Joint Statement from the American Diabetes Association and American Association of Clinical Endocrinologists on the NICE-SUGAR Study on Intensive versus Conventional Glucose Control In Critically Ill Patients

Alexandria, VA and Jacksonville, FLA (March 24, 2009) – A study published online today in the New England Journal of Medicine suggests that intensive blood glucose (sugar) control for critical care patients with hyperglycemia (high blood glucose) does not improve outcomes and is associated with an increase in deaths.

The American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE) maintain that the findings of the Normoglycemia in Intensive Care Evaluation-Survival Using Glucose Algorithm Regulation (NICE-SUGAR) study should NOT lead to an abandonment of the concept of good glucose management in the hospital setting. Uncontrolled high blood glucose can lead to serious problems for hospitalized patients, such as dehydration and increased propensity to infection.

It is important to consider that the severely ill patients in this trial were treated intensively with intravenous insulin to very tight targets (average of 115 mg/dl), and were compared to a control group whose glucose control was good (average glucose 144 mg/dl).

The ADA and AACE caution against letting this study swing the pendulum of glucose control too far in the other direction where providers in hospitals are complacent about uncontrolled hyperglycemia. The two organizations maintain that strategies must be identified to help hospitals establish structured protocols for safe and effective management of blood glucose in both intensive care units and other hospital settings.

“Since 2003, AACE and the ADA have worked together to provide recommendations for treatment of inpatient hyperglycemia, and these efforts have contributed to a growing national movement viewing the management of hyperglycemia in hospitals as a quality care measure,” Dr. Etie S. Moghissi, AACE Chair of Inpatient Glycemic Control Task Force said.

Recognizing the critical importance of controlling hyperglycemic states in conjunction with the results of recent randomized trials such as NICE-SUGAR, the two organizations recently convened a Consensus Panel to extensively review the most current literature and up-to-date recommendations for treatment of hyperglycemia in the hospital.

“The central goal of the ADA/AACE inpatient task force is to identify reasonable, achievable, and safe glucose targets, and to describe the protocols, procedures, and system improvements needed to achieve inpatient optimal glucose control efficiently and safely,” Dr. Mary Korytkowski, ADA Chair of Inpatient Glycemic Control Task Force said.

Complete recommendations from the panel will be published in Endocrine Practice and Diabetes Care later in the spring. Until more information is available, it seems reasonable for clinicians to treat critical care patients with the less intensive – yet good - glucose control strategies used in the conventional arm of the NICE-SUGAR trial.

About The NICE-SUGAR Study

Hyperglycemia in the hospital, whether it occurs in patients with known diabetes or is temporarily stress-induced, has long been known to be associated with poor outcomes such as longer length of stay, increased rates of infection, and in-hospital death. Observational studies and early randomized trials have suggested that lowering glucose levels can improve outcomes, especially in critical care patients treated with intravenous insulin to a range of 80-110 mg/dl. More recent studies in the critical care population were unable to replicate earlier studies, and identified

severe hypoglycemia (low blood glucose) as a significant risk of intensive glucose control. The NICE-SUGAR trial was a very large multicenter, multinational study (with 6,104 participants) designed to definitively examine the risks and benefits of intensive glucose control in critical care units.

Results from the NICE-SUGAR study indicate that critically ill patients treated in the intensive glucose control group were 14 percent more likely to die compared to critically ill patients in the conventional glucose control group.

More than 6,100 patients with hyperglycemia in critical care units were randomized to either intensive glucose control (insulin infusion with target blood glucose between 80-108 mg/dl) or to conventional glucose control (insulin infusion begun if blood glucose was over 180 mg/dl, and discontinued if blood glucose dropped below 144 mg/dl). Severe hypoglycemia (blood glucose below 40 mg/dl) occurred in approximately 6.8 percent of intensively treated patients compared to 0.5 percent of conventionally treated patients. The study showed no difference in length of time in the intensive care unit or in the hospital, or in other major outcomes such as time on ventilators or need for dialysis.