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Dialysis Clinic, Inc. Completes the Largest Dialysis Clinical Trial in the United States: Study Finds Increase in Protein Nutritional Supplements Does Not Improve Mortality Rates for Hemodialysis Patients with Normal Nutritional Status

NASHVILLE, TN (November 17, 2020)

Dialysis Clinic, Inc. (DCI) completed a three-year pragmatic trial of over 10,000 hemodialysis patients and concluded that adding an intensive oral protein nutritional supplement protocol does not improve mortality rates compared to patients receiving standard care.

“It is an accomplishment for the many patients who joined the study and for the clinical staff at DCI units to have undertaken a trial of this size and this scope and answered an important question. While it is disappointing that oral protein supplements, items like protein bars that you can buy at any store, did not lower mortality in hemodialysis patients with good nutritional status, it is important to say that this result does not tell us anything about giving protein supplements to people with low serum albumin. We do have observational data that suggest protein supplements have benefits in dialysis patients with low albumin,” said Daniel Weiner, MD, of Tufts Medical Center in Boston and Medical Director of Clinical Research for DCI.

The cluster randomized pragmatic study, named The HELPS-HD Trial, enrolled 10,457 patients from 105 DCI participating facilities. Patients were randomized to either the standard protocol group, whereby only those patients with an albumin level below 3.5 g/dL received supplement, or the intensive protocol group, where supplements were given to patients regardless of their albumin levels. The most common supplements used were protein bars, and all supplements had approximately 15g to 20g of protein. Mean follow-up was 21.2 months.

“We tried to keep this as real-world and pragmatic as possible,” Weiner said.

At the conclusion of the study, there were 3,628 deaths, with 35.8% from the intensive group and 36.5% from the standard group. There was no significant difference in the death rate between the groups, even after adjusting for age, sex, race, and incident patient status.

“To be able to verbally consent over 10,000 patients in a randomized clinical trial is a testament to the dedication of the DCI staff to our patients and to our mission as a company. I am very

proud to work for DCI and this incredible team in our quest to find the best possible care for our patients,” said Karen Majchrzak, Director of Clinical Research at DCI.

About DCI

Founded in 1971, Dialysis Clinic, Inc. (DCI) is the nation's largest non-profit dialysis provider with over 250 dialysis clinics in 29 states. Headquartered in Nashville, TN, DCI employs more than 5,000 people serving approximately 15,000 dialysis patients. DCI's services include in-center hemodialysis, in-center self-care hemodialysis, home hemodialysis, continuous ambulatory peritoneal dialysis (CAPD), continuous cycling peritoneal dialysis (CCPD) and Hospital Services (inpatient renal replacement therapy). For more information, visit www.dciinc.org.