the general population (40%). Our understanding of the natural history of the disease leads to the identification of multiple time points at which intervention to preserve beta cells may result in clinically relevant benefit. In addition multiple therapies are effective in preventing type 1 diabetes in animal models. In addition given the major problems, both acute metabolic and chronic complications of type 1 diabetes provide a major impetus for disease prevention. A recent report of a large cohort study from Great Britain (1972 to 1993 initial cohorts) indicates that approximately 4.5% of patients with type 1 diabetes by 30 years of age are deceased versus 1.5% of general control population, and approximately _ of the deaths are due to metabolic causes (e.g. ketoacidosis and hypoglycemia). This is a large excess rate of death in a young population.

It is now possible in animal models to prevent the development of type 1 diabetes with multiple immunologic therapies. Therapy in man can be considered prior to initiation of autoimmunity, after appearance of anti-islet autoimmunity, at time of development of subclinical metabolic abnormalities, and after overt hyperglycemia, as well as considerations with islet transplantion (recurrent risk of autoimmunity in transplant). Trials have been initiated at each of these stages. Protection of islet beta cells at any of these stages (or prevention of autoimmunity) would be a worthy clinical goal given the markedly improved prognosis of individuals with preserved insulin/C-peptide secretion. Initial trials in autoantibody positive first degree relatives demonstrate the feasibility of such studies but point out the difficulty of trials when there is at present no immunologic (e.g. T cell) surrogate to determine in a short time period whether islet autoimmunity has been controlled. Newer techniques may overcome this problem, but in parallel it is likely that a number of immunotherapies will prove effective.

ASSESSMENT OF BETA CELL PRESERVATION IN TYPE 1 DIABETES

Jerry P. Palmer, MD

University of Washington
Seattle, WA

Type 1 diabetes is caused by an immune mediated attack on the pancreatic islet beta cells and the consequent loss of beta cell function. Preservation of beta cell function is the ultimate goal of therapeutic interventions in this disease. In this talk I will summarize the information supporting measurement of C-peptide as currently being the best way to assess beta cell function. C-peptide is cosecreted with insulin in a one-to-one molar ratio, experiences little first pass clearance by the liver, and well validated assays are available to accurately measure the low levels found in type 1 diabetes. The rate of decline in c-peptide is variable in patients with type 1 diabetes but is strongly influenced by patient age and degree of glycemic control. Preservation of even modest residual beta cell function results in easier glycemic control with less hypoglycemia and therefore patients with higher c-peptide levels have lower hemoglobin A1c levels in both population based studies and in clinical trials. And, because of the better glycemic control, patients with preserved beta cell function have less severe retinopathy and nephropathy. This relationship has been recognized for many years but was most conclusively demonstrated recently in the DCCT. In addition, although quite controversial, some investigators have reported that c-peptide, in addition to being a measure of insulin secretion, may have direct beneficial effects in patients with diabetes. An ADA workshop report entitled "C-Peptide is the Appropriate Outcome Measure for Type 1 Diabetes Clinical Trials to Preserve Beta Cell Function" was recently published, Diabetes 53: 250-64, 2004 as were specific recommendations for performing c-peptide stimulation tests, Diabetes 52:1059-65, 2003. In addition, an international collaborative study is underway to compare the two most commonly performed c-peptide stimulation tests and a direct laboratory comparison to determine the optimal assay format and to standardize c-peptide assays worldwide has been initiated.

ß-CELL PRESERVATION IN TYPE 2 DIABETES MELLITUS

Steven E. Kahn, MB, ChB

VA Puget Sound Health Care System
University of Washington
Seattle, WA

Islet ß-cell function is critical in the regulation of glucose homeostasis. In type 2 diabetes, alterations in insulin production and secretion along with insulin resistance are major contributors to the development of hyperglycemia. A number of different approaches have been used to assess ß-cell function including examining the early phase secretory responses to oral or intravenous glucose challenges and the ability of the ß-cell to convert proinsulin to insulin. All these measures are defective in type 2 diabetes and progression of these impairments is responsible for the worsening of hyperglycemia that is observed in this disease.

