CDS Patient Enrollment

The USRDS CC notified the Medical Directors and Administrators of facilities that were randomly selected for the study. The Nutrition SSC contacted facilities selected for the Nutrition/QOL arm of the study to review procedures for lab draws.

Initial contact with potential sample participants was made by mailing information addressed to the patient describing the study, a consent form, and participation availability forms to the patient's dialysis facility; mailings were sent to the patient's home for those on home dialysis. Patients who completed and returned a consent form then received a phone call from DataBanque to schedule a time for a phone interview. Facility staff and/or patients also returned information directly to the CC to indicate the following reasons for non-enrollment: refusal, transferred to another facility, deceased, cognitive impairment, regained renal function, patient does not speak English or Spanish, received transplant, or other.

Over the course of the study IRB approval was obtained for the following modifications to the patient contact protocol: (a) follow-up phone calls were made by DataBanque to patients who had not returned a consent form in order to further explain the study, (b) a patient participation incentive of $25 was introduced and offered to all participants, and (c) the opportunity to complete a verbal consent at the time of the DataBanque phone call was made available to patients. For patients selected for the QOL arm of the CDS, mailings to introduce the study were made to the patient's home; complete mailings to the patient's dialysis facility were discontinued (unless no home address was available for the patient), but the facility continued to receive explanatory materials and the name of the patient selected for the study. For patients selected for the Nutrition/QOL arm of the CDS, mailings were sent simultaneously to the patient's dialysis facility and to the patient's home. Follow-up phone calls were made by DataBanque to patients being recruited for both study arms, but an opportunity to complete a verbal consent was not offered to patients selected for the Nutrition/QOL arm. A signed consent form was essential for patients in the Nutrition/QOL arm because facility assistance with provision of quarterly serum specimens was needed for patients in this arm.

Reasons for non-enrollment at the time of the DataBanque follow-up phone calls were: refusal, phone number wrong/disconnected, deceased, received transplant, hearing problem, regained renal function, cognitive impairment, incarcerated, does not speak English or Spanish, and maximum phone call attempts reached.