

## CELEBRATING THE 40<sup>TH</sup> ANNIVERSARY OF THE FIRST INJECTION OF HUMAN INSULIN

Between the dates of December 19, 1980 and June 5, 1981, 45 patients were screened for the Lilly Biosynthetic Human insulin study using regular and NPH insulin. Participants included both children and adults, with ages ranging from 5 to 75.

Mid America Diabetes Associates (MADA) was the only center in this study. MADA was selected due in large part to Dr. Guthrie's relationship with John Galloway MD, the medical director at Lilly. Galloway had met Dr. Guthrie, and knew of his practice, patient population, and reputation.

All patients were hospitalized, initiated on insulin and provided diabetes education. Having taken animal-source insulin did not exclude a patient from participating.

This was an open label study meaning all participants received human insulin.

The data from the first 6 months was submitted to the FDA, which resulted in an early approval.

On December 19, 1980, at Mid American Diabetes Associates in Wichita, Kansas, five patients enrolled in the study were the first in the world to receive doses human insulin. (Two of those are still patients at Great Plains Diabetes, a clinic headed by former MADA associate Belinda Childs, APRN, BC-ADM, CDE.)

All patients were followed for 2 years from the date of their enrollment.

## **SUBSEQUENT STUDIES**

A second, two-year, open-label study to compare animal-source with human insulin began at MADA October 9, 1981. Before completion of the study on March 19, 1982, 39 patients aged 5 to 75 were enrolled.

The study protocol required clinic visits were every 1 to 3 months throughout the study. To confirm that this new insulin did not cause a progression of eye disease in people with diabetes, eye exams were conducted every 6 months by Dr. Nesmith's group at VitreoRetinal Consultants.

MADA was also one of a few centers to do a two-year pediatric study using pork insulin sponsored by Nordisk. The trial compared Insulatard/Velosulin (pork insulin) and Lilly NPH and Regular.

The first patient enrolled in the study on December 2, 1980 was only 12-months old. In all, 23 children ages 1 to 18 were enrolled between December 1980 and May of 1982.

To collect patient data for the two studies, MADA recruited and enrolled 82 people with newly diagnosed diabetes. Tight protocols of the trials barred people who'd had been given even one shot of insulin from participating.