Insulin sensitivity is a well-recognized modulator of many measures of ß-cell function. Understanding this effect has highlighted the critical importance of interpreting insulin responses in the context of the degree of insulin sensitivity. When this is done, it can be clearly demonstrated that individuals at high risk of developing type 2 diabetes have reduced ß-cell responses to a glucose challenge well before they develop hyperglycemia and that this function declines as glucose tolerance deteriorates. Intervention studies have also demonstrated that changes in insulin release must be interpreted in the context of the degree of insulin sensitivity in order to gain a full understanding of the effect of the intervention on ß-cell function.

Using oral glucose tolerance tests, impairments of early insulin release have also been demonstrated in individuals with type 2 diabetes and in high-risk subjects with impaired glucose tolerance. These changes in ß-cell function exist in a number of different ethnic groups in the United States. This delay in early insulin release is responsible for the increased plasma glucose excursion that characterizes states of reduced glucose tolerance.

The mechanisms by which ß-cell dysfunction occurs is felt to include glucotoxicity, lipotoxicity and ß-cell mass reduction. The basis for the loss of ß-cell mass is in part due to the deposition of islet amyloid. These amyloid deposits contain as their unique peptide islet amyloid polypeptide (IAPP, also known as amylin). To study the process of amyloid formation as it pertains to type 2 diabetes, human IAPP transgenic mice have been produced. These mice develop amyloid deposits that increase in severity when dietary fat intake is increased. When ß-cell secretory output is diminished by treatment with either rosiglitazone or metformin, the severity of these deposits is decreased but amyloid formation is not prevented. Thus, while IAPP output may be a factor in determining the severity of islet amyloid deposition, it does appear that other factors are critical in its formation.

In summary, the pathophysiology of glucose metabolism is complex with changes in ß-cell function being a critical element involved in the development and progression of states of altered glucose tolerance. Understanding the role of the ß-cell and the nature of the defects in its function should lead to improved interventions aimed at preventing the development and progression of hyperglycemia.

ISLET TRANSPLANTS: PAST, PRESENT, AND FUTURE

Bernhard J. Hering, MD

Diabetes Institute for Immunology
and Transplantation
University of Minnesota

Demonstration of consistent diabetes reversal after sequential human islet transplants from 2-3 cadaver donors has signaled a quantum leap in the success rate of this procedure. Insulin independence rates at one year posttransplant now approach 85% in leading islet transplant centers.

Three recent achievements have extended these findings and suggest that cell-based therapeutics may soon play an increasingly significant role in the treatment of diabetes.

First, with respect to efficiency, improved pancreas preservation techniques, refined islet processing methods, and novel immunotherapeutic, cytoprotective, and anti-inflammatory strategies tailored to the specific requirements for islet transplants in autoimmune diabetes have increased the efficiency of islet transplants to allow single-donor islet recipients to experience outcomes previously only consistently attainable in pancreas transplantation.

Second, with respect to safety, improvements in the understanding of the mechanisms operative in acceptance of transplants has led to the development of unique and selective immunomodulatory strategies facilitating minimization of maintenance immunosuppression. Several steroid- and calcineurin inhibitor-free regimens are currently under evaluation in nonhuman primate models and clinical trials. Furthermore, the expansion of regulatory T cells as an essential component of immune homeostasis provides a potential therapeutic opportunity for active immune regulation and long-term tolerance induction. These studies will aid the development of safer and more selective yet potent immunotherapeutic strategies for the prevention of rejection and autoimmune destruction of islet allografts in type 1 diabetic recipients.

Third, with respect to tissue availability, exceptional progress has been made in prolonging functional survival of porcine islet xenografts in immunosuppressed non-human primates. The biology of stem cell- and precursor cell-derived beta cells is becoming increasingly well defined, and the profound potential will continue to generate intense interest.

These achievements have triggered further significant surges in research funds making further progress imminent. Documentation of the benefits of islet transplantation using clinically important endpoints will be critical. Considerable efforts and new concepts will be needed to overcome translational obstacles in the implementation and integration of these advances into the health care system.

