

Dr. Randie Litt...: Hello, I'm Dr. Randie Little, and I'm happy to join you today to discuss various topics of hemoglobin A1C measurement, standardization, and hemoglobin variance.

The purpose of the NGSP is to standardize hemoglobin A1C test results to those of the Diabetes Control and Complications Trial, and the United Kingdom Prospective Diabetes Study, which established the direct relationships between hemoglobin A1C levels and outcome risks in patients with diabetes. This is a schematic view of the NGSP. We have a large network that includes 10 network labs in the US, the Netherlands, Japan, and China. The network is monitored monthly and is also monitored against the IFCC network twice yearly. There are three basic processes, including calibration, certification and proficiency testing.

One of the most important processes of the NGSP is certification. The process includes 40 fresh or fresh/frozen whole blood samples that are compared between a manufacturer or laboratory and a network laboratory. In order to pass certification, 36 out of 40 single results must be within 5% of the SRL, or secondary reference lab. This criteria is for manufacturer and level two lab certification. For level one certification, 37 out of 40 results must be within 5%. Almost 30 years after the DCCT, hemoglobin A1C measurement has improved from chaos in 1993 to the present order. In this slide, each point in the error bar represents a different method. The dashed yellow line is the NGSP target value for each sample. You can clearly see improvement in both bias and variability since 1993.