

## **CDS Data Collection Procedures**

### Questionnaires

Phone interviews were conducted in English or Spanish by trained interviewers located at DataBanque in Pittsburgh, PA, with responses entered into a CATI system. This data collection procedure was used for:

- Baseline Patient Questionnaire (All patients)
- 1 year Follow-up Patient Questionnaire (Nutrition/QOL arm patients)
- Baseline and 1-year Follow-up Food Questionnaire (Nutrition/QOL arm patients)

DataBanque provided the following services:

#### Software development/process set-up

DataBanque developed a custom software program for the CDS that incorporated the questions in the Patient Questionnaire into a Computer-Assisted Telephone Interviewing (CATI) system. The system allowed for scheduling of interviews, callbacks, recording of survey answers, and reporting. The software allowed the interviewer to select the participant from the USRDS list and populate that participant's responses. A Spanish version of the software was also made available to the interviewers. An opening and closing script was developed/approved by the CDS Steering Committee.

NutritionQuest provided approval for DataBanque to use their Block Brief 2000 Food Questionnaire, which was also coded into the CATI system.

#### Survey Administration

DataBanque received monthly lists of patients to be contacted from the USRDS CC. Participant names were provided on a rolling basis over the course of the study. DataBanque worked through the list starting with the first individuals provided and concluding with the last individuals provided.

Information provided to DataBanque by the USRDS CC included:

- Patient Name
- Address (if available)
- Phone
- Primary Language (if available)
- Preferred time/day of contact (if available)
- Dialysis clinic name, city and state (to determine time zone of the patient if address was not available)
- Dialysis start date
- Survey to administer: Patient Questionnaire only, or Patient Questionnaire + Food Questionnaire (determined by the study arm of the patient's dialysis facility)

After the participant names were provided, participants with a complete address were mailed an introductory letter thanking them for their agreement to participate in the study and explaining

both the study and the process for participation. The letter included an explanation of the expected length of each interview, etc. Two versions of the letter were prepared – one for participants receiving only the Patient Questionnaire and one for those receiving both the Patient Questionnaire and the Food Questionnaire. For those in the Nutrition/QOL arm of the CDS, DataBanque also mailed information on serving size choices along with a copy of the Food Questionnaire. This allowed patients to review the diet information that they would be asked to complete ahead of time, potentially expediting the phone calls that included the Food Questionnaire. The introductory letter served to provide patients with something they could review in writing about their participation and to help eliminate some of their questions about the process.

On the day of the first call attempt, if the patient was willing, DataBanque conducted the Patient Questionnaire interview (and Food Questionnaire interview when applicable) at that time. If the patient was unable to talk with the interviewer at that time, an appointment was scheduled to conduct the interview in the future. DataBanque attempted to schedule appointments no more than 14 days in advance unless a different appointment day was requested by the participant. For patients with scheduled interviews, DataBanque called to remind participants of their scheduled appointments on the day prior to the interview. When patients could not complete the entire interview at one time, DataBanque allowed them to start an interview and schedule a time when they could complete the rest.

On the day of the appointment, an interviewer phoned the participant at the appropriate time, conducted the survey(s), and recorded responses in the software. At the beginning of the call, the interviewer asked permission for the phone call to be recorded. One Spanish-speaking interviewer was on staff to accommodate the Spanish-speaking participants. Participants were given a toll-free phone number for cases in which a participant needed to call DataBanque.

If an attempt was made to phone a patient and the patient was unreachable, the patient remained “active” on the DataBanque call list for up to 50 call attempts. There were no time restrictions placed on reaching 50 attempts. DataBanque attempted to call the patient every other day for the entire time the patient was on the active call list, varying the call times so that an attempt was made to reach the patient in the morning, afternoon, and evening on each successive attempt. Every effort was made to accommodate patients’ schedules, many of whom requested to be called weeks later. If DataBanque learned that the patient was in the hospital, an attempt was made to reach the individual one week later, and the individual was put back on the active list at that time and remained so up until the maximum call attempts were reached.

Because the sample population was located across US time zones, DataBanque staffed the interviewers to have coverage from 8 AM – 9 PM Eastern time. If activity during the early morning and late evenings was minimal, DataBanque was prepared to revise the interviewers’ schedules to maximize their availability during the busier hours of the day. DataBanque also recognized that there might be times when interviewers would have to work weekends or later in the evenings to accommodate patients on the west coast and Hawaii. These situations were dealt with on a case-by-case basis.

For the follow-up interviews with patients in the Nutrition/QOL arm of the study, it was DataBanque’s goal to interview patients 12 months after the baseline interview +/- 2 weeks, unless the patient was unable to conduct the interview during that timeframe. If that occurred, an attempt was made to interview patients as close as possible to their anniversary date.

A complete download of the Patient Questionnaire database was sent monthly to the USRDS CC via email, with any identifying fields removed to ensure privacy. DataBanque transmitted the Food Questionnaire data to NutritionQuest, Berkeley CA, which then reported usual dietary intake and nutrient data to the USRDS CC.

Serum samples (Nutrition/QOL arm patients)

For patients selected for the Nutrition/QOL arm of the CDS a signed consent form was essential for because facility assistance with provision of quarterly serum specimens was needed for patients in this arm. Upon the USRDS CC's receipt of the signed consent forms the patient's names were forwarded to the CDS lab at University of California, Davis. Participant names were provided on a rolling basis over the course of the study. The UC Davis lab worked through the list starting with the first individuals provided and concluding with the last individuals provided.

Information provided to the UC Davis lab by the USRDS CC included:

- Patient Name
- Patient ID
- Facility ID

After the participant names were provided, the lab contacted the patient's dialysis facility to notify the staff that the serum tubes, directions, and packaging would be arriving via delivery.

Within the directions the facility staff was asked to collect serum for measurement of C-reactive protein and prealbumin quarterly for one year (from bloods drawn for routine monthly laboratory studies). For the patients in whom bloods are drawn, facility personnel were asked to box participants' serum after centrifugation for pick-up by usual laboratory personnel. The USRDS was responsible for covering costs of mailing specimens to UC Davis. It was expected that 15 mL (approximately 1 tablespoon) of blood would be drawn from each patient every three months for one year.