HURDLES IN THE CLINICAL APPLICATION OF ISLET TRANSPLANTATION

Robert S. Sherwin, MD

Yale University School of Medicine
New Haven, CT

The dramatic improvement in islet transplantation success rates following the introduction of the Edmonton protocol 4 years ago has stimulated expansion of islet transplant programs as well as the hope that it will become a therapeutic option for patients with type 1 diabetes. Many obstacles and questions remain before the procedure can receive FDA approval as a clinical therapy. A fundamental problem is the lack of sufficient organs to meet the demand and the excessive delays in providing suitable organs for islet isolation. The quality and viability of the islet graft depends on the condition of the organ donor, the rapidity of procurement, the preservation of pancreas as well as the procedures used during isolation and purification. Given these many variables it is important that predefined criteria and algorithms be established to ensure well defined manufacturing processes, yet maintain flexibility to optimize islet yield. Of particular importance is the development of improved in vitro and in vivo (using rodents) methods to determine the secretory capacity and viability of the islet product. Such methods are likely to require islet culture. The initial success of the procedure is to a large extent determined by the number of islets administered. However, early engraftment is hampered today by limited islet perfusion and local non-specific inflammation, which reduce organ viability. Subsequently, islet viability is further reduced by the limitations of drugs used to suppress allo- and autoimmune responses, and in some cases, by beta cell injury caused by the drugs themselves. Once normal glucose metabolism has been restored, improved methods are required to detect early signs of graft dysfunction/rejection before hyperglycemia occurs. There is a critical need for reliable provocative tests designed to detect mild impairments in beta cell function (including glucose stimulated insulin and C-peptide release, and meal tolerance), imaging techniques to assess islet mass and immune markers of islet graft rejection. Ultimately the value of islet transplantation rests on clinical outcomes and long-term data regarding the risk-benefit ratio in specific patients. The immediate benefit in poorly controlled patients with regard to quality of life and glycemic control is clear, especially those with severe recurrent hypoglycemia. However, whether the transplant restores hypoglycemia awareness, defective counterregulation and alterations in brain function is unknown. While it is likely that islets, much like whole pancreas transplantation, will reduce the microvascular and neuropathic complications of diabetes, it might, on the other hand, accelerate cardiovascular disease, a major cause of death in diabetic patients. Finally, the long-term potential adverse effects of the immunosuppression regimens used need to be clarified. Thus, risk-benefit assessment cannot be made with certainty at the present time. This has implications for patient selection given that new insulin delivery systems are also effective in reducing the complications of diabetes at less cost.

DEVICES ISSUES: GLUCOSE MONITORING

William V. Tamborlane, MD

Yale University School of Medicine
New Haven, CT

Progress towards the development of an artificial endocrine pancreas has been impeded by the lack of reliable devices for continuous monitoring of glucose levels in diabetic patients. Consequently, the introduction of first generation glucose sensing systems is potentially one of the most important therapeutic advances in many years. In this session, we will review current and future approaches to continuous glucose monitoring. The strengths and weaknesses of FDA-approved devices will be reviewed with special emphasis on results of the Diabetes Research in Children Network (DirecNet) studies of the GlucoWatch Biographer and Medtronic MiniMed CGMS systems. The potential for "closing the loop" with the next generation of devices will also be explored.

PUMPS: HOPES AND EXPECTATIONS

Christopher D. Saudek, MD

Hugh P. McCormick Family Professor of Medicine
Johns Hopkins University School of Medicine

External insulin infusion pumps are a widely used, generally available option for the management of diabetes today. Programmable, variable rate implantable insulin infusion pumps (IIP), on the other hand, remain in clinical trials. IIP was first designed in the early 1980's, and the first variable rate pumps were implanted in humans in about 1986. Since the early feasibility trials, it has been clear that unstable diabetes can be treated safely and effectively with IIP. Throughout the 1990's and in the past few years, their design and longevity have been improved, and wide experience has improved our understanding of the advantages as well as the limitations of IIP therapy.

Design: The current IIP includes the following components: The implant itself is a "hockey puck" sized disc (8.1 cm diameter by 2 cm thick, weighing 131 gm empty). The implant includes a 15 cc negative pressure reservoir, pump mechanism, electronics, battery and refill port. The pump is surgically implanted beneath the skin of the abdomen, and insulin is delivered in uL pulses form the pump into a 17 cm catheter, the distal tip of which is placed in the peritoneal space. The patient uses an external communicator to control basal infusion rates and mealtime bolus doses. The insulin is highly concentrated (U-400) human insulin with a surfactant additive, polyethylene polypropylene glycol to prevent adherence to surfaces. Refills are done every 3 months transcutaneously in a 10 minute procedure.

Christopher D. Saudek, MD

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Worldwide Experience: With more than 1200 implants (most in France, where years ago the regulatory bodies approved clinical implantation in university centers), over 18 years, there have been no episodes of catastrophic failure (uncontrolled insulin delivery). Surgical complications, persistent pain, infections and skin erosion are unusual. Glycemic control is on the whole improved. A randomized controlled clinical trial in the U.S. Veterans Administration comparing IIP to multiple dose insulin demonstrated significantly less hypoglycemia, less weight gain and improved quality of life on IIP. Some patients have had an increased anti-insulin antibody with this new route of delivery, and occasionally this has prolonged the action of insulin. There is no increased incidence of autoimmune endocrine disease, however, and usually no clinical effect of the antibody rise, which is often transient. In the mid-1990's, a change in insulin manufacturing method caused increased precipitation of insulin within the pump and catheter. This slowed implantations until the insulin could be re-formulated into a more stable preparation.

Current status of IIP therapy uses the Medtronic/MiniMed model 207, which features a much prolonged battery life (up to 8 years) and smaller, more efficient communicator. Re-implantations and new implantations are underway in France, and under an investigator IND/IDE in at Johns Hopkins. Medtronic/MiniMed has a six center comparative trial in progress in the U.S. that should be completed in 2004.

Future goals include development of a closed loop, sensor-driven insulin delivery device. In theory, this could communicate any permutation of external or implanted sensor or pump. The fully automatic artificial pancreas, however, will depend not only on accurate, reliable insulin delivery (which has been largely demonstrated as described above, but upon accurate, reliable glucose sensing and algorithms to link the sensing with delivery rapidly enough to control glycemia without causing hypoglycemia.

METABOLIC SYNDROME: A POTENTIAL TARGET FOR PREVENTION OF TYPE II DIABETES MELLITUS

Robert H. Eckel, MD

University of Colorado Health Sciences Center
Denver, CO

Assuming the definition of the metabolic syndrome includes a series of components that represent insulin resistance, an approach to the prevention of type II diabetes needs to focus on those components that when modified will impact insulin sensitivity most favorably. Little evidence exists that modifying plasma triglycerides or HDL cholesterol directly improves insulin action or type II diabetes incidence, nor is there reproducible evidence that blood pressure lowering without concomitant weight loss with ACE inhibitors or ARBs modifies these outcomes. Thus, it would appear that interventions that target abdominal obesity and/or impaired fasting glucose (glucose intolerance) deserve the most attention. In addition to the Diabetes Prevention Program (DPP), there are now several studies that have demonstrated the benefit of intensive lifestyle in modifying the incidence of type II diabetes in patients with glucose intolerance. Although there are benefits of both weight loss and exercise, the importance of weight reduction likely predominates. The current controversy around dietary macronutrient composition and long term weight loss remains unanswered. Probably the greatest benefit of exercise is to prevent weight regain. FDA-approved weight loss drugs, i.e. phentermine, sibutramine and orlistat, may all be useful in accomplishing the same outcome, but evidence for efficacy beyond lifestyle only is restricted to orlistat (XENDOS). Among the insulin sensitizers, metformin results in modest weight reduction, and was shown in the DPP to reduce the incidence of type II diabetes. A similar effect was seen with the α-glucosidase inhibitor acarbose in STOP-NIDDM. Thiazolidnediones have pharmacological properties that predict the favorable modification of many of the metabolic syndrome components except waist circumference; however, a transition of deposition of adipose tissue from the viscera to the subcutaneous region may be associated with increases in insulin action despite the absence of weight reduction or changes in waist circumference. Data from women with gestational diabetes suggest a reduction in type II diabetes incidence with troglitazone (TRIPOD). The horizon is bright with a number of agents that may enhance 1. weight reduction (cannabinoid receptor inhibitors, melanin-concentrating hormone-1 antagonists, zonisamide, topiramate) and/or 2. insulin sensitivity (PPAR-α,λ or PPAR-α,λ,δ agonists, dipeptidyl peptidase-IV inhibitors, topiramate, RXR modulators, adiponectin), and reduce the onset of new type II diabetes. Of course with reductions in body weight and/or insulin sensitization, decreases in plasma triglycerides and at least modest increases in HDL cholesterol would also be expected. Although the expectations of an increased intensity of utilization of existing therapies and new drugs for the reduction of type II diabetes are high, the prevention of obesity remains the #1 target for intervention.

Harry Shamoon, MD

General Clinical Research Center
Albert Einstein College of Medicine
Bronx, NY

This presentation will summarize the major findings of the Diabetes Prevention Program (DPP) regarding the prevention of diabetes and more recent analyses conducted by the DPP Research Group on cardiovascular disease (CVD) outcomes and risk factors and on the Metabolic Syndrome (MS) among DPP participants.

The DPP was a multicenter, randomized controlled trial that examined 3 interventions—intensive lifestyle (ILS), metformin (MET), or placebo—designed to prevent T2DM. It enrolled 3,234 participants with IGT (fasting plasma glucose 95-125 mg/dl and plasma glucose 140-199 mg/dl 2 hours after a 75 gm glucose load), in participants who were ≥ 25 years of age and obesity. The average age at entry was 51y, and 68% of participants were women; 55% were Caucasian, 20% African-American, 16% Hispanic, 5% American Indian, and 4% Asian-American. The treatment goals for ILS was weight reduction by at least 7% of body weight, using a low-calorie, low-fat diet, and increased physical activity to at least 150 minutes/wk. In the medication arms, MET or placebo were initiated at a dose of 850 mg once per day, and gradually increased to twice a day. The MET and placebo groups also received standard lifestyle recommendations. The DPP has published its primary outcome—viz, the risk for developing T2DM was reduced by 58% and 31% in the lifestyle and MET-treated groups, respectively, compared with placebo. The DPP cohort continues to be followed up as the "DPP Outcomes Study," and is focused on outcomes including diabetes, CVD, and MS.

After reporting the effects of MET and ILS on the prevention of diabetes, the DPP took the opportunity to analyze the effects of troglitazone—a thiazolidinedione—which was originally a fourth arm in the DPP, but was discontinued in 1998 owing to liver toxicity. Thus, diabetes development was studied in 387 troglitazone participants who had a follow-up visit during ~0.9 years of troglitazone treatment. While the diabetes incidence rate was reduced more with troglitazone (despite an increase in body weight) than either MET or ILS, its preventive action did not persist after withdrawal.

Harry Shamoon, MD

(Continued from previous page)

In addition to preventing diabetes, a further benefit of the DPP interventions may be reduction of CVD risk or amelioration of CVD risk factors. During 3 years of follow-up, combined fatal and non-fatal CVD outcome rates were predictably low, and did not differ among groups. On the other hand, fewer ILS participants had reached treatment criteria for drug therapy for LDLc or triglycerides compared to placebo and MET, and the prevalence of hypertension was also more effectively reduced by ILS. Absolute reductions in both systolic and diastolic blood pressure were seen in all groups and were significantly greater in ILS compared to both placebo and MET.

Because persons with IGT have a high prevalence of insulin resistance and CVD risk factors, we also examined the prevalence of MS at baseline and the effect of DPP interventions on new MS incidence. We recently reported that the prevalence of MS at entry was ~50% of the overall DPP cohort. However, the prevalence of certain MS components varied considerably in different age groups. Among the 1,523 participants without MS at entry, the incidence of MS was reduced by ~40% at 3 y in the ILS group and by 17% in the MET group. Again, ILS and MET had different effects on various components of MS such as high fasting glucose and low HDLc. The component of MS most affected by DPP interventions was abdominal obesity, the incidence of which was reduced dramatically by both ILS and MET compared to placebo.

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Incredible advances have occurred over the past few decades that have dramatically changed the management and outcomes of diabetes. These advances have occurred in all arenas, e.g., treatment and therapy, diagnosis and monitoring, and the relationship between diabetes and other conditions.

Throughout this time, the IVD industry has been intimately linked to these medical advances, providing faster, easier, and better diagnostic and monitoring tests. Medical research shows that the value of the achieved health gains has far outpaced the dollars spent utilizing this improving technology. The IVD industry wishes to continue the course of innovation, to provide ever better technology that will help the healthcare community provide yet better outcomes. However, although Medicare spending overall grew by nearly 400% in the past 20 years, the reimbursement dollars for IVD technology remained virtually unchanged. For the IVD industry to keep pace with healthcare needs, appropriate funding levels must be made available.

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